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**234**

# **Pesticide residues in food 2018**

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

# **REPORT 2018**



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**234**

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

Report of the Joint Meeting of the FAO Panel of Experts on  
Pesticide Residues in Food and the Environment and the  
WHO Core Assessment Group on Pesticide Residues  
Berlin, Germany, 18–27 September 2018

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**R, residue and analytical aspects; T, toxicological evaluation**

**\* New compound**

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

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<sup>\*</sup> Participated in discussion in the topic on the harmonisation of residue definitions

## Abbreviations

AD	Administered Dose
ADI	Acceptable Daily Intake
Ache	Acetylcholinesterase
ALP	Alkaline Phosphatase
APTT	Activated Partial Thromboplastin Time
AR	Applied Radioactivity
Arfd	Acute Reference Dose
APTT	Activated Partial Thromboplastin Time
AUC	Area under the Plasma Concentration–Time Curve
BBCH	<b>B</b> iologische <b>B</b> undesanstalt, <b>B</b> undessortenamt Und <b>C</b> hemische Industrie
BMD	Benchmark Dosing
BMDL <sub>10</sub>	Lower Confidence Limit on the Benchmark Dose for A 10% Response
Bw	Body Weight
CAR	Constitutive Androstane Receptor
CAS	Chemical Abstracts Service
CCPR	Codex Committee on Pesticide Residues
Cgap	Critical GAP
Cifocoss	Chronic Individual Food Consumption – Summary Statistics
C <sub>max</sub>	Maximum Concentration in Blood or Plasma
CYP	Cytochrome P450
DALA	Days after Last Application
DAT	Days after Treatment
DM	Dry Matter
DNA	Deoxyribonucleic Acid
DRA	Dietary Risk Assessment
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
EFSA	European Food Safety Authority
EHC 240	Environmental Health Criteria 240 Monograph
EU	European Union
F <sub>0</sub>	Parental Generation
F <sub>1</sub>	First Filial Generation

F <sub>2</sub>	Second Filial Generation
FAO	Food and Agriculture Organization of the United Nations
FOB	Functional Observational Battery
GAP	Good Agricultural Practice
GC-ECD	Gas Chromatography – Electron Capture Detector
GECDE	Global Estimate of Chronic Dietary Exposure
GEMS	Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme
GGT	Gamma-Glutamyl Transferase
GLP	Good Laboratory Practice
Har	Human Androgen Receptor
Hera	Human Estrogen Receptor Alpha
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
IPCS	International Programme on Chemical Safety
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
Log P <sub>ow</sub>	Octanol-Water Partition Coefficient
LOQ	Limit of Quantification
MRL	Maximum Residue Limit
NOAEC	No-Observed-Adverse-Effect Concentration
NOAEL	No-Observed-Adverse-Effect Level
OECD	Organisation for Economic Co-Operation and Development
OIE	World Organisation for Animal Health

Pam	Pesticide Analytical Manual
PBI	Plant-Back Interval
PES	Post-Extraction Solids
Pf	Processing Factor
PHI	Pre-Harvest Interval
POD	Point Of Departure
Ppm	Parts Per Million
PXR	Pregnane X Receptor
RAC	Raw Agricultural Commodity
RTI	Re-Treatment Interval
STMR	Supervised Trials Median Residue
STMR-P	Supervised Trials Median Residue In A Processed Commodity
T <sub>4</sub>	Thyroxine
TCP	Trichlorophenol
T <sub>max</sub>	Time to Reach Maximum Concentration
TRR	Total Radioactive Residues
TSH	Thyroid-Stimulating Hormone
TTC	Threshold of Toxicological Concern
UL	Uniformly Labelled
USA	USA of America
USEPA	USA Environmental Protection Agency
WHO	World Health Organization





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

Most of the summaries and evaluations contained in this report are based on unpublished proprietary data submitted for use by JMPR in making its assessments. A registration authority should not grant a registration on the basis of an evaluation unless it has first received 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 2018 joint FAO/WHO meeting of experts**

#### **1. Introduction**

The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) was taken place at the headquarters of the Federal Institute for Risk Assessment (BfR) in Berlin, Germany, from 18 to 27 September 2018. The meeting was opened by Dr Roland Solecki, Head of the BfR Department of Pesticides Safety. Over 50 participants from five continents participated in the Meeting.

On behalf of the President of the BfR, Dr Solecki welcomed the JMPR Meeting being held in Berlin. He highlighted that it was the first time the JMPR had been hosted by a national government authority in its 55 year history of assessing consumer health risks of pesticide residues in foods and feeds, and recommending maximum residue levels to the Codex Alimentarius Commission. He remarked, that experts from the BfR, and its predecessor organizations had a long history of participation in the the work of the JMPR and had contributed to both the development of, and international harmonization of many assessment concepts. From that perspective he considered the hosting of the 2018 JMPR another important initiative in that process. The BfR is the scientific body of the Federal Republic of Germany and provides expert reports and opinions on risks related to food ingestion and exposure to consumers including risk assessments of industrial chemicals, food additives, biocides and pesticides. Dr Solecki indicated that the BfR held the view that international harmonization was extremely important, as it forms the basis for national and international acceptance of risk assessments.

He also highlighted that such hosting of the JMPR Meeting would provide opportunities for national competent authorities of Codex Members, to improve linkages and strengthen relationships with the JMPR. Such collaboration would help facilitate a better understanding of the working principles of the JMPR and contribute to the further harmonization of risk assessment principles. The JMPR Secretariats expressed their appreciation to BfR for hosting this meeting and for all the support of BfR to the work of JMPR. The experience gained from this meeting would benefit the JMPR Secretariats for future co-organizing the meeting with other national authorities.

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

The Meeting considered general items addressing procedures for the evaluation and risk assessment of pesticide residues used to recommend maximum residue levels.

### **1.1 Declaration of interests**

The Secretariat informed the Meeting that all experts participating in the 2018 JMPR had completed declaration of interest forms and that no conflicts had been identified.

## 2. General considerations

### 2.1 Toxicological profiling of compounds and less-than-lifetime dietary exposure assessment

The 2015 meeting of JMPR (see section 2.2 of the 2015 JMPR meeting report, “Short-term lifetime exposures”) raised concerns about the risk characterization of less-than-lifetime exposures (i.e. exposures that are longer than 1 day but shorter than a lifetime) to pesticide residues over a season or a life-stage – specifically, the possibility that dietary exposures above the acceptable daily intake (ADI) over short time frames could result in adverse effects in both normal and susceptible subpopulations when the lifetime (long-term or chronic) estimated dietary exposure was below the ADI.

A joint JMPR / Joint FAO/WHO Expert Committee on Food Additives (JECFA) working group meeting was held in October 2017 to explore methods for a harmonized approach to chronic dietary exposure assessments for compounds used as both pesticides and veterinary drugs. The JMPR/JECFA working group concluded that there is a need to better align the dietary exposure model to be used as part of the risk assessment process with the toxicological profile of the compounds and confirmed that the choice of an appropriate exposure model is determined by the toxicological end-point of concern (which includes the time to onset). Following the working group meeting, JECFA, at its eighty-fifth meeting, developed a draft decision-tree to be used to generate a toxicological profile of the chemical of interest (Figure 1).

As a follow-up, the present Meeting discussed options for the risk assessment of pesticide residues with such toxicological profiles.

#### *Toxicological considerations*

The draft decision-tree, together with the wider issue of how best to profile the toxicological effects of pesticides to enable better alignment of the exposure assessment, was discussed at a 1-day meeting of toxicological and exposure experts immediately preceding the 2018 JMPR (the “pre-meeting”).

It was agreed at the pre-meeting that the subpopulations for whom dietary exposures over a season or life-stage might result in short-term exceedances of the ADI that were potentially of toxicological concern were the embryo or fetus (developmental toxicity), infants and young children (0–6 years) (offspring toxicity) and adults who were high consumers of foods containing the pesticide residue. In the draft decision-tree, the factor of 3 used in the decision points to identify populations of toxicological concern was based on the ratio of the 97.5<sup>th</sup> percentile exposure to the mean dietary exposure for consumers. The pre-meeting observed that when comparing points of departure (PODs) across studies, it is necessary to consider the respective power of the toxicological studies. For example, fewer animals are used in a 90-day study of toxicity in rats than in a 2-year study. It was recommended that PODs should be considered similar if they are within one order of magnitude of each other (i.e. differ by less than 10-fold), based on toxicological rather than exposure considerations. It was therefore proposed that the decision-tree be revised to use a factor of 10 (rather than 3) as the trigger at the decision points.

In the draft decision-tree, the first decision point was identification of the end-point used as the basis of the ADI. Once this toxicological effect was identified as being of potential concern (e.g. offspring toxicity), the risk characterization would be completed by comparing exposure in the relevant subpopulation with the ADI. However, it is still possible that estimated dietary exposures for one or both of the remaining subpopulation groups (from the original decision point) could exceed the ADI on a short-term basis. Hence, it was agreed that all three scenarios should be assessed for all compounds.

The pre-meeting discussed which studies should be used to profile less-than-lifetime exposure. It was noted that for the majority of compounds, adequate information on their toxicological effects would be available only in the rat, and hence this should be the species of preference for such comparisons. However, if suitable information is available in other species, this should also be assessed. Data on the dog would not normally be suitable for this purpose, as both the 3-month and the 1-year studies cover only a small fraction of the lifespan of this species<sup>1</sup> and thus are not adequate to assess toxicity after chronic (long-term) exposure. As it is rare for a critical no-observed-adverse-effect level (NOAEL) to change between 2 and 4 weeks of exposure, there should be sufficient information from rat (and mouse) studies conducted for 4–104 weeks to enable assessment of whether there is any specific concern for less-than-lifetime exposure. The pre-meeting therefore recommended that for such assessments, when applying the decision-tree, the PODs from studies in rats with a duration of 4 weeks, 90 days and 2 years (or 1 year) should be compared to assess less-than-lifetime exposure. Additional information on less-than-lifetime exposures might be available from other studies in the database, such as parental animals in studies of developmental or reproductive toxicity or repeated-dose neurotoxicity.

Although there was some concern about how test article intake decreases on a body weight basis as the age of the animals increases (due to changes in feed consumption in grams per kilogram of body weight with ageing, particularly up to 20 weeks of age), the pre-meeting agreed that doses should be compared on a milligram per kilogram of body weight per day basis, as this is the dose metric used in establishing the ADI. It was noted that, to some extent, this age-related change in exposure would be taken into account by the proposed factor of 10 used in the comparison of PODs. It was also noted that care should be taken when comparing PODs determined using different dosing regimens, particularly when comparing gavage and dietary dosing, as would often be the case in a comparison of a developmental toxicity study with a chronic (long-term) toxicity study in rats.

When the basis of the ADI is the critical POD from a study in dogs (a 3-month and/or a 12-month study), this already represents less-than-lifetime exposure. Hence, comparison of the POD in the 2-year rat study with that in the dog study can be used to determine whether there are any additional concerns for less-than-lifetime exposure. In general, if the POD in the 2-year rat study is more than 10-fold higher than the POD in the study in dogs on which the ADI is based, no further assessment of this scenario would be necessary. Comparison with the PODs for developmental and offspring toxicity in the rat would still be necessary.

For compounds for which an acute reference dose (ARfD) is considered necessary, if the POD on which the ARfD is based is numerically the same as the POD on which the ADI is based, there will be no concern for less-than-lifetime exposure if acute exposures (i.e. exposures that are less than 24 hours in duration) of both children and the general population are not of concern (i.e. the estimate of acute exposure is less than the ARfD). The pre-meeting noted that this would also be true when the POD on which the ARfD is based is slightly higher than the POD on which the ADI is based (i.e.  $\text{POD [ARfD]} / \text{POD [ADI]} > 1$ ), but the appropriate margin would need to be determined by analysis of a suitable data set.

The pre-meeting discussed the issue of pesticide metabolites that are more toxic than the parent compound. In the majority of cases, data from long-term studies will not be available for metabolites. If it is possible to reach a conclusion on the potency of the metabolite relative to that of the parent compound, the toxicological profile of the metabolite will be qualitatively the same as that of the parent compound, and a potency factor can be used in the risk characterization. Otherwise, the decision-tree should be applied – if possible, and to the extent possible – for the metabolite.

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<sup>1</sup> WHO (2015). Guidance document for WHO monographers and reviewers. Geneva: World Health Organization (<http://www.who.int/foodsafety/publications/JMPR-guidance-document/en/>).

In summary, it was agreed that the draft decision-tree required revision to better reflect uncertainty in the respective health-based guidance values, and that all three toxicological/exposure scenarios (developmental, offspring, less-than-lifetime) should be considered, regardless of the basis of the ADI. The draft decision-tree will be revised to address these and any other concerns raised in future consultation with JECFA experts.

In preparation for the 2018 JMPR, WHO monographers undertook a pilot exercise using the draft decision-tree developed by JECFA following the JMPR/JECFA working group meeting in 2017 (see Figure.1). The results of the toxicological profiling of compounds were presented and discussed at the pre-meeting. In general, the decision-tree was easy to follow, although a few issues were identified. These were discussed at the pre-meeting and resolved as noted above. It was agreed that for the purpose of the 2018 JMPR, the results of this exercise – i.e. using the draft decision-tree with a factor of 3 for the comparisons, but following the specific clarifications above – would be included in the report of the 2018 meeting (Table 1). ***This table is for illustrative purposes only and should not be interpreted as a definitive toxicological profiling of these substances.***

#### *Dietary exposure considerations*

JMPR has used the average of the estimated chronic dietary exposure for the general population for the comparison with the ADI, which may not be suitable for assessing less-than-lifetime risk. The current approach used by other groups, such as JECFA, is to compare estimated chronic dietary exposures with the ADI for the general population and to compare less-than-lifetime exposures with the ADI for subpopulation groups, including high consumers.

The Meeting currently calculates long-term (chronic) mean dietary exposure estimates for the general population based on the WHO Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme (GEMS/Food) consumption cluster diets (international estimated daily intake, or IEDI); these estimates are compared with the ADI to characterise the risk for each pesticide residue. The GEMS/Food 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 cluster diet, the amount of food available for consumption per capita (apparent food consumption), expressed in grams per day. However, owing to the nature of the FAO supply utilization account data used, the IEDI calculation cannot provide information for specific age/sex population groups or for high consumers of foods containing the pesticide residue of interest that may be required for assessing less-than-lifetime exposures.

As part of the trial exercise, the global estimate of chronic dietary exposure (GECDE) model developed by JECFA (veterinary drugs) in 2011<sup>2</sup> was used for estimating less-than-lifetime dietary exposure to pesticide residues for population subgroups of toxicological concern as identified using the decision-tree for toxicological profiling, such as high consumers in the adult population, women of childbearing age, and 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 only) plus consumption of the remaining commodities at a population mean level.

Food consumption data suitable for use in the GECDE model are available in the WHO Chronic Individual Food Consumption – summary statistics (CIFOCos) database, which contains summary food

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<sup>2</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)).

consumption data derived from national surveys that have two or more records per survey participant. Food consumption data (as reported) in each survey are averaged over the number of records prior to deriving summary statistics for the general population or subpopulation groups of interest and for consumers of each food only. The summary data are suitable for use in chronic dietary exposure assessments using the GECDE; in some cases, however, factors were required to convert the food consumption data as reported to raw commodity equivalents prior to use. It is not possible to derive an overall mean for an “exposed” consumer (i.e. people who have eaten one or more of the foods containing a pesticide residue) from the available summary statistics.

For each pesticide evaluated at this Meeting, results for the IEDI are reported in Chapter 4. As part of the pilot of trialling use of the decision-tree for toxicological profiling for new evaluations, estimated dietary exposures for the mean for the general population and the GECDE for population groups of toxicological concern were also derived using CIFOCoss survey data for each country. The results are summarised in Table 2, for illustrative purposes only.

Generally, the results using individual consumption data from national surveys in the CIFOCoss database to estimate mean dietary exposure to a specified residue for the general population were lower than the highest IEDI cluster estimate from the 17 cluster diets. Dietary exposure estimates from the high consumer GECDE model were of the same order of magnitude as the highest IEDI cluster estimate for the majority of pesticide residues considered in this exercise. However, for some subpopulation groups, the estimated dietary exposure using the GECDE was higher than the highest IEDI cluster estimate.

### *Conclusions*

The Meeting agreed that the decision-tree is a useful approach, but that further work is necessary. The WHO Secretariat for JECFA and JMPR will convene an electronic working group to finalize the approach.

The Meeting noted that it would be useful to consider reporting potential dietary exposures based on national survey data in addition to the IEDI results at future JMPR meetings where there is an identified concern about less-than-lifetime exposures, as it provides additional information on subpopulation groups that is of use to risk assessors and risk managers. The Meeting considered that the GECDE could be a suitable model for this purpose. However, further work is required on a wider range of pesticides before the Meeting can include this approach in JMPR’s general procedures. Work is also required to improve the consistency of coding of foods in each country survey as submitted to WHO for inclusion in the CIFOCoss database. The Meeting noted that WHO is currently updating this database using FoodEx2 coding only for foods reported as consumed, which should address this issue in the future.

The Meeting recommended that the applicability of these considerations to the harmonization of risk assessments of chemicals used as pesticides and as veterinary drugs, particularly those with dual use, should be further discussed with JECFA.



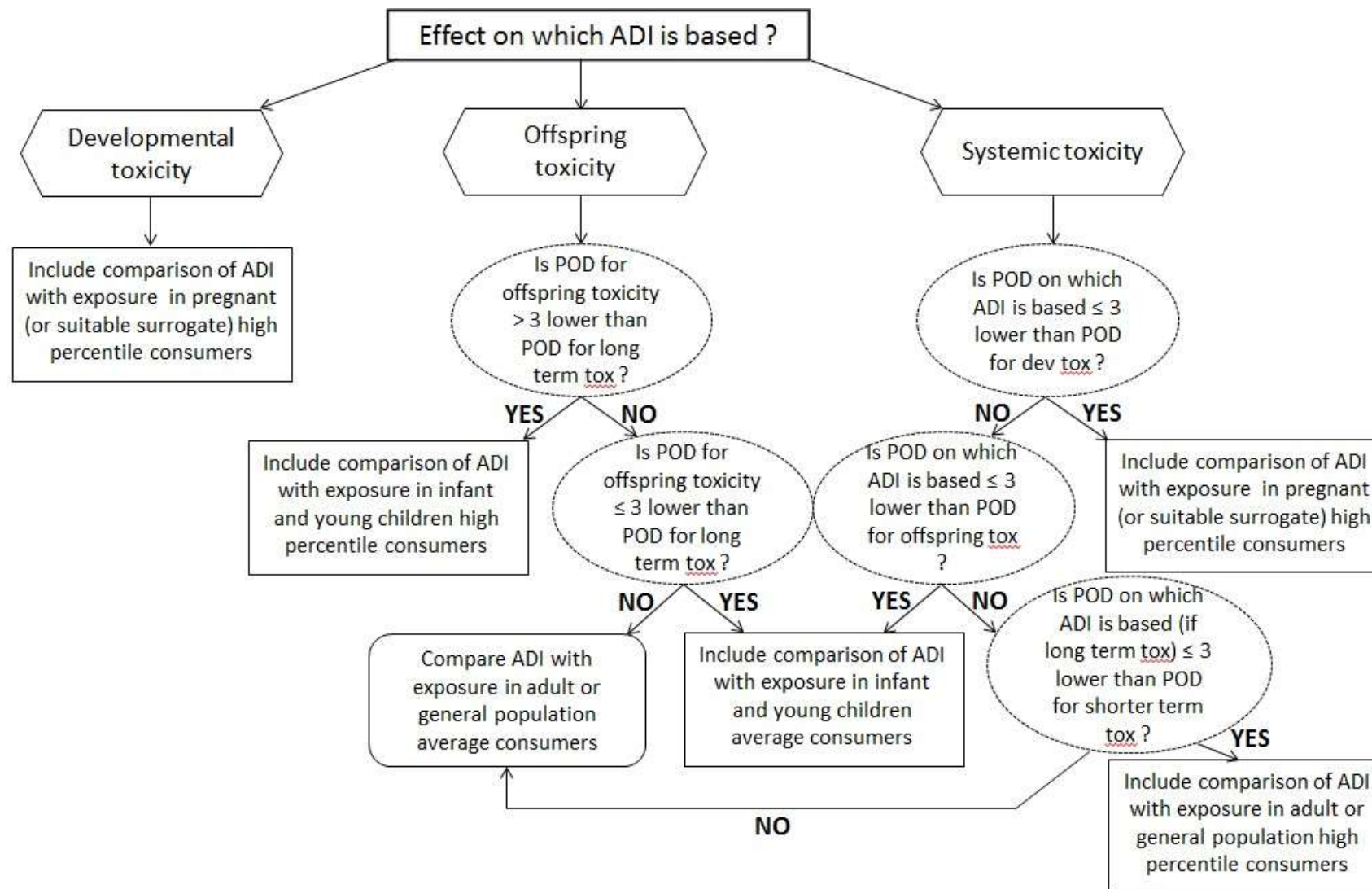


Table 1 Summary of toxicological profiles of compounds not previously evaluated by JMPR, for illustrative purposes only (based on Figure 1)

Pesticide	Study on which the ADI is based	Upper bound of ADI (mg/kg bw)	ARfD (mg/kg bw)	Potential concern in pregnant women	Potential concern in offspring	Potential concern for less-than-lifetime exposure
Ethiprole	Developmental toxicity (rabbit)	0.005	0.005	Appreciable	None	None
Fenpicoxamid	Eighteen-month toxicity (mouse)	0.05	Unnecessary	Moderate	Not applicable	None
Mandestrobin	One-year toxicity (dog)	0.2	3	None	Moderate	None
Norflurazon	Six-month and 1-year toxicity (dog)	0.005	0.3	Moderate	None	None
Pydiflumetofen	Two-year toxicity (rat)	0.1	0.3	None	None	Appreciable
Pyriofenone	Two-year toxicity (rat)	0.09	Unnecessary	None	None	None
Tioxazafen	Two-year toxicity (rat)	0.05	0.5	None	None	Appreciable

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight

Table 2 Summary of estimated dietary exposures to pesticide residues (new evaluations only) for populations of interest <sup>a</sup>

Pesticide	Population group assessed	IEDI (µg/kg bw per day)	Mean dietary exposure (CIFOC0ss <sup>b</sup> ) (µg/kg bw per day)	GECDE (CIFOC0ss <sup>b</sup> ) (µg/kg bw per day)	Upper bound of ADI <sup>c</sup> (µg/kg bw)	IEDI as % of upper bound of ADI	Mean dietary exposure (CIFOC0ss) as % of upper bound of ADI	GECDE (CIFOC0ss) as % of upper bound of ADI
Ethiprole	General population	0.05–0.3	0–0.34	0–1.26	5	1–6	0–7	0–25
	Women of childbearing age		0–0.4	0–0.64			0–8	0–13
Fenpicoxamid	General population	0.0009–0.08	0.001–0.004		50	0	0	
	Women of childbearing age		0–0.02	0–0.09			0	0
Norflurazon	General population	0.2–0.9	0–0.79		5	3–20	0–16	
	Women of childbearing age		0–1.12	0–3.2			0–22	0–65
Pydiflumetofen	General population	0.003–0.29	0.01–0.11	0.04–4.1	100	0	0	0–4
	Adults		0.03–0.18	0.35–1.34			0	0–1
Pyriofenone	General population	0.03–0.77	0–0.1	0–3.2	90	0	0	0–4
Tioxazafen	General population	0.01–0.12	0–0.03	0–0.2	50	0	0	0
	Adults		0.02–0.06	0.06–0.15			0	0

ADI: acceptable daily intake; bw: body weight; CIFOC0ss: 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 CIFOC0ss 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 97.5<sup>th</sup> percentile dietary exposure for consumers only was derived; if there were more than 60 but fewer than 181 consumers, a 95<sup>th</sup> percentile dietary exposure was derived; if there were more than 30 but fewer than 61 consumers, a 90<sup>th</sup> 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 CIFOCC database has the following numbers of national surveys in the database: whole population, seven surveys; adults, 15 surveys; adult women, two surveys; women of childbearing age, two surveys; children less than 6 years of age, two surveys; and toddlers aged 1–3 years, nine surveys.
- <sup>c</sup> For the purposes of this table, the ADI is expressed in µg/kg bw (rather than the usual mg/kg bw).

## 2.2 Need for sponsors to submit all requested data

In the JMPR call for data, sponsors are requested to submit all data and studies, both published and unpublished, for the toxicological and residue evaluations of the compounds.

For fluazinam, the sponsor did not submit critical information on the levels of a toxicologically relevant impurity in batches used in the toxicity studies. The Meeting was aware that this information had been made available to a number of regulatory authorities. The Meeting was therefore unable to proceed with the evaluation of fluazinam.

For mandestrobin, despite repeated requests prior to the meeting for additional data on environmental fate and other registered labels, the sponsor did not submit this information until well into the meeting. Following a review of the draft appraisal, the sponsor submitted another 18 study reports on environmental fate and field residue studies. This information was deemed necessary for determining the residue definitions for compliance and dietary risk assessment. Considering the amount of new information and its likely impact on the conclusions, the Meeting was unable to process the information in the time remaining and decided to postpone the evaluation of the compound to the 2019 meeting.

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

## 2.3 Hazard characterization in the 21st century: assessing data generated using new mechanism-based approaches for JMPR evaluations

JMPR first discussed the potential contribution of data generated using new mechanism-based approaches ("Tox 21"), often referred to as New Approach Methodologies (NAM), in the risk assessment of dietary exposure to pesticide residues at its meeting in 2012. At that time, JMPR offered to evaluate, without prejudice, data generated using new technologies as they become available, in parallel with the results of traditional toxicity testing, to determine their utility and role in pesticide evaluation. JMPR repeated this offer at the 2013 meeting and agreed that, starting from the 2014 meeting, this offer should be regularly included in the call for data for JMPR evaluations. During the five or so years that this opportunity has been available, JMPR has not received any such information, other than in support of mode of action assessments. In no instance has a sponsor made the case that evaluation of specific effects in vivo would not have been necessary because data from NAM were sufficiently reliable to enable the relevant assessment.

It is unclear why this is the case. In discussions with sponsors, it is evident that such data are being generated to support product development. However, there appears to be great reluctance to subject them to independent comparison with data generated using conventional in vivo tests. Regulatory authorities

such as the USA Environmental Protection Agency (USEPA)<sup>3</sup> and the European Commission<sup>4</sup> envisage the application of NAM in the assessment of pesticides at some point in the future and are investing significant resources to achieve this.

It is therefore important that both the regulated and the regulating communities become familiar with the advantages and limitations of such methods in the hazard characterization of pesticides. It is not envisaged that NAM will provide one-for-one replacements for in vivo tests; rather, NAM will provide an alternative means of assessing the risk of end-points of concern (or their necessary precursors, as verified in method development). The offer made by JMPR would enable practical experience in their assessment to be used in the future development of regulatory guidance by other bodies. Hence, JMPR repeats its offer and urges sponsors to submit at least a few case-studies for consideration at future meetings of JMPR.

## **2.4 Update on the revision of principles and methods for risk assessment of chemicals in food (EHC 240).**

### *Benchmark dose approach*

During the application of the benchmark dose (BMD) approach at several JMPR meetings, Members noted that a number of points have emerged since publication of WHO guidance on this approach (Environmental Health Criteria [EHC] 239<sup>5</sup> and EHC 240<sup>6</sup>) that were not adequately addressed in the current guidance documents. The 2016 Meeting therefore recommended that EHC 240 be updated to reflect experience gained in the application of the BMD approach in dose–response modelling since the guidance was published. The BMD approach is also utilized by JECFA in a number of its evaluations, and an update of the guidance to take new scientific developments into account was also recommended by JECFA.

Hence, the WHO Secretariat has established a working group comprising experts from JECFA and JMPR, together with additional specialists in the area, to revise and update Chapter 5 of EHC 240. This will include not only an update of the BMD approach in dose–response modelling, but also consolidation of the sections on PODs in general and on the establishment of health-based guidance values using these PODs. The revised text will be discussed at an expert meeting in spring 2019, following which the text will be finalized and, after a public comment period, published on the WHO website, to replace the existing chapter of EHC 240.

### *Evaluation of genotoxicity*

At its meeting in May 2016, JMPR assessed the toxicity of glyphosate and malathion. The toxicological database for both compounds was large and comprised studies of diverse quality and design. This was particularly true for genotoxicity. During evaluation of these data, it became apparent that the guidance in section 4.5 of EHC 240 did not cover a number of the key points requiring consideration. Hence, the May 2016 Meeting recommended that a guidance document be developed for the evaluation of genotoxicity studies, taking the experience gained from the meeting into account.

Also following recommendations from JECFA, including the need for guidance to address scenarios where few genotoxicity data are available, the Joint Secretariat convened a working group,

<sup>3</sup> <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/strategic-vision-adopting-21st-century-science>

<sup>4</sup> [https://www.sapea.info/wp-content/uploads/SAPEA\\_PESTICIDES\\_forJune.pdf](https://www.sapea.info/wp-content/uploads/SAPEA_PESTICIDES_forJune.pdf)

<sup>5</sup> WHO (2009). Principles for modelling dose–response for the risk assessment of chemicals. Geneva: World Health Organization (Environmental Health Criteria 239; <http://www.inchem.org/documents/ehc/ehc/ehc239.pdf>).

<sup>6</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/>).

comprising experts from JMPR and JECFA, together with additional specialists in the area, to update and expand section 4.5 of EHC 240. The revised text will be discussed at an expert meeting to be held in October 2018, following which the text will be finalized and, after a public comment period, published on the WHO website, to replace the existing section of EHC 240.

## 2.5 Microbiological effects

The use of pesticides, particularly fungicides, in agriculture to control plant pathogens in crops could result in residues in food, which, on ingestion, may interact with the microbiome in the human gastrointestinal tract. The intestinal microbiome is a diverse microbial community consisting of bacteria, fungi, viruses and protozoa.<sup>7,8</sup> Disruption in the composition of the intestinal microbiome, including the fungal communities, by residues of fungicides or by other pesticides could have an impact on intestinal homeostasis and systemic immunity. In 2017, JMPR therefore recommended that studies of the effects of pesticides on the intestinal microbiota should be routinely considered, following the step-wise decision-tree approach used by JECFA when establishing a microbiological ADI and ARfD for veterinary drugs.<sup>9</sup>

Therefore, the fungicides fenpicoxamid, fluazinam, mandestrobin, pydiflumetofen and pyriofenone were evaluated for JMPR 2018 to determine their impact on the microbiota in the gastrointestinal tract. As no data were submitted by the sponsors, a literature search was performed using a number of search engines. These included Google Scholar<sup>10</sup>, Google search engine<sup>11</sup>, PubMed<sup>12</sup>, Web of Science<sup>13</sup>, BioOne<sup>14</sup> and ScienceDirect<sup>15</sup>.

The search strategy used included the input keywords of the fungicide chemical name (fenpicoxamid, fluazinam, mandestrobin, pydiflumetofen and pyriofenone), chemical structure, antimicrobial mode of action, antimicrobial spectrum of activity, antimicrobial resistance, resistance mechanisms and genetics, microbiome, microbiota, gut microbiota, gut microbiome, gastrointestinal microbiota, gastrointestinal microbiome, etc., and the Boolean operators AND, OR and NOT.

The extensive search and review of the scientific literature did not find any reports on the effects of the fungicides evaluated by JMPR 2018 on the intestinal microbiome to include in the toxicological risk assessments. This is an important information gap, as recent literature has reported on the critical role of the microbiota in maintaining intestinal health.

## 2.6 Transparency of JMPR procedures

JMPR is a scientific body producing two types of documents: namely, JMPR reports and JMPR monographs.

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<sup>7</sup> Paterson MJ, Oh S, Underhill DM (2017). Host–microbe interactions: commensal fungi in the gut. *Curr Opin Microbiol.*40:131–7. doi:10.1016/j.mib.2017.11.012.

<sup>8</sup> Gilbert JA, Blaser MJ, Caporaso JG, Jansson JK, Lynch SV, Knight R (2018). Current understanding of the human microbiome. *Nat Med.*24(4):392–400. doi:10.1038/nm.4517.

<sup>9</sup> Boobis A, Cerniglia CE, Chicoine A, Fattori V, Lipp M, Reuss R et al. (2017). Characterizing chronic and acute health risks of residues of veterinary drugs in food: latest methodological developments by the Joint FAO/WHO Expert Committee on Food Additives. *Crit Rev Toxicol.*47(10):889–903. doi:10.1080/10408444.2017.1340259.

<sup>10</sup> <http://scholar.google.com/>

<sup>11</sup> <https://www.google.com/>

<sup>12</sup> <http://www.ncbi.nlm.nih.gov/pubmed>

<sup>13</sup> <https://apps.webofknowledge.com>

<sup>14</sup> <http://www.bioone.org/>

<sup>15</sup> <http://www.sciencedirect.com/>

Each JMPR monograph is prepared by the experts assigned to the compound prior to the Meeting based on the original studies and the toxicological and residue dossiers submitted by the sponsor(s) (i.e. industry or Codex members), on the relevant published scientific literature and on data provided by Codex members. The monographs describe and evaluate in detail the design and the results of the studies performed to assess the toxicological effects and the residue aspects of the pesticides and include tables summarising the data submitted. The experts carefully check the study descriptions, data and the submitted tables for completeness, accuracy and consistency.

The JMPR report is prepared by the experts during the Meeting and adopted by the whole group. The report consists of an evaluation and interpretation of the data compiled in the monograph and concludes on the possible risk of the chemical from dietary exposure.

The Meeting noted that while the JMPR reports constitute original publications, the JMPR monographs may contain study descriptions and tables based on those in the dossier submitted by the sponsors. The Meeting considers this to be an appropriate use of the submitted materials.

The Meeting agreed that a disclaimer will be prepared by the Joint Secretariat to be included in future JMPR monographs.

## **2.7 Review of the large portion data used for the IESTI equation**

FAO and WHO regularly collect so-called “large food portions” to be used by JMPR, JECFA and other international scientific bodies for acute dietary exposure assessments. These large portions are based on the 97.5<sup>th</sup> percentile consumption for consumers only on a single day or eating occasion.

The last data call was launched in 2012, and a new call should be posted in 2019. In order to obtain fully comparable data between countries, this call should describe suitable procedures for deriving the 97.5<sup>th</sup> percentile, for establishing the number of consumers necessary to derive statistically robust percentiles as well as for disaggregating food as consumed into its component ingredients (processed and raw commodities), when needed.

JMPR encourages Member States and relevant institutions to update their data by responding to the upcoming call.

## **2.8 Update of the iedi and iesti models used for the calculation of dietary exposure: commodity grouping according to the revised codex classification and new large portion data**

The 2003 Meeting agreed to adopt automated spreadsheet applications for the calculation of dietary exposure in order to facilitate the process. The IEDI model for long-term dietary exposure and the IESTI model for acute dietary exposure were constructed by RIVM (National Institute for Public Health and the Environment) of the Netherlands in cooperation with WHO/GEMS/Food. The IEDI model had last been updated by the 2014 JMPR, while the IESTI model had last been updated by the 2017 JMPR.

The 2017 Codex Alimentarius Commission (CAC) had adopted the revision of the Classification of Food and Feed for Vegetable Commodity Groups and the Group of Grasses and Cereal Grains. To enable dietary exposure assessments for commodity groups and subgroups as presented in this revised classification, the food consumption data in the IEDI and IESTI models were regrouped according to this revised classification. Furthermore, the amendments to the Fruit Commodity Groups adopted by the 2017 CAC were implemented in the IEDI and IESTI models.

In addition, since dual uses from pesticides and veterinary drugs can be expected in the future, available food consumption data for fish have been added to both models.

Furthermore, the IESTI model has been updated for the present Meeting to contain the more recent large portion data from Finland and the EFSA PRIMo rev 3 model. The large portion data for Finland, France, Germany, the Netherlands and the United Kingdom that were submitted to WHO/GEMS/Food, are also taken into account in the EFSA PRIMo rev 3 model. To avoid any discrepancies between the PRIMo rev 3 model and the JMPR IESTI model, any large portion data from these individual European countries were replaced by the large portion data for equivalent commodities in the PRIMo rev 3 model. When no equivalent commodities were present in the PRIMo rev 3 model, the large portion data from these individual European countries were kept. The current model now contains large portion data for Australia, Brazil, Canada, China, 13 European countries (BE, CZ, DE, DK, ES, FI, FR, IE, IT, NL, PL, LT, UK), Japan, Thailand and the USA.

The IEDI model, the IESTI large portion data overview and the IESTI model, as used by the JMPR 2018, are available on the WHO<sup>16</sup> and FAO<sup>17</sup> websites.

## **2.9 Recommendations for (sub) group maximum residue levels for fruiting vegetables, other than cucurbits revisited.**

Some delegations at the Fiftieth Session of the CCPR expressed concern that the 2017 JMPR had not recommended (sub) group maximum residue levels for the tomato and pepper groups for a number of pesticides. The JMPR secretariat agreed that, based on information to be supplied by the EU and Canada, the 2018 JMPR would revisit those recommendations for the subgroup peppers that were made with exceptions for martynia, okra and roselle.

The Meeting did not receive any data relating to the relative residues in the various crops, rather the information supplied comprised national and regional policy and guidance documents.

From the EU the current meeting received:

- the EU guidance document relating to extrapolations and crop groupings (Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs, SANCO 7525/VI/95 Rev.10.3 13 June 2017)
- a listing of crop grouping used in the EU (COMMISSION REGULATION (EU) 2018/62 of 17 January 2018 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council).

From Canada the meeting received an explanation of the Canadian policy regarding extrapolation for the commodities under consideration. The document from Canada also noted that a comparison of EU MRLs for okra, sweet peppers/bell peppers, and hibiscus/roselle indicated that when quantifiable residues were observed in these crops, in almost all cases (except 3 of over 400 MRLs) the MRLs were the same. However, the EU reported that for martynia and roselle, that they have no experience of the residue situation in these crops. In addition, the Meeting noted MRLs in the EU for okra are likely extrapolations from peppers and so offer no insight into the relative residue potential for the different commodities.

The Meeting recalled the guiding principles and the criteria for crop group of the Classification (CL 2017/22-PR) and that the characteristics for crop grouping are:

<sup>16</sup> [http://www.who.int/foodsafety/areas\\_work/chemical-risks/gems-food/en/](http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/)

<sup>17</sup> <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/>

1. Commodities' 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.

To provide an evidence-based justification for extrapolation within subgroups, a review was conducted of the residue potential of the crops in the tomato and pepper 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 (waxy surface versus hairy surface etc.) 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 even with relative differences in growth dilution within a group or subgroup and the potential impact on residues at longer post-application intervals.

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 that data from trials where more than one spray had been applied could be used provided there was sufficient evidence to conclude the earlier spray did not contribute more than 25% to the observed residue. The Meeting utilised JMPR evaluations in the period 1993 to 2017 and supplemented these with other publicly 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 2 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.



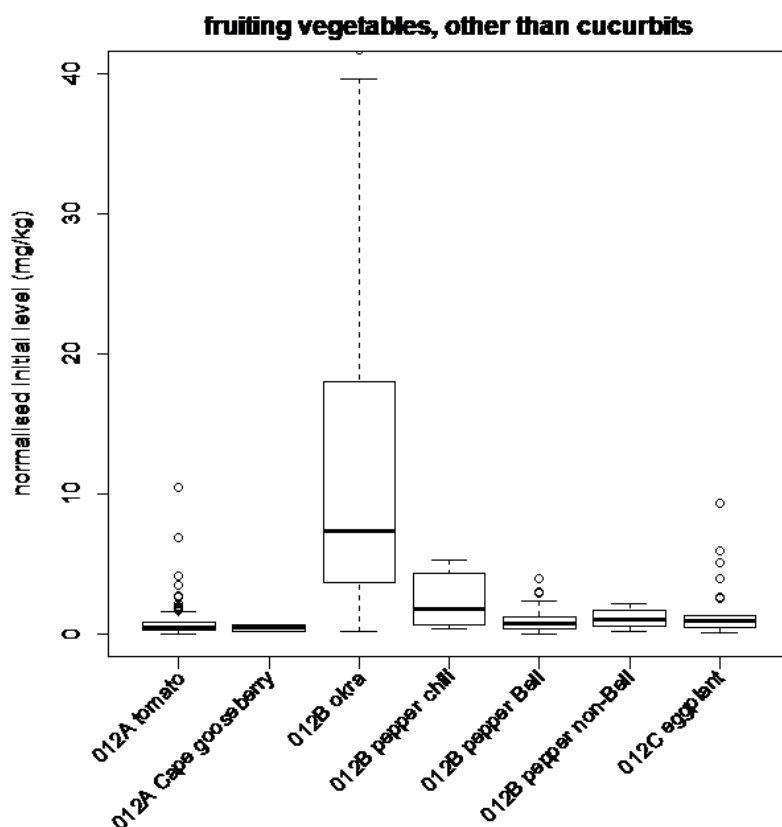


Figure 2 Initial residue (normalised to application rate 1 kg ai/ha) for fruiting vegetables, other than cucurbits

#### *Subgroup Tomatoes*

Data for tomato were not separated into cherry and other tomatoes due to the difficulty in assigning the size classification based on the crop variety information available. The data for Cape gooseberries were obtained from the Australian Pesticides and Veterinary Medicines Authority with permission of the data owner. For members of the subgroup tomato (012A), median normalised initial residues are 0.52 mg/kg (n = 213) for tomato and 0.47 mg/kg (n = 2) for Cape gooseberry (including husk). The limited data resolve the concerns expressed by the 2017 JMPR and support the extrapolation of residue data on tomatoes to the whole subgroup.

#### *Subgroup Peppers*

In the case of subgroup peppers (012B), median normalised initial residues for okra 7.4 mg/kg (n = 108) are much higher than for peppers chili 1.8 mg/kg (n = 9), peppers Bell 0.74 mg/kg (n = 40) and peppers non-Bell 1.1 mg/kg (n = 4). The data suggest that peppers are unlikely to reflect the residues present in okra when treated according to the same cGAP. Using the principles and criteria for crop grouping, this finding is explained by differences in size and shape of okra fruit (ridged and slight hairy surface) when compared to pepper (smooth-skinned surface) and their relative residue potentials due to fruit morphology.

The Meeting confirmed the conclusion of the 2017 JMPR for the subgroup of peppers - available information suggests residues in okra differ from those in peppers. While the JMPR is not aware of trials comparing residues in peppers, roselle and martynia, differences in crop growth habit, commodity size and shape lead the Meeting to suspect that residues in Bell and non-Bell peppers may not be representative of residues in the other commodities, i.e. okra, martynia and roselle. In the absence of data on relative residues

in these crops, the Meeting decided when data are available for Bell and non-Bell peppers to recommend maximum residue level for:

VO 0051 Subgroup of Peppers (except okra, martynia and roselle).

#### *Subgroup Eggplants*

It is current practice of the JMPR to extrapolate recommendations for tomatoes to eggplants when the crops share a common use pattern (GAP) and no residue data is available for eggplants. As noted earlier, residues on the day of application of foliar sprays provides a good indication of the relative residue potential of different crops. The median normalised initial level for eggplant was 0.97 mg/kg (n = 28) whereas the levels for tomato were 0.52 mg/kg (n = 213) (Figure 2). Extrapolation of recommendations for tomato to eggplant may result in maximum residue level recommendations that are too low for eggplant. The Meeting observed that normalised levels in peppers are closer to eggplant (peppers Bell 0.74 mg/kg, n = 40; peppers non-Bell 1.1 mg/kg, n = 4) suggesting peppers is a better representative commodity for extrapolation to eggplants.

The Meeting agreed that when GAPs allow for extrapolation to the subgroup Eggplant, the extrapolation would be based on peppers

The Meeting agreed to use the dataset for peppers or tomatoes that would lead to the higher maximum residue level recommendation.

### **2.10 Preliminary 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 should be performed by WHO based on a probabilistic approach and combining results from national food consumption surveys and reported concentrations of pesticide residues from official monitoring programmes.

The data submitted by countries, the protocol for probabilistic assessment and preliminary results for Australia and the USA of America (USA) were presented to the meeting by the WHO Secretariat for information only. No further comments were made. A final report, including additional results for Brazil, Canada and four European countries (Czech Republic, France, Italy and the Netherlands), should be presented to the Meeting in 2019.

### 3. Responses to specific concerns raised by the codex committee on pesticide residues (CCPR)

#### 3.1 BENZOVINDIFLUPYR (261)

##### *Background*

The 2016 JMPR estimated a maximum residue level of 0.15 mg/kg for benzovindiflupyr in beans (dry) and a maximum residue level of 0.2 mg/kg in peas (dry). However, many specific species of dry pulses, including but not limited to fava bean, chick-pea and lentils, have no CXL. This has resulted in difficulties within the Canadian export market for dry beans and peas. The current Meeting received a request from the manufacturer to expand the maximum residue levels for beans, dry (VD 0071) and peas, dry (VD 0072) to Subgroup 15A, Dry beans (VD 2065) and Subgroup 15B, Dry peas (VD 2066), respectively.

##### *Comments by JMPR*

The 2016 JMPR estimated a maximum residue level of 0.15 mg/kg and a STMR of 0.011 mg/kg for benzovindiflupyr in beans (dry) based on the critical GAP for Canada in pulses (not including soya beans). In addition, the 2016 JMPR estimated a maximum residue level of 0.08 mg/kg and a STMR of 0.01 mg/kg in soya beans (dry) based on the critical GAP of Paraguay.

The GAPs for Canada and Paraguay are different:  $2 \times 0.075$  kg ai/ha with a 7 day interval and a 15 day PHI for Canada and  $3 \times 0.045$  kg ai/ha with 14 day intervals and a PHI of 21 days for Paraguay. Since the GAPs were different, the maximum residue level recommendation for dry beans cannot be expanded to the whole subgroup of dry beans. The current Meeting decided to expand the current maximum residue level recommendation of 0.15 mg/kg for beans, dry (VD 0071) to the Subgroup 15A, Dry beans (VD 2065), excluding soya beans, and to withdraw its previous recommendation of 0.15 mg/kg for beans, dry (VD 0071).

The 2016 JMPR estimated a maximum residue level of 0.2 mg/kg, a STMR of 0.014 mg/kg for benzovindiflupyr in peas (dry) based on the critical GAP for Canada in pulses (not including soya beans).

The current Meeting decided to expand the maximum residue level recommendation of 0.2 mg/kg for peas, dry (VD 0072) to the Subgroup 15B, Dry peas (VD 2066), and to withdraw its previous recommendation of 0.2 mg/kg for peas, dry (VD 0072).

##### *Dietary burden*

The expansion to the subgroup of dry beans and dry peas does not affect the dietary burden calculation and therefore the previously recommended maximum residue levels for animal commodities are not affected.

##### *Recommendation*

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

### 3.2 BROMOPROPYLATE (070)

A public health concern was raised by the European Union (EU) about the acute toxicity of bromopropylate, and therefore this compound was listed by WHO in the call for data for periodic review by JMPR in 2018. This compound is not supported by industry, and no data were submitted. 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, but because the JMPR assessments are outdated.

A review of the last JMPR monograph on bromopropylate (1993) shows that the lowest NOAEL for a possible acute effect (body weight deficit) was 20 mg/kg body weight (bw) per day (pregnant rabbits in a developmental toxicity study), indicating that any ARfD would be significantly higher than the upper bound of the ADI of 0–0.03 mg/kg bw. The acute oral median lethal dose (LD<sub>50</sub>) is greater than 5000 mg/kg bw, and there are no indications of any other toxicological effects that would be likely to be elicited by a single dose.

The Meeting recognized that the existing JMPR assessment is outdated and, in the absence of data, was not able to re-evaluate bromopropylate according to current JMPR requirements. However, based on the 1993 JMPR monograph, the Meeting also concluded that the critical driver identified for a potential ARfD, reduced body weight, was unlikely to represent a major, acute public health concern from dietary exposure to bromopropylate.

### 3.3 Crop groups – Reconsideration of maximum residue estimations made by the 2017 JMPR for FENPYROXIMATE (193), FLUOPYRAM (243), OXAMYL (126) AND SPINETORAM (233)

The meeting reconsidered its policy for extrapolation in the subgroups of tomatoes and peppers (see item 2.9 of this Summary Report) and subsequently agreed to reconsider maximum residue level estimations made by the 2017 JMPR for these subgroups. Specifically, the estimations made for four pesticides (fenpyroximate, fluopyram, oxamyl and spinetoram) were revisited following concerns raised by the EU and Canada. The resulting maximum residue level estimations are summarised below.

#### *Fenpyroximate*

The critical GAP in the USA is for fruiting vegetables (US crop group 8-10 which includes all commodities in the Codex subgroups tomatoes, peppers and eggplants) and is 2×117 g ai/ha with a PHI of 1 day.

#### *Tomato*

The Meeting agreed to extrapolate its previous maximum residue level estimation of 0.3 mg/kg for tomato to the subgroup of tomatoes. The Meeting agreed to withdraw its previous maximum residue level estimations for tomato and for cherry tomato of 0.3 mg/kg.

Further to the dietary exposure conclusions in 2017, a recently amended consumption figure resulted in the meeting concluding that residues of fenpyroximate in dried tomatoes were unlikely to exceed the ARfD.

The International Estimated Short-Term Intake (IESTI) for fenpyroximate was calculated for all the food commodities in the Subgroup of Tomatoes (and their processed fractions) for which maximum residue levels were estimated and for which consumption data were available. The results are shown in Annex 4 in the 2018 JMPR Report.

For tomatoes (including dried tomatoes), the IESTI represented 2–20% of the ARfD for the general population and 5–60% for children. The Meeting concluded that the acute dietary exposure to residues of

fenpyroximate in food commodities in the Subgroup of Tomatoes, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

#### *Fluopyram*

The critical GAP in the USA for fruiting vegetables is  $2 \times 0.25$  kg ai/ha with a PHI of 0 days.

#### *Tomato*

The Meeting agreed to extrapolate its previous maximum residue level recommendation of 0.5 mg/kg for tomato to the subgroup of tomatoes to replace the previous recommendations of 0.5 mg/kg for tomato and 0.4 mg/kg for cherry tomato.

#### *Oxamyl*

The GAP available to the 2017 JMPR was for tomato and peppers only. As a GAP is not available for the other members of the subgroup of tomatoes and the subgroup of peppers the Meeting confirmed its previous maximum residue level estimations.

#### *Spinetoram*

The 2017 JMPR only considered peppers. No change required.

### **3.4 CYPRODINIL (207) AND PROPICONAZOLE (160) – POST-HARVEST USES**

#### *Background*

Cyprodinil and propiconazole were evaluated for new maximum residue levels by the 2017 JMPR. At the 50<sup>th</sup> Session of the CCPR the EU submitted a concern over the decision of the 2017 JMPR to use the CF\*3 Mean to recommend maximum residue levels for post-harvest uses.

The EU also raised a concern that for both cyprodinil and propiconazole the plant metabolism data were generated using foliar applications only and there were no specific metabolism data generated via post-harvest applications.

#### *Comments by the current Meeting*

The 3\*mean is used to ensure the coefficient of variance is at least 0.5, given small data sets can underestimate the standard deviation (SD). The SD of the data sets for the post-harvest uses of cyprodinil and propiconazole were low (for cyprodinil/pomegranate it was 0.37, propiconazole/ cherry it was 0.34, for propiconazole/peach it was 0.032 and propiconazole/plum it was 0.049). However, the Meeting considered that as more homogenous residues are expected for post-harvest uses it is not appropriate to account for the low SD when estimating the maximum residue level and therefore base it on the CF\*3 Mean. The Meeting agreed that more refined maximum residue levels are possible for the post-harvest uses considered by the 2017 JMPR using the mean + 4SD.

With respect to plant metabolism, data are available for each active to cover the metabolism following foliar applications in three crop categories. The plant metabolism data for both actives also included data where applications were made with the mature commodities present and therefore exposed to the applications. For both actives the metabolic profiles observed in the different crop groups were similar and therefore residue definitions for estimating both maximum residue levels and dietary exposure cover all crop categories.

The Meeting concluded that it was unlikely a post-harvest application would result in more extensive metabolism than that observed from the foliar applications. The residue definitions for both actives include the parent compound and therefore there are no concerns with respect to determining the residue levels of the parent if less extensive metabolism occurs in the post-harvest treated crops. In addition, the data for both actives show that there are no concerns with respect to degradation of the total residue on storage.

The Meeting concluded that the residue definitions for cyprodinil and propiconazole will cover post-harvest uses. The residues data assessed by the 2017 JMPR for post-harvest uses are suitable for estimating maximum residue levels, and for estimating STMR and HR for long-term and acute dietary exposure assessments.

The Meeting recommended the following maximum residue levels based on the mean + 4SD for the post-harvest uses of cyprodinil and propiconazole on the crops considered in the 2017 Meeting.

CNN	Commodity	Number of trials	2017 JMPR		2018 JMPR	
			CF*3 Mean	Maximum residue level (mg/kg)	Mean+4SD	Maximum residue level (mg/kg)
	Cyprodinil					
FI 0355	Pomegranate	4	9.450	10 Po	4.629	5 Po
	Propiconazole					
FC 0004	Subgroup of Oranges, Sweet, Sour (including orange-like hybrids)	16 (combined)	11.213	15 Po	9.026	10 Po
FC 0003	Subgroup of Mandarins (including Mandarin-like hybrids)	16 (combine)	11.213	15 Po	9.026	10 Po
FC 0002	Subgroup of Lemons and Limes (including Citron)	16 (combined)	11.213	15 Po	9.026	10 Po
FC 0005	Subgroup of Pumelo and grapefruit (including Shaddock-like hybrids)	4	5.775	6 Po	3.435	4 Po
FS 0247	Peach	3	1.430	1.5 Po	0.605	0.7 Po
FS 0013	Subgroup of Cherries (including all commodities	4	2.970	3 Po	2.337	3 Po

CNN	Commodity	Number of trials	2017 JMPR		2018 JMPR	
			CF*3 Mean	Maximum residue level (mg/kg)	Mean+4SD	Maximum residue level (mg/kg)
	in this subgroup)					
FS 0014	Subgroup of Plums (includes all commodities in this subgroup)	5	0.480 (error) (correct, 0.390)	0.5 Po (error) (correct, 0.4))	0.326	0.4 Po
FS 0353	Pineapple	4	3.143	4 Po	1.555	2 Po
OR 0001	Orange oil			2800 (MRL, $15 \times Pf$ , 185)		1850 (MRL, $10 \times Pf$ , 185)

### 3.5 2, 4-D (020)

#### *Background*

The 2017 JMPR evaluated residues arising from the use of 2,4-D on a genetically modified cotton crop (AAD-12), in which expression of the aryloxyalkanoate dioxygenase-12 confers tolerance to 2,4-D and an associated increase in the metabolism of 2,4-D. No maximum residue level had been recommended by JMPR for cotton seed.

The residue definition established by the 1998 JMPR is 2,4-D for enforcement of MRLs and for dietary risk assessment.

The USA submitted a concern form at the 50<sup>th</sup> Session of the CCPR. The USA requested clarification on the conclusion of the 2017 JMPR regarding the lack of stability of residues in cotton seed in frozen storage noting that a storage stability study on soya beans indicated stability of 2,4-D in soya beans under frozen condition.

#### *Comments by the current Meeting*

The 2017 JMPR was aware of the evaluation and conclusion of the 1998 JMPR on frozen storage stability studies. The 1998 JMPR reviewed studies on soya bean (high oil matrix) as well as maize and rice bran, and concluded that 2,4-D was stable in soya bean matrices for at least 365 days.

A new storage stability study on 2,4-D in AAD-12 cotton seeds and related matrices at -20 °C was reviewed by the 2017 JMPR. During frozen storage at the fortification level of 0.10 mg/kg, 2,4-D was stable in undelinted cotton seed for up to one month, with the percentage remaining becoming lower than 70% thereafter. The 2017 Meeting considered that the results of the stability study in cotton seed were of higher relevance to the interpretation of the submitted supervised trial data. The periods of frozen storage of samples in the supervised trials were in a range of 84–118 days, much longer than the period of demonstrated stability.

Therefore, the 2017 Meeting concluded that due to the questionable storage stability of 2,4-D in cotton seed, the residue data were inadequate for estimating a maximum residue level.

The current Meeting confirmed the conclusion of the 2017 Meeting.

### 3.6 FLUOPYRAM (243)

Fluopyram was evaluated by the 2017 JMPR for a number of additional uses, including rice. Based on the available data, the Meeting recommended a maximum residue level of 4 mg/kg and a STMR of 0.615 mg/kg for fluopyram on rice grain.

The Fiftieth Session of the CCPR noted that processing factor data were available, and that it might also be possible to derive maximum residue level recommendations for husked and polished rice.

Based on the processing factor of 0.29 estimated by the 2017 JMPR for husked (brown) rice, and applying this to the maximum residue level of 4 mg/kg and the STMR of 0.615 mg/kg for rice grain, the Meeting estimated a maximum residue level of 1.5 mg/kg and a STMR of 0.18 mg/kg for fluopyram on rice, husked.

Based on the processing factor of 0.11 estimated by the 2017 JMPR for polished rice, and applying this to the maximum residue level of 4 mg/kg and the STMR of 0.615 mg/kg for rice grain the Meeting estimated a maximum residue level of 0.5 mg/kg and a STMR of 0.068 mg/kg for fluopyram on rice, polished.

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI assessment.

CCN	Commodity Name	Recommended maximum residue level (mg/kg)		STMR or STMR-P (mg/kg)	HR or HR-P (mg/kg)
		New	Previous		
CM 0649	Rice, husked	1.5	-	0.18	-
CM 1205	Rice, polished	0.5	-	0.068	-

### 3.7 PHOSPHONIC ACID (301) / FOSETYL-ALUMINIUM (302)

Phosphonic acid, as the major metabolite of fosetyl-aluminium and fosetyl, is toxicologically similar to fosetyl-aluminium and is covered by the ADI for fosetyl-aluminium. In response to a request for clarification from CCPR, the Meeting confirmed that the ADI of 0–1 mg/kg bw established in 2017 for fosetyl-aluminium (302), while derived from toxicological studies on fosetyl-aluminium, also applies directly to phosphonic acid.

### 3.8 PICOXYSTROBIN (258)

#### *Background*

Picoxystrobin was reviewed for the first time by the JMPR in 2012. The 2017 JMPR recommended a maximum residue level for picoxystrobin in rape seed.

The USA of America submitted a concern form at the Fiftieth Session of the CCPR. The USA noted that “the JMPR review concluded that there were an insufficient number of field trials at the GAP to estimate



an maximum residue level for oilseed rape. We note that eighteen residue trials were conducted and summarised in the 2012 JMPR Evaluation document with the correct application use pattern and additional GAP or near-GAP trials are listed in the 2017 JMPR report (Table 29). " The USA sought "a clear explanation of why the JMPR concluded that there were an inadequate number of MOR [magnitude of residue] trials available for review to recommend a maximum residue level for picoxystrobin on oilseed rape".

#### *Comment by the JMPR*

The 2017 JMPR identified the critical GAP for rape in the USA is  $2 \times 0.22$  kg ai/ha with a 28 day PHI. Three trials, two from Canada and one from the USA, matched cGAP and residues of picoxystrobin in rapeseed were < 0.01, 0.012 and 0.031 mg/kg. In another 14 trials on rape seed two applications were made at 0.22 kg ai/ha with seed harvested at a PHI of 19 to 21 days.

In assessing whether trials that deviate from cGAP can be considered to approximate cGAP, the JMPR considers tolerances on the parameters should be those that would result in  $\pm 25\%$  change in the residue concentration, not  $\pm 25\%$  changes in the parameters themselves. The JMPR considered whether there was sufficient information available to conclude residues in seed harvested at 21 days and residues at 28 days would be the same, or within  $\pm 25\%$ .

Residues at 21 days ranged from < 0.01 to 0.047 mg/kg with most samples having residues above the LOQ.

Two residue decline trials in rape were available and were inconclusive. Residues in seed at 21 and 28 days were <LOQ in the first study, while in the second study residues at 21 and 28 days were similar at 0.013 and 0.012 mg/kg. Additionally, the 2017 JMPR also considered information on the decline of residues in rape pods with seeds that occurred with half-lives of two to four days. The limited information available was inadequate to enable the JMPR to conclude with confidence that residues in rape seed at 21 days would be within  $\pm 25\%$  of residues at 28 days. Therefore the 14 trials where seeds were harvested at 19 to 21 days were not considered as approximating cGAP.

Consequently, the number of trials available to the 2017 JMPR approximating cGAP was three, which was inadequate for the purposes of estimating a maximum residue level for rape seed.

The current Meeting confirmed its previous decision.

### **3.9 QUINCLORAC (287)**

#### *Background*

Quinclorac was reviewed for the first time by the JMPR in 2015. The 2015 JMPR determined that the definition of the residue for plant commodities for compliance with the MRL was quinclorac plus quinclorac conjugates.

At the Forty-ninth Session of the CCPR in 2017, the European Union submitted a concern form that the residue definition should be reconsidered because quinclorac methyl ester, which is ten times more toxic than quinclorac, was not included in the residue definition for enforcement.

The 2017 JMPR reconfirmed the residue definition established by the 2015 JMPR.

At the 50<sup>th</sup> Session of the CCPR, the European Union reserved their position on the advancement of the maximum residue level recommendation for rape seed due to the exclusion of the more toxic quinclorac methyl ester from the residue definition for enforcement.

The 2017 JMPR received an analytical method D1607/01 developed for more precise accounting of quinclorac and quinclorac methyl ester in rape seed, and also received a multi-residue analytical method D1502/1 for quinclorac in plant matrices and for quinclorac methyl ester in rape seed. Those methods are suitable for the analysis of quinclorac and quinclorac methyl ester residues in rape seed.

The residue data using the analytical method D160701 from supervised field trials on oilseed rape were submitted to the 2017 JMPR.

The Meeting noted that monitoring quinclorac and its conjugates is an adequate residue definition for determining compliance with cGAP as residues may be found in treated crops above the LOQ. The residue definition for dietary risk assessment is the appropriate location for compounds that contribute to the toxicological burden and are required for assessing consumer risk. The Meeting also noted that even though the methyl ester has a toxicological potency that is 10 times that of quinclorac, residues (including the methyl ester) are low as rape seed oil is a blended commodity resulting in negligible consumer risk. As reported by the 2015 JMPR, the IESTI associated with rape seed oil is less than 1% of the ARfD.

The Meeting confirmed its previous conclusions regarding the residue definitions for plant commodities:

*Plant commodities:*

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

*Quinclorac plus quinclorac conjugates*

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

*Quinclorac plus quinclorac conjugates plus quinclorac methyl ester expressed as quinclorac.*

## 4. Dietary risk assessment for pesticide residues in food

### 4.1 Long-term 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 (supervised trials median residues [STMRs] and/or supervised trials median residues in a processed commodity [STMR-Ps]) for each commodity, for which maximum residue levels were recommended, by the average daily per capita consumption, estimated on the basis of 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>18</sup>

Fluazinam was not evaluated for toxicology because of missing critical information. No chronic dietary risk assessment was conducted.

Mandestrobin was evaluated for toxicology, and an ADI was established. It was not possible to complete the evaluation for residues at the current Meeting due to late submission of critical information. Chronic dietary risk assessments will be conducted when the compound is evaluated for residues.

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 from the WHO website<sup>19</sup>.

The detailed calculations of the chronic dietary exposure assessments are given in Annex 3.

Table 1 Summary of long-term dietary exposure assessments (IEDI)

CCPR code	Compound name	ADI (mg/kg bw)	Range of IEDI, as % of the upper bound of the ADI
177	Abamectin	0–0.001	1–6
172	Bentazone	0–0.09	0–1
254	Chlorfenapyr	0–0.03	1–6
263	Cyantraniliprole	0–0.3	4–40
281	Cyazofamid	0–0.2	0–5
031	Diquat	0–0.006	2–30
304	Ethiprole	0–0.005	1–6
305	Fenpicoxamid	0–0.05	0
211	Fludioxonil	0–0.4	1–6
256	Fluxapyroxad	0–0.02	6–20
110	Imazalil	0–0.03	2–40
290	Isofetamid	0–0.05	0–6
199	Kresoxim-methyl	0–0.3	0–0.5
286	Lufenuron	0–0.02	2–10

<sup>18</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/>).

<sup>19</sup> [http://www.who.int/foodsafety/areas\\_work/chemical-risks/gems-food/en/](http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/)

CCPR code	Compound name	ADI (mg/kg bw)	Range of IEDI, as % of the upper bound of the ADI
231	Mandipropamid	0–0.2	0–6
308	Norflurazon	0–0.005	0–20
291	Oxathiapiprolin	0–4	0
171	Profenofos	0–0.03	0–20
148	Propamocarb	0–0.4	0–2
309	Pydiflumetofen	0–0.1	0
210	Pyraclostrobin	0–0.03	1–7
310	Pyriofenone	0–0.09	0
200	Pyriproxyfen	0–0.1	0–1
252	Sulfoxaflor	0–0.05	2–9
311	Tioxazafen	0–0.05	0

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

## 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 data for the general population (all ages) and children (6 years and under) were used for the calculation of the IESTI. In the case where a separate ARfD was established for women of childbearing age, the IESTI was calculated for this population group only. A detailed description of the method is included in EHC 240.

These IESTI results are expressed as a percentage of the ARfD (Table 2). The spreadsheet application is available from the WHO website<sup>20</sup>.

Fluazinam was not evaluated for toxicology due to missing critical information. No acute dietary risk assessment was conducted.

No acute dietary risk assessment was conducted for mandestrobin, as the evaluation for residues could not be completed at the current Meeting due to late submission of critical information. Acute dietary risk assessments will be conducted when the compound is evaluated for residues.

The present or previous Meetings agreed that ARfDs for cyantraniliprole, fenpicoxamid, fludioxinil, kresoxim-methyl, lufenuron, mandipropamid, oxathiapiprolin, pyriofenone, pyriproxyfen and sulfoxaflor 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 2 Summary of acute dietary exposure assessments (IESTI)

CCPR code	Compound name	ARfD (mg/kg bw)	Commodity (maximum % of ARfD)	Exceeding: population, (country)
177	Abamectin	0.003	40	
172	Bentazone	0.5	0	
254	Chlorfenapyr	0.03	60	

<sup>20</sup> [http://www.who.int/foodsafety/areas\\_work/chemical-risks/gems-food/en/](http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/)

CCPR code	Compound name	ARfD (mg/kg bw)	Commodity (maximum % of ARfD)	Exceeding: population, (country)
281	Cyazofamid	0.2 (CCIM)	90	
031	Diquat	0.8	10	
304	Ethiprole	0.005	80	
256	Fluxapyroxad	0.3	10	
110	Imazalil	0.05	90	
290	Isofetamid	3	3	
308	Norflurazon	0.3	10	
171	Profenofos	1	0	
148	Propamocarb	2	1	
309	Pydiflumetofen	0.3	20	
210	Pyraclostrobin	0.7	60	
311	Tioxazafen	0.5	0	

ARfD: acute reference dose; bw: body weight; CCIM: 4-chloro-5-*p*-tolylimidazole-2-carbonitrile (metabolite); CCPR: Codex Committee on Pesticide Residues; IESTI: international estimate of short-term intake

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

None of the compounds evaluated at the meeting had acute dietary exposures that exceeded the relevant ARfD.



## 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 ABAMECTIN (177)

#### RESIDUE AND ANALYTICAL ASPECTS

Abamectin is used to control insect and mite pests of a wide range of crops. Abamectin was first evaluated for toxicology and residues by the 1992 JMPR and was reviewed by the 2015 JMPR as part of the periodic review program of CCPR. The compound has an ADI of 0–0.001 mg/kg bw and an ARfD of 0.003 mg/kg bw. The residue definition for compliance with the MRL and dietary risk assessment for plant and animal commodities is avermectin B1a. The residue is fat-soluble.

Abamectin was scheduled at the Forty-ninth Session of the CCPR for the evaluation of additional uses in 2018 JMPR. The current Meeting received information on GAP and supervised residue trials on various crops; processing studies for soya bean, herbs, mint and citrus fruit; and storage stability data for cane berries.

#### *Methods of analysis*

The methods of analysis for abamectin residues in various plant and animal commodities were reviewed by the 2015 JMPR. The current Meeting received concurrent recovery data for the crops considered at by the Meeting.

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

The 2015 JMPR concluded that abamectin residues in a variety of crop samples except raisins, when stored under frozen conditions were stable for at least 12 months. The current Meeting received storage stability data for cane berry spiked at 0.02 mg/kg and stored concurrently with residue trial samples. The stability of abamectin residues in stored samples of cane berry was demonstrated for at least 978 days.

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

The Meeting received supervised residue trial data for foliar applications of abamectin on grape, cane berries, pineapple, spring onion, dry bean, soya bean, sweet corn, basil, chives and mint.

#### *Berries and other small fruits*

##### *Grapes*

The critical GAP for abamectin on grapes in Brazil is 2 foliar applications of 0.0108 kg ai/ha with a re-treatment interval (RTI) of 7 days and a PHI of 7 days.

Trials were conducted on grapes in Brazil with 3–5 foliar applications at 0.0144 or 0.018 kg ai/ha, a PHI of 7 days. Residue decline data demonstrated that residues dissipate extensively over seven days, and as a result the first applications would be unlikely to affect the final residue at harvest. Therefore, the Meeting agreed to use the proportionality approach to estimate the residues at cGAP.

In six trials conducted at higher application rates the residues of abamectin in grapes were: < 0.002(3), < 0.004, 0.007 and 0.022 mg/kg. Using the proportionality approach (with scaling factors of 0.75 or 0.6) the residues of abamectin in grapes were (n = 6): 0.0012 (3), 0.003, 0.0042 and 0.016 mg/kg.

The Meeting estimated a maximum residue level of 0.03 mg/kg, a STMR of 0.0021 mg/kg and a HR of 0.016 mg/kg for abamectin in grapes. This estimation replaces the previous of 0.01 mg/kg for abamectin in grapes.

#### *Cane berries*

The critical GAP for abamectin on cane berries in the USA, is 2 foliar applications at 0.0213 kg ai/ha, a RTI of 7 days and a PHI of 7 days.

Seven trials were conducted on blackberry and raspberry in the USA with 3 foliar applications at 0.021 kg ai/ha with a re-treatment interval of 7 days and a PHI of 7 days. Based on residue decline data the first application is unlikely to contribute significantly to the residue level at harvest and therefore the Meeting considered that these trials approximated GAP. The residues of abamectin in cane berries were (n = 7): 0.0047, 0.0064, 0.015, 0.018, 0.024, 0.050 and 0.11 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg, a STMR of 0.018 mg/kg and a HR of 0.11 mg/kg for abamectin in the subgroup of Cane berries.

The Meeting withdraw the previous recommendation of 0.05 mg/kg for abamectin in Blackberries and Raspberries, Red, Black.

#### *Pineapple*

The critical GAP for abamectin on pineapple in the USA is 2 foliar applications of 0.0261 kg ai/ha, a 7 day RTI and a PHI of 112 days.

In six trials matching the GAP, the residues of abamectin in pineapples were (n = 6): < 0.002 mg/kg.

The Meeting estimated a maximum residue level of 0.002(\*) mg/kg, a STMR of 0 mg/kg, and a HR of 0 mg/kg for abamectin on pineapple.

#### *Green onions*

The critical GAP for abamectin on green onions (includes chives) in the USA is 2 foliar applications of 0.0213 kg ai/ha, a 7 day RTI and a PHI of 7 days.

Eight trials were conducted in the USA on spring onions with 4 foliar applications at 0.021–0.023 kg ai/ha. Two decline studies indicated that abamectin residues dissipated quickly in spring onions. The earlier applications were considered unlikely to contribute significantly to the residue level at harvest and therefore the Meeting considered that these trials approximated GAP. In six trials, where samples were harvested at a 7 day PHI, the residues of abamectin in spring onions were < 0.002(3), 0.002, 0.003 and 0.004 mg/kg.

In three trials matching GAP, and conducted in the USA, on chives residues of abamectin were < 0.002 (2) and 0.002 mg/kg.

Based on the residue data on spring onion, the Meeting estimated a maximum residue level of 0.01 mg/kg, a STMR of 0.002 mg/kg, and a HR of 0.004 mg/kg and for abamectin on the subgroup of Green onions.

The Meeting withdraw the previous recommendation of 0.005 mg/kg for abamectin in leek.

#### *Beans without pods*

The critical GAP for abamectin on beans, shelled in the USA is 2 foliar applications of 0.0213 kg ai/ha, a 6 day RTI and a PHI of 7 days.



Seven trials were conducted in the USA with 3–4 foliar applications at 0.021 kg ai/ha. Based on the rapid decline of abamectin residues in other crops the Meeting considered that these trials approximated GAP. The residues of abamectin in shelled beans at a 7 day PHI were (n = 7): < 0.002 mg/kg.

The Meeting estimated a maximum residue level of 0.002(\*) mg/kg a STMR of 0.002 mg/kg, and a HR of 0.002 mg/kg and for abamectin on beans without pods.

#### *Soya bean (dry)*

The critical GAP for abamectin on soya bean in the USA is 2 foliar applications of 0.0213 kg ai/ha a 7 day RTI and with a PHI of 28 days.

In 19 trials conducted on soya bean in the USA a seed treatment followed by 2 foliar applications at 0.021 kg ai/ha were applied. Based on the rapid decline of abamectin residues in other crops the Meeting considered that these trials approximated GAP. The residues of abamectin in soya bean at a 28 day PHI were (n = 19): < 0.002 mg/kg.

The Meeting estimated a maximum residue level of 0.002(\*) mg/kg, and a STMR of 0.002 mg/kg for abamectin on soya bean (dry).

#### *Sweet corns*

The critical GAP for abamectin on sweet corn in the USA is 2 foliar applications of 0.0213 kg ai/ha, a 7 day RTI and a PHI of 7 days.

In twelve trials conducted on sweet corn in the USA matching cGAP, the residues of abamectin in sweet corn (kernels+cobs with husks removed) were (n = 12): < 0.002 mg/kg .

The Meeting estimated a maximum residue level of 0.002(\*) mg/kg, a STMR of 0.002 mg/kg and a HR of 0.002 mg/kg for abamectin on sweet corns (whole kernel with husk removed).

#### *Herbs*

The critical GAP for abamectin on herbs in the USA is 2 foliar applications of 0.0213 kg ai/ha (7 days RTI) and a PHI of 14 days.

In five trials conducted in the USA on basil (3) and mint (2) 3 foliar applications at 0.021 kg ai/ha were applied with samples collected at a PHI of 14 days. Based on the rapid decline of abamectin residues in other crops the Meeting considered that these trials approximated GAP. The residues of abamectin in basil and mint at a PHI of 14 days were: < 0.002, 0.002, 0.003 and 0.007 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.015 mg/kg, a STMR of 0.003 mg/kg and a HR of 0.008 mg/kg (highest individual) for abamectin on herbs.

#### ***Animal feed commodities***

The GAP in the USA does not permit the grazing of livestock on treated crops or harvesting of treated soya bean forage, straw or hay as feed for meat or dairy animals. As a result, the animal feed items from soya bean were not considered in the animal dietary burden calculations.

#### *Sweet corn forage*

The critical GAP for abamectin on sweet corn in the USA is for up to 2 foliar applications of 0.0213 kg ai/ha applied at a 7 day RTI and with a PHI of 7 days.

In twelve trials conducted on sweet corn in the USA matching the cGAP, residues of abamectin in sweet corn forage were (n = 12): 0.011, 0.015, 0.021, 0.027, 0.051, 0.053, 0.06, 0.061, 0.062, 0.067, 0.096 and 0.098 mg/kg.

The Meeting estimated a median and a highest residue of 0.056 mg/kg and 0.10 mg/kg (highest individual), respectively, for abamectin in sweet corn forage.

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

The Meeting received processing studies for soya bean, herbs, mint, and citrus fruit. The 2015 JMPR also considered processing studies on grape. In two processing studies on soya bean, residues in seed were < 0.002 mg/kg, therefore, no processing factors could be estimated. In one processing study conducted on chives residues were 0.002 mg/kg in fresh leaves and 0.010 mg/kg in dried leaves, leading to a processing factor of 5. In three processing studies on mint abamectin residues in fresh mint leaves were 0.0055, 0.034 and 0.032 mg/kg while residues in mint oil were < 0.002 (3) mg/kg; the median processing factor was 0.06. In three processing studies on citrus fruit abamectin residues in citrus fruits were 0.0092, 0.0099 and 0.017 mg/kg while residues in orange oil were 0.054, 0.087 and 0.118 mg/kg; the median processing factor was 5.5.

The estimated processing factors with the respective recommendations for STMR-Ps are shown in the following table.

RAC	Matrix	Processing factor	Median Processing Factors	STMR RAC (mg/kg)	STMR-P (mg/kg)
Chives	Chives, dried	5	5	0.003	0.015
Mint	Mint oil	< 0.06, < 0.06, < 0.36	0.06	0.003	0.00002
Citrus fruits	Orange oil	4.3, 5.5, 9.7	5.5	0.005	0.0275
Grapes	dried grape (= currants, raisins and sultanas)		2.8	0.0021	0.0059
	Grape juice		1.4		0.0029
	Grape pomace	4.75			0.01

Based on the estimated maximum residue level of 0.015 mg/kg for herbs, the Meeting estimated a maximum residue level of 0.08 mg/kg for abamectin in chives, dried.

Based on the recommended maximum residue level of 0.02 mg/kg for citrus fruits, the Meeting estimated a maximum residue level of 0.1 mg/kg for abamectin in orange oil.

Based on processing data on raisin and grape juice considered by the 2015 JMPR, the current Meeting recommended a maximum residue level of 0.1 mg/kg for dried grape (= currants, raisins and sultanas), to replace the previous recommendation of 0.03 mg/kg and recommended a maximum residue level of 0.05 mg/kg for grape juice, to replace the previous recommendation of 0.015 mg/kg.

### ***Residues in animal commodities***

The additional animal feed commodities considered by the present Meeting (soya beans, sweet corn forage and grape pomace) do not significantly impact the dietary burden estimated by the 2015 JMPR. The Meeting confirmed its previous conclusions for abamectin in 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 and dietary risk assessment for plant and animal commodities: *avermectin B1a*.

*The residue is fat-soluble.*

## DIETARY RISK ASSESSMENT

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

The ADI for abamectin is 0–0.001 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for abamectin were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the previous and present JMPR. The results are shown in Annex 3 of the 2018 JMPR Report. The IEDIs ranged 1–6% of the maximum ADI.

The Meeting concluded that the long-term dietary exposure to residues of abamectin from uses considered by the JMPR is unlikely to present a public health concern.

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

The ARfD for abamectin is 0.003 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for abamectin were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the current JMPR and for which consumption data were available. The results are shown in Annex 4 of the 2018 JMPR Report. The IESTIs varied from 0–40% of the ARfD for children and 0–30% for the general population.

The Meeting concluded that the acute dietary exposure to residues of abamectin from uses considered by the current JMPR is unlikely to present a public health concern.



## 5.2 BENTAZONE (172)

### RESIDUE AND ANALYTICAL ASPECTS

Bentazone is a selective herbicide belonging to the thiadiazine group of chemicals. Bentazone was first evaluated for toxicology and residues by JMPR in 1991, and was re-evaluated in 2012 and 2013, as part of the periodic review programme of the CCPR. The 2012 Meeting established an ADI for bentazone of 0–0.09 mg/kg bw, and the 2016 Meeting established an ARfD of 0.5 mg/kg bw. The residue definition for compliance with the MRL and for dietary risk assessment for plant and animal commodities is the parent bentazone. The residue is not fat-soluble.

Bentazone was scheduled at the Forty-ninth Session of the CCPR for the evaluation of additional uses by the 2018 JMPR. The Meeting received a dairy cow feeding study, GAP information and supervised residue trials on dry peas.

#### ***Methods of analysis***

Analytical methods for determining bentazone residues in various raw agricultural commodities, feed commodities and animal commodities were evaluated by JMPR in 2013. The methods typically use an initial extraction and a further conjugate hydrolysis step, followed by clean-up and GC-MS, or LC-MS/MS determination. LOQs of 0.01 mg/kg were achievable in most matrices.

The analytical method used to determine bentazone residues in kidney and fat matrices was evaluated previously by JMPR in 2013.

The available methods are sufficiently validated and are suitable to measure bentazone in the commodities being considered.

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

The 2013 JMPR concluded that bentazone residues were stable at -20 °C for at least 24 months in representative plant matrices.

The current Meeting received residue stability data in animal commodities performed alongside the dairy cow feeding study. Bentazone was shown to be stable in incurred samples of liver after 316 days and kidney after 305 days in frozen storage. In other animal matrices including milk, cream, muscle and fat bentazone residues were stable for at least 120 days.

The Meeting agreed that the demonstrated storage stability in various representative plant and animal commodities covered the residue sample storage intervals used in the studies.

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

The Meeting received information on supervised residue trials for bentazone in dry peas.

##### ***Dry peas***

The critical GAP for bentazone in pulses (including dry pea) in the USA is for two foliar application at 1.12 kg ai/ha with a PHI of 30 days.

In six trials conducted in the USA and matching cGAP, abamectin residues in dry peas were (n = 6): < 0.01, 0.052, 0.12, 0.17, 0.19 and 0.29 mg/kg.

The 2013 JMPR reviewed field trials on dry peas, concluding that two trials with residue levels less than < 0.02 mg/kg met the GAP of 2×1.12 kg ai/ha. There were insufficient trials to recommend maximum residue levels at the 2013 JMPR. These two trials were considered alongside the submitted data.

The combined data set were (n = 8): < 0.01, < 0.02(2), 0.052, 0.12, 0.17, 0.19 and 0.29 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, and STMR of 0.09 mg/kg for bentazone in the subgroup of Dry peas. As the USA GAP is also applicable to the subgroup of dry beans, the Meeting decide to extrapolate the recommendations to subgroup Dry beans, and withdraw the previous recommendations of 0.04 mg/kg for dry beans, and 0.01(\*) mg/kg for soya bean.

### ***Residues in animal commodities***

#### ***Farm animal feeding studies***

The Meeting received a dairy cow feeding study. Bentazone was administered orally once daily to dairy cows for 28 days at levels equivalent to 11.6, 37.2 and 118.1 ppm dry weight in the feed. The cows in the control group received placebos (empty capsules) concurrently with the treated animals. Three additional cows from the high dose group were maintained for up to 7 days after the 28 day dosing period to provide depuration information.

Bentazone residues were observed in liver at up to 0.011 mg/kg and 0.049 mg/kg in the mid and high dose groups, respectively. Bentazone residues were observed in kidney at up to 0.010, 0.040 and 0.144 mg/kg in the low-, mid- and high-dose groups respectively. In all other matrices, including milk, residues were less than LOQ (0.01 mg/kg) in each dose group and (for milk) at all time points. The only bentazone residue detected above LOQ in any matrix, including milk, during the 7 day depuration phase was 0.016 mg/kg after 2 days in kidney.

#### ***Estimation of livestock dietary burdens***

The 2013 JMPR estimated the animal burden resulting from feed commodities however decided not to estimate maximum residue levels for mammalian tissues and milk. In the current evaluation, new recommendations are made for dry peas and dry beans. The addition of these items did not significantly add to the estimated burden therefore the Meeting decided to use the livestock dietary burdens calculated by the 2013 JMPR and the dairy cow feeding study to estimate potential residues in mammalian tissues and milk.

### ***Animal commodity maximum residue levels***

The calculations used in estimating maximum residue levels, STMR and HR values in mammalian tissues and milk are shown below.

	Feed level (ppm) for milk residues	Residues (mg/kg) in milk	Feed level (ppm) for tissue residues	Residues (mg/kg) in			
				Muscle	Liver	Kidney	Fat
maximum residue level beef or dairy cattle							
Feeding study <sup>a</sup>	11.6	< 0.01	11.6	< 0.01	< 0.01	0.010	< 0.01
	37.2	< 0.01	37.2	< 0.01	0.011	0.040	< 0.01
Dietary burden and high residue	<b>21.8</b>	< 0.01	<b>32.0</b>	< 0.01	0.011	0.035	< 0.01
STMR beef or dairy cattle							
Feeding study <sup>b</sup>	11.6	< 0.01	11.6	< 0.01	< 0.01	0.010	< 0.01
	37.2	< 0.01	37.2	< 0.01	0.010	0.028	< 0.01
Dietary burden and median residue estimate	<b>0.76</b>	< 0.01	<b>0.80</b>	< 0.01	< 0.01	< 0.01	< 0.01

<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 maximum residue levels of 0.01(\*) mg/kg for milks, mammalian meat and mammalian fats (except milk fats). The meeting estimated a maximum residue level of 0.04 mg/kg for edible offal (mammalian).

The Meeting estimated STMRs of 0 mg/kg for milk, mammalian meat and mammalian fats (except milk fats). The meeting estimated a STMR of 0.01 mg/kg for edible offal (mammalian).

The Meeting estimated HRs of 0 mg/kg, 0 mg/kg, and 0.035 mg/kg for mammalian muscle, mammalian fat, and edible offal (mammalian), respectively.

### 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 and dietary risk assessment in plant and animal commodities: *bentazone*.

*The residue is not fat soluble.*

### DIETARY RISK ASSESSMENT

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

The ADI for bentazone is 0–0.09 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for bentazone were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the previous and present JMPR. The results are shown in Annex 3 of the 2018 JMPR Report. The IEDIs ranged 0–1% of the maximum ADI.

The Meeting concluded that the long-term dietary exposure to residues of bentazone from uses considered by the JMPR is unlikely to present a public health concern.

#### ***Short-term dietary exposure***

The ARfD for bentazone is 0.5 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for bentazone were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the current JMPR and for which consumption data were available. The results are shown in Annex 4 of the 2018 JMPR Report. The IESTIs were 0% of the ARfD.

The Meeting concluded that acute dietary exposure to residues of bentazone from uses considered by the current JMPR is unlikely to present a public health concern.





### 5.3 CHLORFENAPYR (254)

#### TOXICOLOGY

Chlorfenapyr was evaluated in 2012 by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), which established an acceptable daily intake (ADI) of 0–0.03 mg/kg body weight (bw) and an acute reference dose (ARfD) of 0.03 mg/kg bw.

Studies with the metabolite tralopyril were reviewed during the 2013 Meeting, and a potency factor of 10 was established for a comparison of exposure of tralopyril with both the ADI and the ARfD of chlorfenapyr.

Following a request for maximum residue levels by the Codex Committee on Pesticide Residues (CCPR), chlorfenapyr was placed on the agenda of the present Meeting, which assessed additional toxicological information on chlorfenapyr available since the last review.

A study on the in vitro metabolism of chlorfenapyr was submitted. An updated literature search was performed, and studies relevant to the assessment of chlorfenapyr were evaluated.

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

Tralopyril was shown to be the main phase I metabolite in a good laboratory practice (GLP)–compliant in vitro study on the metabolism of chlorfenapyr in rats. In the context of the data previously reviewed by JMPR, this study provides assurance that rats exposed to chlorfenapyr are also exposed systemically to tralopyril. It was not possible to estimate quantitative exposure to this metabolite in vivo from this study.

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

No new information on the toxicity of chlorfenapyr or tralopyril was submitted to the 2018 Meeting, nor was any new information identified in the open literature.

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

Six metabolites were identified in residue studies that were not addressed by previous Meetings and were of potential relevance for the residue definition for risk assessment. These metabolites are CL322250 (M-5A), CL325195 (M-5), CL152837 (M-4), CL152832 (M-7A), CL152835 (M-6) and CL325157 (M-6A). No toxicological data were submitted for these metabolites, but they did not show any alerts for genotoxicity. For chronic toxicity, the threshold of toxicological concern (TTC) approach can be applied (Cramer class III).

#### ***Human data***

Several case reports were identified in the scientific literature that described human poisonings after self-reported ingestion or, in one case, intra-abdominal injection of chlorfenapyr solutions. Neurological signs and symptoms (diaphoresis, dizziness, weakness, fever, paralysis) were common and progressed in severity until death by cardiac arrest in all but one case. In some cases, imaging techniques were used to characterise white matter lesions in the patients, which appeared consistent with the effects noted after chlorfenapyr or tralopyril exposure in rats. In cases where an estimate of dose was feasible, lethal doses appeared to range from 200 to 420 mg/kg bw (compare with the rat acute median lethal dose [LD<sub>50</sub>] of 441 mg/kg bw). The Meeting noted that the ARfD provided a margin of four orders of magnitude relative to these estimated lethal doses.

The human clinical data suggest that, compared with rats, humans are of similar or greater sensitivity to the acute effects of chlorfenapyr, and the toxicological consequences to the nervous system are very similar. There is no information available on the comparative metabolism of chlorfenapyr in rats and humans.

### Toxicological evaluation

The Meeting concluded that no revision of the ADI or ARfD was necessary.

The Meeting also concluded that six metabolites identified in residue studies – CL322250 (M-5A), CL325195 (M-5), CL152837 (M-4), CL152832 (M-7A), CL152835 (M-6) and CL325157 (M-6A) – were toxicologically not relevant at currently estimated dietary exposures.

An addendum to the toxicological monograph was prepared.

### RESIDUE AND ANALYTICAL ASPECTS

Chlorfenapyr is a pro-insecticide-miticide. Its biological activity depends upon its activation to tralopyril (CL303268). Oxidative removal of the N-ethoxymethyl group of chlorfenapyr by mixed function oxidases forms CL303268. This compound uncouples oxidative phosphorylation at the mitochondria, resulting in the disruption of ATP production, cellular death, and ultimately organism mortality. It was first considered for toxicology and residues by the 2012 JMPR, when an ADI of 0–0.03 mg/kg bw and an ARfD of 0.03 mg/kg bw were established.

The 2012 JMPR recommended the following residue definition for chlorfenapyr:

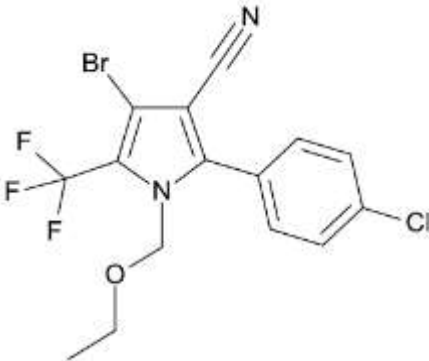
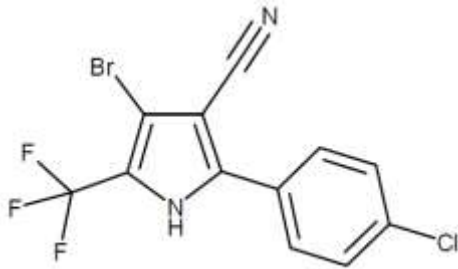
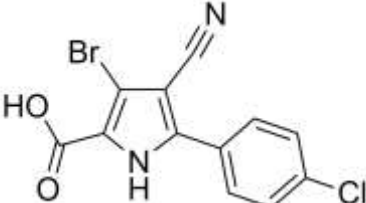
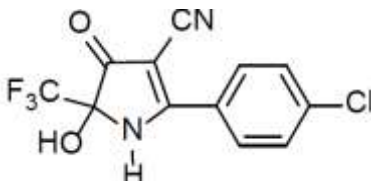
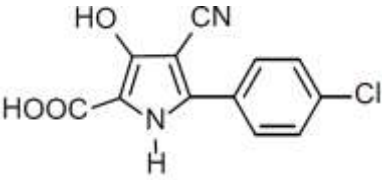
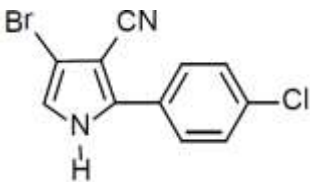
Definition of the residue for compliance with the MRL for plant and animal commodities: *chlorfenapyr*.

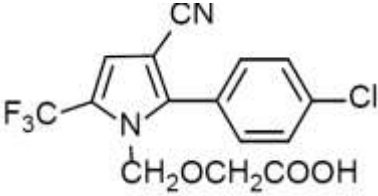
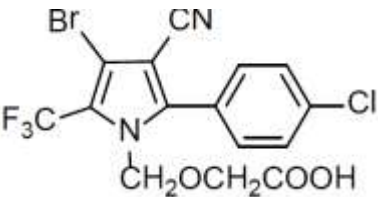
The residue is fat-soluble.

However, the 2012 Meeting did not reach a conclusion on the definition of the residue for dietary risk assessment for plant and animal commodities, since no appropriate health-guidance values for the metabolite CL303268 could be derived.

Chlorfenapyr was scheduled at the Forty-ninth Session of the CCPR for the evaluation of both toxicology and residues by the 2018 JMPR. The Meeting received new information on plant metabolism, analytical methods, storage stability, supervised field trials, fate during processing and the magnitude of residues during processing.

The following abbreviations are used for the metabolites discussed below:

Code Names	Chemical name	Structure	Where found
Chlorfenapyr BAS 306 I	4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-pyrrole-3-carbonitrile		Rat, plants, animals, rotational crops, soil
Tralopyril CL303268	4-bromo-2-(p-chlorophenyl)-5-(trifluoromethyl)-pyrrole-3-carbonitrile		Plants, processed products
CL322250	4-bromo-2-(p-chlorophenyl)-5-(carboxylic)- pyrrole-3-carbonitrile		Processed products
CL325195	2-(4-chlorophenyl)-5-hydroxyl-4-oxo-5-(trifluoromethyl)-3-pyrrole-3-carbonitrile		Animals
CL152837	4-hydroxy-2-(p-chlorophenyl)-5-(carboxylic)- pyrrole-3-carbonitrile  a hydroxylated CL303268 metabolite		Animals
CL152832	destrifluoromethyl CL303268		Animals

Code Names	Chemical name	Structure	Where found
CL152835	desbromo-N-carboxymethylmethoxy chlorfenapyr		Animals
CL325157	{[3-bromo-5-(p-chlorophenyl)-4-cyano-2-(trifluoromethyl) pyrrol-1-yl]methyl}- acetic acid		Animals

### ***Plant metabolism***

The fate of chlorfenapyr in plants was investigated by the 2012 JMPR following foliar spray application of <sup>14</sup>C-radiolabelled substance to oranges, tomatoes, head lettuce, potatoes and cotton. A detail assessment of these studies is presented in the 2012 JMPR Report. For the current Meeting, an additional plant metabolism study on tomatoes was submitted

The metabolism of chlorfenapyr in field grown tomatoes was investigated by application of phenyl- or pyrrole-<sup>14</sup>C-radiolabelled substance with three foliar sprayings of 0.48 kg ai/ha (29 days before harvest), 0.48 kg ai/ha (15 days before harvest) and 0.24 kg ai/ha (1 day before harvest). Leaves and fruit collected one day after the last application were analysed for the composition of residues.

Both in leaves and fruits, the extraction of radioactivity with methanol, followed by water, was nearly complete (99.2–99.6% TRR). TRR levels in fruits ranged from 1.3 to 1.8 mg eq/kg and in leaves from 34 to 44 mg eq/kg.

The identification of the radioactive residues revealed mostly unchanged chlorfenapyr, representing 92–97% of the TRR in the fruits and 96–98% TRR in the leaves. The only metabolite identified was tralopyril (CL303268) in fruits (1.0% TRR, 0.018 mg eq/kg) and leaves (0.8% TRR, 0.35 mg eq/kg) treated with the pyrrole-label. However, small amounts of this compound were also found in the spraying solution, suggesting its formation before application.

### ***Methods of analysis***

The current Meeting received two additional analytical methods for plant matrices.

Method G0001/01 involves extraction with methanol/water (85:15, v/v) and partitioning with ethyl acetate. Analysis of chlorfenapyr and tralopyril (CL303268) is performed by LC-MS/MS. The method is suitable for measuring both analytes in matrices of high water, high protein and high acid content with a LOQ of 0.01 mg/kg.

Method G0002/01 is comparable to G0001/01, but targets the metabolite CL322250. The method is suitable for measuring the analyte in matrices of high protein and high oil content with a LOQ of 0.01 mg/kg.

Using radiovalidation, the extraction efficiency of the QuEChERS multimethod (submitted in 2012) and of the newly submitted method G0001/01 (methanol/water, 85:15 v/v) was tested on tomato leaves and fruits obtained from the plant metabolism study summarised above. Both methods were capable of extracting 97–104% of the TRR from the fruits and 88–105% of the TRR from the leaves.

A specialised method for the analysis of chlorfenapyr in tea (dried tea and infusion) was submitted in 2012. Dried tea was extracted with acetone/water. The dried tea extract or the tea infusion are cleaned by Florisil column chromatography and analysed with GC-ECD detection. The current Meeting noted that the method was tested with a lowest fortification level of 0.8 mg/kg for both matrices and, in contrast to its previous evaluation in 2012, did not reach a sufficiently low LOQ to quantify residues found in infusions with acceptable reliability.

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

The current Meeting received additional information on the storage stability of chlorfenapyr, tralopyril (CL303268) and CL322250 in plant matrices stored at -18 °C.

The parent compound and its metabolite tralopyril (CL303268) were stable for at least 12 months in grapes and rice grain, for at least 14 months in apples and dry beans and for at least 15 months in dry soya beans.

CL322250 was stable in dry soya beans for at least 12 months.

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

The current Meeting received new data on the toxicity of the metabolite tralopyril (CL303268) to allow consideration of residue definitions for dietary exposure to plant and animal commodities.

The Meeting also received an additional plant metabolism study on tomatoes, which exclusively showed unchanged chlorfenapyr in the samples investigated. No additional data on animal commodities was submitted.

The Meeting therefore confirms its previous recommendation of chlorfenapyr for compliance with the MRL for plant and animal commodities.

For dietary exposure purposes, the 2012 Meeting could not reach a conclusion on the residue definition due to absence of appropriate health-based guidance values for tralopyril (CL303268). The current Meeting received new toxicological information and established a potency factor of 10 for a comparison of exposure of tralopyril (CL303268) with both the ADI and the ARfD for parent chlorfenapyr. The Meeting concluded that tralopyril (CL303268), although present in low proportions up to 3.3% TRR, has the potential to contribute significantly to the overall toxicological burden due to its potency factor of 10 and – besides chlorfenapyr – should be considered for the estimation of the dietary exposure in plant commodities.

New information on the nature of residues during processing was submitted to the current Meeting (see Fate of residues during processing). Under simulated sterilization (pH6, 120°C, 20min), chlorfenapyr was significantly degraded (ca. 70% AR remaining) into CL322250 (32-34% AR). Formation of tralopyril (CL303268) was not observed. In an additional study conducted with tralopyril (CL303268), it was completely degraded into CL322250 under simulated baking/brewing/cooking and sterilization.

For dietary exposure assessment of CL322250, the Meeting noted that as no specific toxicity data were available for the metabolite the TTC approach could be followed<sup>21</sup>. The toxicological threshold for a

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<sup>21</sup> See Toxicology section for further details

Cramer Class 3 compound was applied (1.5 µg/kg bw). The estimated exposure based on plant commodities that may potentially be subject to sterilization (tomatoes, peppers, soya beans) and on animal commodities from the goat and laying hen metabolism studies, adjusted to the estimated livestock animals dietary burden, resulted in a maximum long-term exposure of 0.003 µg/kg bw, below the applicable threshold of toxicological concern. The Meeting concluded that CL322250 was unlikely to present a dietary exposure concern from the uses evaluated by the current Meeting.

The Meeting decided to define the residue for dietary risk assessment for plant commodities to be the sum of chlorfenapyr and 10 times its metabolite tralopyril.

For dietary risk assessment for animal commodities, chlorfenapyr was the predominant residue in most goat and poultry matrices with tralopyril (CL303268) often being present as a major metabolite (4.5–31% TRR). The Meeting concluded that both compounds should be considered for the estimation of dietary exposure in animal commodities, especially taking into account the higher relative toxicity of tralopyril compared to parent.

In ruminants, CL325195 together with its conjugates (goat liver and kidney) and CL152837 together with its conjugates (goat liver and kidney) were found in major proportions (12–48% TRR and 7–24% TRR, respectively), mainly released by hydrolysis.

In poultry tissues, the primarily conjugated metabolites CL152832 (chicken muscle and kidney, 2–23% TRR), CL152835 and CL325157 (chicken liver and kidney, 23–51% TRR) were found in major proportions, in total exceeding the residues of chlorfenapyr by up to a factor of 10.

For dietary risk assessment, the Meeting noted that for metabolites CL325195, CL152837, CL152832, CL152835 and CL325157 no information is available on their toxicity. The Meeting decided to apply the TTC approach to these metabolites. The estimated exposure based on animal commodities from the goat and laying hen metabolism studies, adjusted to the estimated livestock animals dietary burden, resulted in the following maximum long-term exposures:

CL325195	0.018 µg/kg bw
CL152837	0.015 µg/kg bw
CL152832	< 0.001 µg/kg bw
CL152835	0.003 µg/kg bw
CL325157	0.003 µg/kg bw

The Meeting noted that all estimated exposures are below the applicable threshold of toxicological concern for Cramer Class 3 compounds. The Meeting concluded that CL325195, CL152837, CL152832, CL152835 and CL325157 were unlikely to present a dietary exposure concern from the uses evaluated by the current Meeting.

In summary, the Meeting decided to define the residue for dietary risk assessment for animal commodities as the sum of chlorfenapyr and 10 times its metabolite tralopyril.

The Meeting confirmed the following residue definition for chlorfenapyr:

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

*The residue is fat soluble.*

The Meeting recommended the following residue definition for chlorfenapyr:

Definition of the residue for dietary risk assessment for plant and animal commodities: *sum of chlorfenapyr plus  $10 \times 4$ -bromo-2-(*p*-chlorophenyl)-5-(trifluoromethyl)-pyrrole-3-carbonitrile (tralopyril)*

The Meeting concluded that if future uses of chlorfenapyr result in an increase in the exposure to the metabolites CL322250, CL325195, CL152837, CL152832, CL152835 and CL325157, a reconsideration of the residue definition for dietary risk assessment may become necessary.

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

The current Meeting received supervised trial data for applications of chlorfenapyr on soya beans and tea conducted in Brazil and Japan, respectively.

In 2012, the Meeting evaluated uses of chlorfenapyr on citrus fruit, papaya, garlic, bulb onions, melons (except watermelons), peppers, egg plants, tomatoes, potatoes and green tea. However, none of the supervised field trials submitted in 2012 analysed the metabolite tralopyril (CL303268), which was considered relevant for estimating dietary exposure by the current Meeting. Based on the plant metabolism data available, the Meeting estimated the following conversion factors to account for the contribution of tralopyril:

$$\text{Conversion Factor} = 1 + \frac{10 \times \% \text{TRR}_{\text{Tralopyril}}}{\% \text{TRR}_{\text{Chlorfenapyr}}}$$

Crop group	Chlorfenapyr	% TRR tralopyril (CL303268)	Conversion factor
Citrus fruits	75.0% TRR <sup>(a)</sup>	3.3% TRR <sup>a</sup>	1.44 (1 + (10*3.3% TRR) ÷ 75.0% TRR)
Papaya	No data	No data	1.44 (extrapolation from citrus fruit, based on comparable GAP and metabolism crop group)
Garlic, bulb onions	<LOQ <sup>(b)</sup>	<LOQ <sup>(b)</sup>	1
Melons (except watermelons)	38-50% TRR <sup>(c)</sup>	Not detected	1
Peppers, eggplant, tomato	92-97% TRR <sup>(d)</sup>	Up to 1% TRR <sup>(d)</sup> (probable contamination)	1
Potato	<LOQ <sup>(b)</sup>	<LOQ <sup>(b)</sup>	1
Tea	75.1% TRR <sup>(e)</sup>	1.3% TRR <sup>(e)</sup>	1.17 (1+(10*1.3% TRR) ÷ 75.1% TRR)

<sup>a</sup> Highest chlorfenapyr/tralopyril ratio obtained from the orange metabolism study evaluated in 2012, DALA 14 following application of [2-pyrrole-<sup>14</sup>C]-chlorfenapyr, corresponding to 14 day PHI from the maximum GAP used in 2012

<sup>b</sup> Based on the 2012 potato metabolism study as representative for root and tuberous crops, Mallipudi 1995 CK-640-008

<sup>c</sup> Based on the 2012 tomato metabolism study DALA 14 by Kao 1995 CK-640-007, corresponding to 14 day PHI from the maximum GAP used in 2012

<sup>d</sup> Based on tomato metabolism study evaluated in 2018, DALA 1 corresponding to 0 day PHI from the maximum GAP used in 2012

<sup>e</sup> Highest chlorfenapyr/tralopyril ratio obtained from lettuce metabolism study evaluated in 2012, DALA 3 following application of [2-pyrrole-<sup>14</sup>C]-chlorfenapyr, approximating the 7 day PHI from the maximum GAPs used in 2012 and 2018

For the purpose of estimating the livestock animal's dietary burden, the Meeting noted that chlorfenapyr is the predominant residue in plants. Tralopyril (CL303286) only makes a small contribution to the residue concentration in feed commodities. Since most of tralopyril (CL303268) found in animal commodities is formed by animal metabolism after exposure to the parent, the Meeting decided that

chlorfenapyr sufficiently addresses residues in feed commodities for the estimation the livestock animals dietary burden.

The current Meeting received supervised field trial data for applications of chlorfenapyr on soya beans and tea conducted in Brazil and Japan, respectively. In soya bean trials, parent chlorfenapyr and tralopyril (CL303268) were analysed but found at levels near the LOQ (parent) or below the LOQ (tralopyril). In the metabolism study on cotton evaluated in 2012, which represents pulse and oilseed crops, no tralopyril was found in the seeds. Taking into account the overall low proportion of tralopyril in the total residue (up to 3.3% TRR) in all crops investigated, the Meeting concluded that the LOQ in combination with a toxicological potency factor of 10 results in a strong overestimation of the true residue. Therefore, the metabolite is only added to the parent residue, when both analytes were found at levels above the LOQ. An example of the calculation is presented in the table below:

Chlorfenapyr	Tralopyril (CL303268)	Total residue (sum of chlorfenapyr and 10 × tralopyril, expressed as chlorfenapyr)
< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
0.03 mg/kg	< 0.01 mg/kg	0.03 mg/kg
0.03 mg/kg	0.01 mg/kg	0.13 mg/kg (0.03 mg/kg + 10×0.01 mg/kg)

#### *Citrus fruit (2012)*

The 2012 Meeting evaluated the data supporting the use of chlorfenapyr on citrus in Brazil (three foliar spray applications at 15 g ai/hL with a PHI of 14 days) and identified the following residue populations based on the supervised field trials submitted:

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

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

The 2012 Meeting estimated a maximum residue level of 1.5 mg/kg for citrus fruits, based on the dataset for orange fruits. However, the current Meeting noted that the previous proposal on citrus fruits was not in line with the current procedure for estimating crop group maximum residue levels and the Codex Food Classification System. As a result the Meeting decided to limit its recommendations to the specific citrus crop subgroups.

The Meeting estimated a maximum residue level of 0.8 mg/kg for the subgroup of Lemons and Limes.

The Meeting estimated a maximum residue level of 1.5 mg/kg for the subgroup of Oranges, Sweet, Sour.

The current Meeting noted that in the metabolism study on oranges evaluated in 2012 the pulp (7 DAT) contained a maximum of 1.7% of the TRR.

The current Meeting applied a conversion factor of 1.44 and a whole fruit to pulp factor of 0.017 (based on the highest relative amount of TRR found in the pulp) to the median and highest residues in limes and estimated a STMR value of 0.004 mg/kg (0.16 mg/kg × 1.44 × 0.017) and a HR value of 0.012 mg/kg (0.49 mg/kg × 1.44 × 0.017) for total chlorfenapyr in the pulp of limes and lemons. For kumquats, which are consumed with peel, the Meeting estimated a STMR value of 0.23 mg/kg (0.16 mg/kg × 1.44) and a HR value of 0.71 mg/kg (0.49 mg/kg × 1.44).



The current Meeting applied a conversion factor of 1.44 and a whole fruit to pulp factor of 0.017 (based on the highest relative amount of TRR found in the pulp) to the median and highest residues in oranges and estimated a STMR value of 0.011 mg/kg ( $0.44 \text{ mg/kg} \times 1.44 \times 0.017$ ) and a HR value of 0.021 mg/kg ( $0.87 \text{ mg/kg} \times 1.44 \times 0.017$ ) for total chlorfenapyr in orange pulp.

For the purpose of estimating residues in processed and animal commodities, the current Meeting also estimated a median residue of 0.44 mg/kg for chlorfenapyr in citrus fruits, based on oranges.

#### *Papaya (2012)*

The 2012 Meeting evaluated the data supporting the use of chlorfenapyr on papaya in Brazil (three foliar spray applications at 12 g ai/hL with a PHI of 14 days) and identified the following residue population based on the supervised field trials submitted:

In papaya, chlorfenapyr residues in whole fruit from trials in Brazil, matching the GAP in Brazil were (n = 5): < 0.01, 0.03, 0.05, 0.11 and 0.12 mg/kg.

The 2012 Meeting estimated a maximum residue level of 0.3 mg/kg for papaya.

The current Meeting applied a conversion factor of 1.44 to the median and highest residue in papaya and estimated a STMR value of 0.072 mg/kg ( $0.05 \text{ mg/kg} \times 1.44$ ) and a HR value of 0.17 mg/kg ( $0.12 \text{ mg/kg} \times 1.44$ ).

#### *Garlic (2012)*

The 2012 Meeting evaluated the data supporting the use of chlorfenapyr to garlic in Brazil (three foliar spray applications at 24 g ai/hL with a PHI of 14 days) and identified the following residue population based on the supervised field trials submitted:

In garlic, chlorfenapyr residues from trials in Brazil, matching the GAP in Brazil were: (n = 5): < 0.01(5) mg/kg.

The 2012 Meeting estimated a maximum residue level of 0.01(\*) mg/kg for garlic.

The current Meeting applied a conversion factor of 1 to the median and highest residue in garlic and estimated STMR and HR values of 0.01 mg/kg ( $0.01 \text{ mg/kg} \times 1$ ), respectively.

#### *Onion, bulb (2012)*

The 2012 Meeting evaluated the data supporting the use of chlorfenapyr on bulb onions in Brazil (three foliar spray applications at 180 g ai/ha with a PHI of 14 days) and identified the following residue population based on the supervised field trials submitted:

In bulb onions, chlorfenapyr residues from trials in Brazil, matching the GAP in Brazil were: (n = 9): < 0.01(9) mg/kg.

The 2012 Meeting estimated a maximum residue level of 0.01(\*) mg/kg for onions, bulb.

The current Meeting applied a conversion factor of 1 to the median and highest residue in bulb onions and estimated STMR and HR values of 0.01 mg/kg ( $0.01 \text{ mg/kg} \times 1$ ), respectively.

#### *Melons, except watermelons (2012)*

The 2012 Meeting evaluated the data supporting the use of chlorfenapyr on melons in Brazil (three foliar spray applications at 24 g ai/hL with a PHI of 14 days) and identified the following residue population based on the supervised field trials submitted:

In whole fruits, chlorfenapyr residues from trials in Brazil, matching the GAP in Brazil were (n = 9): < 0.01(2), 0.01, 0.02(2), 0.06(2) and 0.17(2) mg/kg.

In melon pulp, chlorfenapyr residues from trials in Brazil, matching the GAP in Brazil were (n = 5): < 0.01(4) and 0.01 mg/kg.

The 2012 Meeting estimated a maximum residue level of 0.4 mg/kg for melons, except watermelons.

The current Meeting applied a conversion factor of 1 to the median and highest residue in melon pulp and estimated a STMR value of 0.01 mg/kg (< 0.01 mg/kg × 1) and a HR value of 0.01 mg/kg (0.01 mg/kg × 1).

#### *Peppers (including pepper, chili and pepper sweet) (2012)*

The 2012 Meeting evaluated the data supporting the use of chlorfenapyr on peppers in Brazil (three foliar spray applications at 7.2 g ai/hL with a PHI of 14 days) and identified the following residue population based on the supervised field trials submitted:

In peppers, chlorfenapyr residues from trials in Brazil, matching the GAP in Brazil were (n = 7): < 0.01, 0.01, 0.04, 0.05, 0.06, 0.13 and 0.15 mg/kg.

The 2012 Meeting estimated a maximum residue level of 0.3 mg/kg for peppers.

The current Meeting applied a conversion factor of 1 to the median and highest residue in peppers and estimated a STMR value of 0.05 mg/kg (0.05 mg/kg × 1) and a HR value of 0.15 mg/kg (0.15 mg/kg × 1).

Based on the estimated maximum residue level for peppers and a default dehydration factor of 10, the 2012 Meeting recommended a maximum residue level of 3 mg/kg for chili peppers (dry).

The current Meeting estimated a STMR value of 0.5 mg/kg (0.05 mg/kg × default factor 10) and a HR value of 1.5 mg/kg (0.15 mg/kg × default factor 10) for chili pepper (dry).

#### *Egg plant (2012)*

The 2012 Meeting evaluated the data supporting the use of chlorfenapyr on eggplant in Mexico (up to 96 g ai/ha with a PHI of 0 days) and identified the following residue population based on the supervised field trials submitted:

In eggplant, chlorfenapyr residues from trials matching the GAP were (n = 4): 0.08, 0.09, 0.1 and 0.2 mg/kg.

The 2012 Meeting estimated a maximum residue level of 0.3 mg/kg for eggplant. However, the current Meeting noted that eggplant is a major commodity in consumption. Based on current practice, regarding the minimum number of supervised field trials required for estimating maximum residue levels, the Meeting considered four trials as insufficient to estimate a maximum residue level for eggplant.

#### *Tomatoes (2012)*

The 2012 Meeting evaluated the data supporting the use of chlorfenapyr to tomatoes in Brazil (three foliar spray applications at 12g ai/hL with a PHI 7 days) and identified the following residue population based on the supervised field trials submitted:

In tomatoes, proportionally adjusted chlorfenapyr residues from trials in Brazil and Argentina were (n = 8): 0.02, 0.05, 0.05, 0.06, 0.07, 0.11, 0.19 and 0.19 mg/kg.

The 2012 Meeting estimated a maximum residue level of 0.4 mg/kg for tomatoes.

The current Meeting applied a conversion factor of 1 to the median and highest residue in tomatoes and estimated a STMR value of 0.065 mg/kg ( $0.065 \text{ mg/kg} \times 1$ ) and a HR value of 0.19 mg/kg ( $0.19 \text{ mg/kg} \times 1$ ). The current Meeting also estimated a median residue of 0.065 mg/kg for the estimation of maximum residue levels in processed commodities.

#### *Potato (2012)*

The 2012 Meeting evaluated the data supporting the use of chlorfenapyr on potatoes in Brazil (180 g ai/ha with a PHI of 7 days) and identified the following residue population based on the supervised field trials submitted:

In potatoes, chlorfenapyr residues from trials matching the GAP were ( $n = 9$ ):  $< 0.01(9) \text{ mg/kg}$ .

The 2012 Meeting estimated a maximum residue level of 0.01(\*) mg/kg for potatoes.

The current Meeting applied a conversion factor of 1 to the median and highest residue in potatoes and estimated STMR and HR values of 0.01 mg/kg ( $< 0.01 \text{ mg/kg} \times 1$ ), respectively.

#### *Soya beans (dry)*

Chlorfenapyr is registered in Brazil for soya beans at maximum rates of  $3 \times 0.29 \text{ kg ai/ha}$  (5 days interval) with a PHI of 30 days. Supervised field trials from Brazil matching this GAP were submitted.

The Meeting noted that in the metabolism study on cotton seed, which is representative for pulse and oilseed crops, no formation of tralopyril was observed. Therefore supervised field trial data on soya beans without analysis of tralopyril are acceptable both for the estimation of maximum residue levels and of the dietary risk assessment.

In soya bean seeds (dry) residues of chlorfenapyr following GAP treatment ( $\pm 25\%$ ) were ( $n = 14$ ):  $< 0.01(8)$ , 0.01, 0.013, 0.019, 0.024, 0.046 and 0.05 mg/kg.

The Meeting estimated a maximum residue level of 0.08 mg/kg and a STMR of 0.01 mg/kg for soya beans (dry).

#### *Tea, Green, Black (black, fermented and dried) (2012)*

The 2012 Meeting evaluated the data supporting the use of chlorfenapyr to tea, green, black (black, fermented and dried) in Japan ( $5 \text{ g ai/hL}$ , 7 day interval with a PHI of 7 days) and identified the following residue population based on the supervised field trials submitted:

In green tea, chlorfenapyr residues from trials matching the GAP were ( $n = 4$ ): 4.2, 4.5, 16 and 28 mg/kg.

The 2012 Meeting estimated a maximum residue level of 60 mg/kg for tea, green, black (black, fermented and dried).

The current Meeting applied a conversion factor of 1.17 to the median residue and estimated a STMR value of 12 mg/kg ( $10.25 \text{ mg/kg} \times 1.17$ ), in tea, green, black (black, fermented and dried).

#### *Soya bean fodder (hay)*

Chlorfenapyr is registered in Brazil for soya beans at maximum rates of  $3 \times 0.29 \text{ kg ai/ha}$  with a PHI of 30 days. Supervised field trials from Brazil according to this GAP were submitted.

In soya bean fodder (as received) residues of chlorfenapyr following GAP treatment ( $\pm 25\%$ ) were ( $n = 8$ ): 0.99, 1.4, 1.5, 1.7, 1.9, 2.2, 2.4 and 3.9 mg/kg.

The current Meeting estimated a maximum residue level of 7 mg/kg (DM, 85% DM content assumed) for soya bean fodder.

For the purpose of estimating residues in animal commodities, the Meeting estimated a median residue of 1.6 mg/kg and a highest residue of 3.9 mg/kg for chlorfenapyr in soya bean fodder (as received).

#### *Soya bean aspirated grain fractions (AGF)*

Chlorfenapyr is registered in Brazil for soya beans at maximum rates of  $3 \times 0.29$  kg ai/ha (5 days interval) with a PHI of 30 days. Supervised field trials from Brazil according to this GAP were submitted.

In soya bean AGF residues of chlorfenapyr following GAP treatment ( $\pm 25\%$ ) were ( $n = 4$ ): 6.5, 12, 91 mg/kg.

For the purpose of estimating residues in animal commodities, the Meeting estimated a median residue of 12 mg/kg for chlorfenapyr in soya bean, aspirated grain fraction.

#### ***Residues in rotational crops***

The 2012 Meeting concluded that residues of chlorfenapyr in rotational crop at the minimum plant back interval of 31 days could occur, but that residues would be at or near the limit of quantification of the analytical method (0.01 mg/kg) and do not require further consideration.

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

The Meeting received information on the hydrolysis of  $^{14}\text{C}$ -phenyl-chlorfenapyr and -tralopyril (CL303268) as well as processing studies using unlabelled material on soya beans.

In a hydrolysis study using  $^{14}\text{C}$ -phenyl-chlorfenapyr or  $^{14}\text{C}$ -phenyl-tralopyril (CL303268) typical processing conditions were simulated (pasteurisation, pH 4, 90 °C, 20 minutes; baking/brewing/cooking, pH 5, 100 °C, 60 minutes; and sterilisation, pH 6, 120 °C for 20 minutes).

Chlorfenapyr remained stable (98.7–100% AR remaining) for simulated pasteurization and baking/brewing/cooking. However, significant degradation into CL322250 (chlorfenapyr: 69–72% AR, CL322250: 32–34% AR) was observed during simulated sterilization.

Tralopyril (CL303268) only remained stable during simulated pasteurisation (85–86% AR remaining). For baking/brewing/cooking and sterilization it was completely degraded into CL322250.

The fate of chlorfenapyr residues has been examined in commercial processing studies on soya beans (evaluated by the current Meeting) and on citrus fruits and tomatoes (evaluated by the 2012 JMPR).

In soya beans, residues of chlorfenapyr, tralopyril (CL303268) and CL322250 were analysed. However, only parent chlorfenapyr was found above the LOQ of 0.01 mg/kg in raw commodities and in processed products. Processing factors for soya bean seeds are therefore based on parent chlorfenapyr only.

In citrus fruits and tomatoes only parent chlorfenapyr was analysed. Tralopyril (CL 303268) is included in the residue definition for dietary risk assessment purposes for plant commodities and it is more toxic than parent chlorfenapyr. The Meeting decided that the processing factors derived in 2012 do not reflect the transfer or formation potential of tralopyril residues in processed products intended for human consumption and cannot be used for the estimation of STMR-P values. However, the Meeting noted that residues in processed feed commodities based on parent can be used for estimating the livestock animals

dietary burden and are not affected by the potency factor of 10 for tralopyril. The Meeting decided to use the processing factors estimated by the 2012 JMPR for this purpose.

Estimated processing factors for the commodities considered at this Meeting are summarised below.

Raw commodity	Processed commodity	Chlorfenapyr Individual processing factors	Mean or best estimate processing factor	Median or STMR-P in mg/kg
Citrus ( see 2012 Report) Median: 0.44 mg/kg <sup>(a)</sup>	Citrus pulp, wet	0.99, 1.08	1.0	Median: 0.44
	Citrus pulp, dry	0.55, 0.87, 2.3, 2.4	1.6	Median: 0.704
	Orange oil	3.1, 17, 23, 70	70 (best estimate)	-
Soya bean seeds, dry Median and STMR: 0.01 mg/kg	Meal	0.1, <u>0.21</u> , 0.27	0.21	Median: 0.0021
	Oil, crude	3.3, <u>4.5</u> , 5.2	4.5	STMR-P: 0.045
Tomato (see 2012 Report) Median: 0.065 mg/kg	Tomato pomace, wet	63	63 (best estimate)	Median: 4.095
	Tomato pomace, dry	157	157 (best estimate)	Median: 10.2

<sup>a</sup> For oranges

Based on the maximum residue level for citrus fruits of 1.5 mg/kg and the PF of 70 for orange oil, the Meeting estimated a maximum residue level of 100 mg/kg for orange oil. As no information was available on the behaviour of the metabolites tralopyril (CL303268) and CL322250 during citrus processing, no corresponding STMR-P value could be estimated.

Based on the maximum residue level for soya bean seeds, dry of 0.08 mg/kg and the PF of 4.5 for crude oil, the Meeting estimated a maximum residue level of 0.4 mg/kg for soya bean oil, crude.

### ***Residues in animal commodities***

#### ***Farm animal feeding studies***

No additional information on farm animal feeding was submitted to the current Meeting. Please refer to the 2012 JMPR Report.

#### ***Estimation of livestock dietary burdens***

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 OECD diets listed in Appendix IX of the 2016 edition of the FAO manual, are presented in Annex 6 and summarised below

The Meeting was informed by an official communication of the government of Australia that no fodder crops are imported. Therefore soya bean hay, which would represent the predominant feed item for the Australian dietary burden, has been excluded for that region. Potential feed items include: citrus pulp, tomato pomace, potato culls, soya beans, soya bean meal, soya bean hay and soya bean aspirated grain fractions.

	Livestock dietary burdens for the estimation of maximum residue levels, STMRs and HRs (chlorfenapyr, ppm of dry matter diet)							
	US-Canada		EU		Australia		Japan	
	max.	mean	max.	Mean	max.	mean	max.	mean
Beef cattle	0.89	0.89	0.01	0.1	2.4	2.4	0.003	0.003
Dairy cattle	1.1	0.56	0.37	0.37	2.4 <sup>a</sup>	2.4 <sup>a</sup>	0.003	0.0025
Poultry - broiler	0.003	0.003	0.008	0.008	0.002	0.002	< 0.001	< 0.001
Poultry - layer	0.003	0.003	0.47 <sup>b</sup>	0.20 <sup>c</sup>	0.002	0.002	< 0.001	< 0.001

<sup>a</sup> Highest maximum and mean beef or dairy cattle burden suitable for maximum residue level, STMR and HR (except milk) estimates for mammalian meat and milk

<sup>b</sup> Highest maximum broiler or laying hen burden suitable for maximum residue level and HR estimates for poultry tissues and eggs

<sup>c</sup> Highest mean broiler or laying hen burden suitable for STMR estimates for poultry tissues and eggs

### Animal commodities maximum residue levels

For maximum residue level estimation, the highest residues of chlorfenapyr were estimated for the maximum dietary burden (2.4 ppm) by interpolating between the 2.2 ppm and the 6.8 ppm feeding level in the dairy cow feeding study. The highest tissue concentrations of chlorfenapyr from individual animals within those feeding groups were selected and for milk the mean residues were used.

Chlorfenapyr feeding study	Feed level	Chlorfenapyr				
	(ppm)	(mg/kg) in milk	(mg/kg) in muscle	(mg/kg) in kidney	(mg/kg) in liver	(mg/kg) in fat
Maximum residue level: dairy cattle						
Feeding study (HR for each dose group, except for milk)	2.2	0.017	0.017	< 0.05	< 0.05	0.429
	6.8	0.019	0.022	< 0.05	0.054	0.597
Dietary burden and residue estimate	2.4	0.017	0.017	< 0.05	0.05	0.436

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

For dietary exposure purposes, the available dairy cattle feeding study did not include analysis of tralopyril (CL303268). The Meeting decided to derive conversion factors based on the goat metabolism study to estimate the contribution of tralopyril (CL303268).

$$\text{Conversion Factor} = 1 + \frac{10 \times \% \text{TRR}_{\text{Tralopyril}}}{\% \text{TRR}_{\text{Chlorfenapyr}}}$$

Matrix	% TRR found per label		Total conversion factor (based on mean % TRR)
	Chlorfenapyr	Tralopyril	
Milk	Phenyl: 24.7%	Phenyl: 8.4%	2.5 [1 + 10×6.95% ÷ 46.6%]
	Pyrrole: 68.4%	Pyrrole: 5.5%	

Matrix	% TRR found per label		Total conversion factor (based on mean % TRR)
	Chlorfenapyr	Tralopyril	
	Mean: 46.6%	Mean: 6.95%	
Muscle	Phenyl: 52% Pyrrole: 28.7% Mean: 40.4%	Phenyl: 1.9% Pyrrole: 2.5% Mean: 2.2%	<b>1.5</b> [1 + 10×2.2% ÷ 40.4%]
Kidney	Phenyl: 2.0% Pyrrole: 3.8% Mean: 2.9%	Phenyl: 1.2% Pyrrole: 3.8% Mean: 2.5%	<b>9.6</b> [1 + 10×2.5% ÷ 2.9%]
Liver	Phenyl: 3.5% Pyrrole: 6.9% Mean: 5.2%	Phenyl: 5.6% Pyrrole: 4.1% Mean: 4.85%	<b>10</b> [1 + 10×4.85% ÷ 5.2%]
Fat	Phenyl: 60.9% Pyrrole: 60.8% Mean: 60.8%	Phenyl: 4.5% Pyrrole: 12.3% Mean: 8.4%	<b>2.4</b> [1 + 10×8.4% ÷ 60.8%]

Taking into account the conversion factors derived above, the Meeting estimated both STMR and HR values of 0.043 mg/kg (0.017 mg/kg × 2.5) in milk (STMR only), 0.026 mg/kg in muscle (0.017 mg/kg × 1.5), 0.48 mg/kg in kidney (0.05 mg/kg × 9.6), 0.54 mg/kg in liver (0.054 mg/kg × 10) and 1.0 mg/kg in fat (0.436 mg/kg × 2.4), based on the total residue.

No feeding study on poultry was available to be compared with the maximum and mean dietary burden for laying hens of 0.47 ppm and 0.2 ppm, respectively. The Meeting decided to estimate maximum residues levels, STMR and HR values in poultry matrices and eggs based on the metabolism study.

Since most of the residue for dietary exposure purposes includes conjugates, only the highest dose rates involving hydrolysis were considered. Also, for the estimation of maximum residue levels and the HR, the highest single residue from each of the radiolabels is taken into account. For the estimation of STMR values, the mean of both radiolabels is considered, since no cleavage of the parent molecule was observed.

Chlorfenapyr metabolism study	Feed level	Chlorfenapyr				
	(ppm)	(mg/kg) in eggs	(mg/kg) in muscle	(mg/kg) in kidney	(mg/kg) in liver	(mg/kg) in fat
Maximum residue level: laying hens						
Metabolism study (HR for each dose group)	15 (ph)	<b>0.168</b>	<b>0.005</b>			<b>0.39</b>
	16 (ph)			<b>0.095</b>	<b>0.107</b>	
	14 (py)	<b>0.16</b>	<b>0.0062</b>			0.29
	17 (py)			<b>0.103</b>	<b>0.154</b>	
Dietary burden and residue estimate (selected radiolabel)	0.47	0.005 (both labels)	< 0.001 (both labels)	0.003 (both labels)	0.004 (both labels)	0.012

Values in bold represent the radio-label selected for the estimation

ph: phenyl-radiolabel

py: pyrrole-radiolabel

The Meeting estimated maximum residue levels of 0.02 mg/kg for poultry meat (fat), 0.02 mg/kg for poultry fat and 0.01 mg/kg for poultry, edible offal and eggs.

Chlorfenapyr metabolism study	Feed level	Total residue				
	(ppm)	(mg/kg) in eggs	(mg/kg) in muscle	(mg/kg) in kidney	(mg/kg) in liver	(mg/kg) in fat
Dietary exposure: laying hens						
Metabolism study (HR for each dose group)	15 (ph)	<b>1.5</b>	0.015			<b>0.58</b>
	16 (ph)			0.56	1.4	
	14 (py)	0.84	<b>0.02</b>			0.48
	17 (py)			<b>0.79</b>	<b>2.1</b>	
Dietary burden and residue estimate (selected radiolabel)	0.47 (max)	0.047	0.0007	0.022	0.058	0.018
	0.2 (mean)	0.02	0.0003	0.009	0.025	0.008

Values in bold represent the radio-label selected for the estimation

ph: phenyl-radiolabel

py: pyrrole-radiolabel

The Meeting estimated HR and STMR values of 0.047 and 0.02 mg/kg for eggs, 0.007 and 0.003 mg/kg for poultry muscle, 0.018 and 0.008 mg/kg for poultry fat, 0.022 and 0.009 mg/kg for poultry kidney and 0.058 and 0.025 mg/kg for poultry liver, respectively.

### 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.

The Meeting confirmed the following residue definitions for chlorfenapyr:

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

Definition of the residue for dietary risk assessment for plant and animal commodities: *sum of chlorfenapyr plus 10 × 4-bromo-2-(p-chlorophenyl)-5-(trifluoromethyl)-pyrrole-3-carbonitrile (tralopyril)*

The residue is fat soluble.

The Meeting concluded that if future uses of chlorfenapyr result in an increase in exposure to the metabolites CL322250, CL325195, CL152837, CL152832, CL152835 and CL325157, a reconsideration of the residue definition for dietary risk assessment may become necessary.

### FURTHER WORK OR INFORMATION

- Supervised field trial data involving analysis of tralopyril
- Ruminant feeding study involving analysis according to the residue definition for dietary risk assessment
- Laying hen feeding study
- Processing studies involving analysis of tralopyril and CL322250



## DIETARY RISK ASSESSMENT

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

The ADI for chlorfenapyr is 0–0.03 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for chlorfenapyr were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the present JMPR. The results are shown in Annex 3 of the 2018 JMPR Report. The IEDIs ranged 1–6% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of chlorfenapyr from uses considered by the JMPR is unlikely to present a public health concern.

### ***Acute exposure***

The ARfD for chlorfenapyr is 0.03 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for chlorfenapyr 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 2018 JMPR Report. The IESTIs varied from 0–60% of the ARfD for children and 0–60% for the general population.

The Meeting concluded that acute dietary exposure to residues of chlorfenapyr from uses considered by the present Meeting is unlikely to present a public health concern.



## 5.4 CYANTRANILIPROLE (263)

### RESIDUE AND ANALYTICAL ASPECTS

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

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

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

Definition of the residue for dietary risk assessment for processed plant commodities: *sum of cyantraniliprole and IN-J9Z38, expressed as cyantraniliprole*.

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

The residue is not fat-soluble.

At the Forty-ninth Session of the CCPR (2017), cyantraniliprole was scheduled for evaluation of additional use patterns by the 2018 JMPR.

The Meeting received a soil degradation study in rice, various supervised residue trial data for foliar and soil applications of cyantraniliprole on grapes, strawberries (outdoor), cranberries (outdoor), mango (outdoor), cucumber (glasshouse), and paddy rice and information on registered uses of cyantraniliprole on corresponding crops. In addition a processing study on grapes was resubmitted.

#### **Environmental fate**

In a supervised residue trial on rice, the degradation of cyantraniliprole and its metabolite IN-J9Z38 was investigated at three sites. A single application of 150 g ai/ha was sprayed over the rice paddies. Soil, plant and water samples were taken at various intervals ranging from 1 hour to 60 days after application.

The calculated half lives in water ranged from 2.0–6.2 days for cyantraniliprole (n = 3) and 10.3 days (one site only) for IN-J9Z38. The calculated half lives in plants ranged from 3.2–6.3 days for cyantraniliprole (n = 3). No residue of IN-J9Z38 was detected in the plant samples at any time point and no half-life could be calculated. The calculated half-life in soil was 6.8 days for cyantraniliprole (n = 1). No residue of parent or IN-J9Z38 was detected in any of the other soil samples at any time point.

Parent cyantraniliprole and metabolite IN-J9Z38 are not persistent in soil/water systems.

#### **Methods of analysis**

The methods for analysing cyantraniliprole and metabolites IN-F6L99, IN-J9Z38, IN-JCZ38, IN-K7H19, IN-MLA84, IN-MYX98, IN-N5M09, and IN-N7B69 as previously evaluated (2013 Meeting) were supported with additional recovery data from supervised trials. The methods are considered valid for the commodities

evaluated

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

The stability of residues of cyantraniliprole and its metabolites in stored samples was covered by the freezer stability studies evaluated by the 2013 JMPR. Additional storage stability data on cranberries were submitted and support the conclusions on storage stability from previous Meetings. Analysis of the samples from the residues trials and processing studies submitted for the current Meeting are sufficiently covered.

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

The Meeting received supervised trials data for cyantraniliprole on grapes (field), strawberries (greenhouse and field), cranberries (field), mango (field), cucumber (glasshouse), and paddy rice (field).

The Meeting noted that GAPs have been authorised for the use of cyantraniliprole and the product labels were available from Belgium, Cambodia, Canada, China, the United Kingdom, and the USA.

For the estimation of maximum residue levels and STMRs, the 2018 Meeting also used data from the 2013 and 2015 JMPR evaluations.

#### ***Wine grapes***

The critical GAP for cyantraniliprole on wine grapes is from Italy with 2 foliar applications of 112.5 g ai/ha, a re-treatment interval of 14 days and PHI of 10 days.

Only four trials conducted in the 2014 growing season, conducted in Europe and evaluated by the current Meeting, matched this GAP. European trials conducted in the 2009/2010 growing seasons evaluated by the 2013 JMPR and additional trials from the 2014 season could be matched using the proportionality principle.

Cyantraniliprole residues from trials matching GAP without applying proportionality are (n = 27): 0.031, 0.058, 0.070, 0.071, 0.096, 0.099, 0.11, 0.14, 0.14, 0.16, 0.18, 0.19, 0.21, 0.24, 0.28, 0.30, 0.33, 0.34, 0.40, 0.41, 0.42, 0.43, 0.48, 0.64, 0.67, 0.68 and 0.80 mg/kg.

Scaling factors applied ranged from 0.74–1.0.

Scaled residues were (n = 27): 0.30, 0.054, 0.059, 0.068, 0.090, 0.099, 0.11, 0.11, 0.12, 0.15, 0.16, 0.18, 0.18, 0.21, 0.22, 0.23, 0.24, 0.32, 0.34, 0.40, 0.42, 0.42, 0.45, 0.50, 0.53, 0.59, and 0.75 mg/kg.

The Meeting estimated a maximum residue level of 1.0 mg/kg and a STMR of 0.21 mg/kg for wine grapes on the basis of the critical GAP from Italy.

#### ***Table grapes***

The critical GAP for table grapes was from Belgium where the GAP for both table and wine grapes consists of 2 foliar applications of 53 g ai/ha, a re-treatment interval of 10 days and a PHI of 10 days.

As no trials matched this GAP the Meeting did not estimate a maximum residue level for table grapes.

#### ***Cranberries***

The critical GAP for cyantraniliprole on cranberries is from Canada and comprises 3 foliar applications of 150 g ai/ha, a re-treatment interval of 7 days with a PHI of 14 days.

Five trials conducted in the 2009 growing season in Canada and the USA matched this GAP. The resulting residues were (n = 5): < 0.01, 0.010, 0.012, 0.030, and 0.041 mg/kg.

The Meeting estimated a maximum residue level for cyantraniliprole of 0.08 mg/kg and a STMR value of 0.012 mg/kg for cranberries.

#### *Strawberries*

The critical GAP for cyantraniliprole on strawberries is the GAP from Canada (field) with 3 foliar applications of 150 g ai/ha, a re-treatment interval of 5 days and a PHI of 1 day. Residue levels in trials from Canada and the USA matching this GAP were (n = 8): 0.086, 0.20, 0.22, 0.27, 0.64, 0.64, 0.70, and 0.84 mg/kg.

Based on the USA/Canadian data set the Meeting estimated a maximum residue level for cyantraniliprole of 1.5 mg/kg and a STMR value of 0.455 mg/kg for strawberries.

#### *Mango*

The critical GAP for cyantraniliprole on mangoes is the Cambodian GAP which comprises 2 foliar applications of 180 g ai/ha, with a re-treatment interval of 7 days and a PHI of 7 days.

Eight trials performed in the 2017 growing season in Thailand and Vietnam matched this GAP. The resulting residues in the RAC (whole fruit with stone and peel) were (n = 8): 0.035, 0.064, 0.064, 0.086, 0.11, 0.12, 0.18, and 0.45 mg/kg.

Residues in the edible portion (mango pulp) for dietary risk assessment were (n = 8): < 0.01 (7) and 0.028 mg/kg.

The Meeting estimated a maximum residue level for cyantraniliprole of 0.7 mg/kg and a STMR value of 0.01 mg/kg for mango.

#### *Cucurbits, cucumbers - Greenhouse*

The 2013 Meeting recommended a maximum residue level of 0.3 mg/kg for fruiting vegetables, cucurbits, based on outdoor uses on cucumber, summer squash and melons. The current Meeting received labels from Canada and the USA for the use of cyantraniliprole on greenhouse grown cucumbers.

The critical greenhouse GAP for cyantraniliprole on cucumbers is the GAP in the USA which comprises 3 foliar applications of 150 g ai/ha, a re-treatment interval of 5 days and a PHI of 0 days.

Five trials performed in the 2010 growing season in the USA (evaluated by the 2015 JMPR) matched this GAP. The resulting residues were (n = 5): 0.032, 0.043, 0.18, 0.19 and 0.33 mg/kg. However, five trials were considered insufficient to estimate a maximum residue level for a major crop.

An alternate GAP for greenhouse grown cucumbers submitted to the current Meeting is the Canadian GAP of 4 × 100 g ai/ha, a RTI of 7 days, and a PHI of 0 days. Only four greenhouse trials from Europe (2013 JMPR) could be matched to this GAP. The number of trials was considered insufficient for the estimation of a maximum residue level for cucumbers.

The trials from Europe could not be matched to the USA GAP using the “GAP versus trial” model introduced by the 2017 Meeting either, as the model estimated the residue levels to be 29% lower than the GAP in the European trials.

The Meeting decided to withdraw its previous recommendation for “Fruiting vegetables, cucurbits” of 0.3 mg/kg, based on outdoor uses, and to replace it with a maximum residue level 0.3 mg/kg for the “Group of Fruiting vegetables, Cucurbits”.

### *Rice*

Residue trials on rice evaluated by the 2013 Meeting could not be matched to the GAP from Vietnam (50–100 g ai/ha, PHI 5 days) submitted in 2013. The 2018 Meeting received a new label for a use on rice in China for 2 spray applications at 60 g ai/ha, with a re-treatment interval of 7 days and a PHI of 21 days.

Supervised residue trials conducted in the 2010 and 2011 growing season in China (JMPR 2013), did not match the GAP submitted to the current Meeting.

However, residues in husked rice in overdosed trials conducted with 2 or 3 × 100 g ai/ha, RTI 7 days and a PHI of 21 days were all < 0.01 mg/kg (n = 12). In trials using 2 or 3 × 150 g ai/ha, RTI 7 days and PHI 21 days residues ranged from < 0.01 (9) to 0.019 mg/kg (n = 12). The data suggested a residue below LOQ at the critical GAP.

The Meeting concluded that residues above LOQ are not anticipated, when applied according to GAP and estimated a maximum residue level for cyantraniliprole of 0.01(\*) mg/kg and a STMR value of 0.01 mg/kg for rice, husked. As residues in husked rice were below LOQ and residues in polished rice are expected to be even less, the Meeting decided to apply the estimations for husked rice to polish rice.

### *Cereal and grass forages, straws and hays*

#### *Rice straw*

The supervised trials data were available for rice straw from China.

Overdosed trials conducted with 2 (n = 6) or 3 (n = 6) × 100 g ai/ha, RTI 7 days and a PHI of 21 days could be matched to the Chinese GAP by applying proportionality. The trials using different application rates were performed at the same location and were considered replicate trials. The highest residue level after scaling was selected per site. Unscaled cyantraniliprole residues in rice straw from trials matching the critical GAP were (n = 6): 0.075 (2), 0.17, 0.18, 0.4, and 1.9 mg/kg.

Scaling factors ranging from 0.4–0.6 were applied, resulting in scaled residues of (n = 6): 0.030, 0.045, 0.068, 0.11, 0.24, and 0.76 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg (1.7 mg/kg dry weight) for cyantraniliprole in rice straw. The Meeting estimated median residue level of 0.089 mg/kg (0.099 mg/kg dry weight assuming 90% DM) and a highest residue of 0.76 mg/kg (0.84 mg/kg dry weight assuming 90% DM) for rice straw.

### *Miscellaneous*

#### *Rice hulls*

The same trials as for rice were considered for rice hulls. Overdosed trials conducted with 2 (n = 6) or 3 (n = 6) × 100 g ai/ha, RTI 7 days and PHI of 21 days could be matched to this GAP by applying proportionality. The trials using different application rates were performed at the same location and were considered replicate trials. The highest residue level after scaling was selected per site. Unscaled cyantraniliprole residues in rice straw from trials matching the critical GAP were (n = 6): 0.32, 0.57, 0.95, 1.5, 1.6, and 2.3 mg/kg.

Scaling factors ranging from 0.4–0.6 were applied, resulting in scaled residues of (n = 6): 0.19, 0.34, 0.38, 0.60, 0.96 and 1.4 mg/kg.

The Meeting estimated a median residue level of 0.49 mg/kg (0.54 mg/kg dry weight assuming 90% DM) for rice hulls.

*Residues in processed commodities*

Processing studies were undertaken for grapes and were evaluated by the 2013 Meeting. STMR-Ps were derived by the current Meeting.

Commodity	PF Residue: parent + IN-J9Z38	PF median <sup>a</sup>	STMR-RAC	STMR-P
Grape				
- must	0.79, 1.5, 1.6	1.5	0.21	0.32
- juice	0.48, 0.52, 1.4	0.52	0.21	0.11
- wine (bottled)	0.5, 1.0, 1.2	1.0	0.21	0.21
- raisin	0.48, 0.52, 2.3	0.52	<sup>b</sup>	<sup>b</sup>
- wet pomace	1.4, 2.7, 3.9	2.7	0.21	0.57

<sup>a</sup> Values were taken from the 2013 evaluation.

<sup>b</sup> The Meeting did not estimate a STMR-P for raisins, since the labels refer to wine-grapes only.

*Residues in animal commodities**Farm animal dietary burden*

The 2018 Meeting evaluated residues in grapes (pomace) and rice (hulls, grain and straw), which were listed in the OECD feeding table in addition to dietary burden calculated in 2015. The Meeting noted that the estimation did not result in a significant change to the dietary burdens of farm animals; a maximum increase of 9.6% of the maximum dietary burden was observed. The previous recommendations of maximum residue levels for animal commodities were maintained.

**RECOMMENDATIONS**

On the basis of the data from supervised residue 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 both plant and animal commodities: *cyantraniliprole*.

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

Definition of the residue for dietary risk assessment for processed plant commodities: *sum of cyantraniliprole and IN-J9Z38, expressed as cyantraniliprole*.

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

The residue is not fat-soluble.

**DIETARY RISK ASSESSMENT*****Long-term dietary exposure***

The ADI for cyantraniliprole is 0–0.03 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for cyantraniliprole were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the 2013, 2015 and 2018 JMPR. The results are shown in Annex 3 of the 2018 JMPR Report. The IEDIs ranged from 4–40% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of cyantraniliprole from uses considered by the JMPR is unlikely to present a public health concern.

***Acute dietary exposure***

The 2013 JMPR decided that an ARfD for cyantraniliprole was unnecessary. The current Meeting therefore concluded that the acute dietary exposure to residues of cyantraniliprole from the uses considered is unlikely to present a public health concern.



## 5.5 CYAZOFAMID (281)

### RESIDUE AND ANALYTICAL ASPECTS

Cyazofamid, a cyanoimidazole fungicide was considered for the first time by the JMPR in 2015 when residue definitions and health-based guidance values were established and a number of maximum residue limits were recommended for grapes and a range of vegetables.

The 2015 JMPR established an ADI of 0–0.2 mg/kg bw for cyazofamid. An ARfD of 0.2 mg/kg bw was established for 4-chloro-5-p-tolylimidazole-2-carbonitrile (CCIM) and an ARfD was determined to be unnecessary for cyazofamid.

The 2015 JMPR established the following residue definitions:

The residue definition for compliance with the MRL for plant commodities: *cyazofamid*.

The residue definition for long-term dietary risk assessment: *cyazofamid plus CCIM, expressed as cyazofamid*

The residue definition for acute dietary risk assessment: *CCIM*

The Forty-ninth Session of the CCPR (2017) scheduled cyazofamid for the evaluation of additional uses by the 2018 JMPR. The current Meeting received new GAP information for bulb vegetables, new supporting residue trial and storage stability studies.

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

The stability of residues of cyazofamid and CCIM in crops was evaluated by the JMPR in 2015. In the listed commodities with a high water content (in the fresh legume, brassica vegetable, leafy vegetable and fruiting vegetable groups), cyazofamid residues in stored frozen samples were shown to be stable for at least 284 days and except for basil (fresh), CCIM residues were stable for at least 634 days.

In the recent studies on chives, a storage stability component was included in the experimental design, and while the fortified samples were not analysed at the beginning of the storage intervals, the data indicate that cyazofamid and CCIM are stable in stored frozen samples of fresh chives for at least 472 days, but that residues were not shown to be stable in dried chives in frozen storage.

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

The Meeting received new GAP information and/or new supporting residue information from the manufacturer for spring onions, chives and bulb onions.

For estimating dietary exposure, combined residues (cyazofamid + CCIM) were calculated by multiplying the individual sample results from field trials of CCIM by the molecular weight factor of 1.49 (cyazofamid mol. weight = 324.8, CCIM mol. weight = 217.7) and adding the result to the corresponding residue of cyazofamid. For calculation purposes, when residues below the LOQ, the residue was assumed to be at the LOQ. The “less than” designation was retained only if both residues were below the LOQ. Examples are shown below:

Cyazofamid	CCIM	Combined (expressed to two significant figures)
0.5 mg/kg	0.06 mg/kg	$0.5 \text{ mg/kg} + (0.06 \text{ mg/kg} \times 1.49) = 0.59 \text{ mg/kg}$
0.5 mg/kg	< 0.01 mg/kg	$0.5 \text{ mg/kg} + (0.01 \text{ mg/kg} \times 1.49) = 0.51 \text{ mg/kg}$

*Bulb vegetables**Bulb onions, subgroup of*

The GAP for cyazofamid on bulb vegetables (including dry bulb onions) in the USA is  $6 \times 0.087$  kg ai/ha, with a minimum re-treatment interval of 7 days, a PHI of 0 days and a maximum seasonal rate of 0.47 kg ai/ha.

In 10 trials conducted in North America and matching the USA bulb vegetables GAP, residues found in onion bulbs were:

Cyazofamid: 0.032, 0.038, 0.039, 0.039, 0.041, 0.055, 0.059, 0.09, 0.097 and 0.86 mg/kg.

CCIM: < 0.01 (9) and 0.026 mg/kg with the highest individual sample residue being 0.03 mg/kg

Combined residues(cyazofamid+CCIM): 0.047, 0.053, 0.054, 0.054, 0.056, 0.067, 0.074, 0.1, 0.11 and 0.895 mg/kg (n = 10).

Noting that bulb onion is a representative commodity for the Bulb Onions subgroup, and that the GAP in the USA covered all commodities in this subgroup, the Meeting estimated a maximum residue level of 1.5 mg/kg for cyazofamid, a STMR of 0.0615 mg/kg for the combined residues of cyazofamid and CCIM and a HR of 0.03 mg/kg and STMR of 0.01 mg/kg for CCIM on the subgroup of Bulb onions.

*Green onions, subgroup of*

The GAP for bulb vegetables (including spring onions and chive leaves) in the USA for cyazofamid is  $6 \times 0.087$  kg ai/ha, a minimum re-treatment interval of 7 days, a PHI of 0 days and a maximum seasonal rate of 0.47 kg ai/ha.

Five trials on spring onions matching the GAP in the USA for bulb vegetables were available and a further five trials on chives, involving the same application rate (0.087 kg ai/ha), re-treatment intervals and PHI but with 9 applications of 0.087 kg ai/ha.

Residues in spring onions were:

Cyazofamid: 0.46, 0.48, 0.54, 0.77 and 1.1 mg/kg.

CCIM: 0.011, 0.012, 0.012, 0.013 and 0.018 mg/kg (highest single residue of 0.019 mg/kg)

Combined residues (cyazofamid+CCIM): 0.49, 0.50, 0.56, 0.79 and 1.1 mg/kg (n = 5).

The Meeting noted that in chives, residues declined rapidly (half-life of about 2 days), such that the contribution of residues from applications made more than 35 days prior to harvest would be negligible. The Meeting agreed to consider combining the data on spring onions and chives to estimate a maximum residue level for the subgroup of Green onions.

The residues in chives were:

Cyazofamid: 1.1, 1.2, 1.7, 2.8 and 3.3 mg/kg.

CCIM: 0.025, 0.029, 0.044, 0.16 and 0.2 mg/kg (highest single residue of 0.2 mg/kg)

Combined residues (cyazofamid+CCIM): 1.3, 1.3, 1.7, 3.0, and 3.3 mg/kg (n = 5).

As the median residues are within the 5-times range, and a Mann-Whitney test showed the residue populations were not from the same distribution, the Meeting agreed to estimate a maximum residue level for the green onion subgroup, based on the data set for chives.

The Meeting estimated a maximum residue level of 6 mg/kg for cyazofamid and a STMR of 1.5 mg/kg for the combined residues of cyazofamid and CCIM on the subgroup of Green onions. The Meeting estimated a HR of 0.2 mg/kg and a STMR of 0.044 mg/kg for CCIM on the subgroup of green onions.

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

In five of the outdoor trials conducted in the USA on chives, samples of fresh leaves were air-dried or dehydrated for 1–2 days before being frozen and stored for 413 days before being analysed for cyazofamid and CCIM.

The Meeting noted that residues of CCIM were not stable in dried chives and agreed the data were not sufficient to estimate maximum residue levels in dried chives.

### **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: *cyazofamid*

Definition of the residue for estimating long-term dietary risk assessment for plant commodities: *cyazofamid plus CCIM, expressed as cyazofamid*

Definition of the residue for acute dietary risk assessment for plant commodities: *CCIM*

Definition of the residue for compliance with the MRL and for estimating dietary exposure from animal commodities: *not defined*

### **DIETARY RISK ASSESSMENT**

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

The ADI for cyazofamid is 0–0.2 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for cyazofamid 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 2018 JMPR Report. The IEDIs ranged from 0–5% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of cyazofamid from uses considered by the JMPR is unlikely to present a public health concern

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

The ARfD for CCIM is 0.2 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for CCIM 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 2018 JMPR Report. The IESTIs varied from 0–3% of the ARfD for children and 0–1% for the general population.

The Meeting concluded that acute dietary exposure to residues of cyazofamid from uses considered by the present Meeting is unlikely to present a public health concern.



## 5.6 DIQUAT (031)

### RESIDUE AND ANALYTICAL ASPECTS

Diquat was first reviewed by the 1970 JMPR. The toxicology and residues aspects of diquat were reconsidered by the 2013 JMPR as part of the periodic review program. The 2013 JMPR established an ADI of 0–0.006 mg/kg bw and an ARfD of 0.8 mg/kg bw, and recommended a residue definition for compliance with the MRL and dietary risk assessment for plant and animal commodities of *diquat cation*, along with maximum residue levels in a number of plant and animal commodities.

Diquat was scheduled by the Forty-ninth Session of the CCPR (2017) for evaluation of additional residues data in pulses and cereals.

#### ***Methods of analysis***

No new methods of analysis were submitted to the Meeting. In all trials presented to the Meeting, samples were analysed using a LC-MS/MS method (method number GRM012.03A), which was considered by the 2013 JMPR. Additional validation data in pulse matrices (chickpea, lentil, dry bean and dry pea seed) were generated for the current Meeting, since the previous validation data for this method did not include a high protein commodity. Acceptable recovery values were achieved in these matrices over a fortification range of 0.01–3.0 mg/kg.

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

The Meeting received the final version of a storage stability study provided as an interim report to the 2013 JMPR, together with storage stability data generated concurrently with the cereal residue trials. The final version of the storage stability study confirmed the assessment of the 2013 JMPR, that residues of diquat are stable in a range of commodities (spinach, wheat grain, oilseed rape seed, lentil, whole orange, potato and wheat straw) over 24 months frozen storage. This data covers a sufficient time interval to support the proposition that residues of diquat will have remained stable for the storage times used in the trials presented to the Meeting.

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

The Meeting received supervised residue trial data for foliar application of diquat to beans, dry, chickpeas, lentils and peas, dry for pre-harvest desiccation, and for foliar application to barley, oats and wheat for weed control both early in the crop and immediately pre-harvest.

All rates discussed below are expressed in terms of g ai/ha of diquat cation.

#### ***Pulses***

In the discussion of uses on the label from Canada below, the following applies concerning harvesting of pulses. There is no specific harvest interval on the label, however information on the label regarding harvesting states that 'harvesting can normally commence within 4–10 days of desiccation'. The Meeting considered that 4 days represented the minimum interval likely to be used in practice, as sufficient time is required for effective desiccation or weed control.

#### ***Dry beans, Subgroup of***

The critical GAP for beans (including white and red kidney beans, soya beans, adzuki beans and faba beans) in Canada is a single aerial application at 552 g ai/ha for pre-harvest desiccation.

Residue trials in beans, dry were conducted in Canada during the 2015 season and matching the Canadian GAP (1 application at 0.87–0.95× the maximum Canadian rate, and with sampling at a 4–5 day PHI). Residues observed in these trials are shown below (*in italics*) together with residues observed in data from JMPR 2013, from trials conducted in Germany in 1984 and the USA in 1994 matching the Canadian GAP.

Residues of diquat in beans, dry after treatment at GAP were (n = 24): *0.01, 0.012, 0.019, < 0.02 (3), 0.040, 0.044, < 0.05 (8), 0.05, 0.08, 0.09, 0.15, 0.15, 0.18 (2), and 0.35 mg/kg.*

Similarly data was available in the 2013 JMPR for dry soya beans from trials conducted in France matching the Canadian GAP.

Residues of diquat in soya beans, dry after treatment at GAP were (n = 3): < 0.05, 0.06 and < 0.1 mg/kg.

The combined dataset in ranked order is (n = 27) were: 0.01, 0.012, 0.019, < 0.02 (3), 0.040, 0.044, < 0.05 (9), 0.05, 0.06, 0.08, 0.09, < 0.1, 0.15 (2), 0.18 (2) and 0.35 mg/kg.

The Meeting noted that several commodities in the subgroup of dry beans were covered by the Canadian GAP, and decided to estimate a maximum residue level for the subgroup. The Meeting estimated a maximum residue level of 0.4 mg/kg for diquat in the subgroup of Dry beans, together with a STMR of 0.05 mg/kg. The Meeting withdrew the previous recommendation of 0.2 and 0.3 mg/kg for beans (dry) and soya bean (dry), respectively.

#### *Chickpeas*

The critical GAP for chickpeas in Australia is a single application at 600 g ai/ha for pre-harvest crop desiccation, with a 2-day PHI. No trials were available with a 2-day PHI, and only two were available with a 1-day PHI.

The GAP for chickpeas in Canada is a single ground foliar spray application at 408 g ai/ha for pre-harvest desiccation.

Residue trials in chickpeas were conducted in Canada during the 2015 season and matching the Canadian GAP (1 application at 1.1–1.29× the maximum Canadian rate, and with sampling at a 4–5 day PHI).

Residues of diquat in chickpeas after treatment at GAP were (n = 9): 0.070, 0.10, 0.16, 0.18, 0.24, 0.26, 0.32, 0.38, and 0.58 mg/kg.

The Meeting estimated a maximum residue level of 0.9 mg/kg, together with a STMR of 0.24 mg/kg, for diquat in chickpea (dry).

#### *Subgroup – Dry peas (except chick-peas)*

#### *Lentils*

The critical GAP for lentils in Australia is a single application at 600 g ai/ha for pre-harvest crop desiccation, with a 2-day PHI. No trials were available with a 2-day PHI, and only two were available with a 1-day PHI.

The GAP for lentils in Canada is a single aerial application at 552 g ai/ha for pre-harvest desiccation.

Residue trials in lentils were conducted in Canada during the 2015 season and matching the Canadian GAP (1 application at 0.85–0.91× the maximum Canadian rate, and with sampling at a 4–5 day PHI).

Residues of diquat in lentils after treatment at GAP were (n = 8): 0.052, 0.070, 0.10, 0.16, 0.18, 0.21, 0.33, and 0.57 mg/kg.

#### *Peas, dry*

The GAP for dry peas in Australia is a single application at 600 g ai/ha for pre-harvest crop desiccation, with a harvest withholding period not required.

The GAP for peas, dry in Canada is a single application at 552 g ai/ha for pre-harvest desiccation.

Residue trials in peas, dry were conducted in Canada during the 2015 season and matching Canadian GAP (1 application at 0.87–0.93× the maximum Canadian rate, and with sampling at a 4–5 day PHI). Residues observed in these trials are shown below (*in italics*) together with data from JMPR 2013, from trials conducted in Germany in 1984/5 and the UK in 1992, and the USA in 1994 matching the Canadian GAP.

The combined dataset is (n = 21): *0.014*, *0.020*, 0.03, *0.038*, 0.04, < 0.05 (3), 0.05 (4), *0.054*, 0.06 (2), *0.061*, 0.09, 0.10, 0.11, *0.13*, and 0.56 mg/kg.

The Meeting noted that data were available for lentils, and peas, dry and considered a maximum residue level for the subgroup of dry peas (except chickpeas). The Meeting noted that the median residues for the datasets for the two crops differed by less than 5-fold, and noted that the datasets were not statistically similar (Mann-Whitney). The Meeting therefore decided to estimate a maximum residue level for the subgroup of dry peas based on the lentil dataset.

The Meeting estimated a maximum residue level of 0.9 mg/kg, together with a STMR of 0.17 mg/kg, for diquat in the subgroup of dry peas (except chickpeas). The Meeting withdrew the previous recommendation of 0.3 mg/kg for peas (dry).

#### *Cereals*

In the discussion of uses on the label from Australia below, the following applies concerning harvesting of cereals after a single pre-harvest application. Where a harvest withholding period is stated as being not required when used as directed, the Meeting considered that at least 4 days would be required for effective weed and crop dry down. The Meeting considered that harvest at a minimum of 4 days was consistent with expected agricultural practice in Australia.

#### *Barley*

The GAP for barley in Australia is a single application at 600 g ai/ha made shortly before harvest for weed control. A harvest withholding period is stated as being not required when used as directed. Residue data were available at 2-4 day harvest intervals and at a 7-day harvest interval.

Residues of diquat cation in barley at 4 days after application were (n = 1): 0.15 mg/kg.

Considering that decline data were available for all trial sites, the Meeting noted that for several of the barley trial sites, the interpolated residue level at 4 days after application differed by less than ±25% from the measured level at 2 or 3 days after application.

Residues of diquat cation in barley approximating GAP were (n = 6): 0.15, 0.53, 1.1, 2.0 (2), and 2.1 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg for diquat in barley, together with a STMR of 1.55 mg/kg.

*Oats*

The GAP for oats in Australia is an early application for weed control at 140 g ai/ha made between the 3-leaf and early tillering stage (BBCH 13–22) plus a pre-harvest weed control application at 600 g ai/ha shortly before harvest.

Residue trials generated in Australia for oats were provided to the Meeting but did not match GAP.

*Rye and triticale*

The GAP for winter cereals in Australia is a single application at 600 g ai/ha made shortly before harvest for weed control. A harvest withholding period is stated as being not required when used as directed.

The Meeting agreed to use the wheat data to estimate maximum residue levels for rye and triticale.

Considering that decline data were available for all trial sites, the Meeting noted that for several of the trial sites, the interpolated residue level at 4 days after application generally differed by less than  $\pm 25\%$  from the measured level at 2 or 3 days after application.

Residues of diquat cation in wheat at 2–4 days after application (at trial sites where values consistent with those expected from use in accordance with GAP were obtained) were (n = 6): 0.28, 0.41, 0.45, 0.56, 0.57 and 0.78 mg/kg.

Based on the wheat data, the Meeting estimated maximum residue levels and STMRs of 1.5 mg/kg and 0.505 mg/kg respectively for rye and triticale.

*Wheat*

The GAP for wheat in Australia is an early application for weed control at 140 g ai/ha made between the 4-leaf and early tillering stage (BBCH 14–22) plus a pre-harvest weed control application at 600 g ai/ha shortly before harvest.

Residue trials generated in Australia for wheat were provided to the Meeting but did not match GAP.

***Animal feeds****Barley forage*

Residue data were available from the Australian cereal residue trials for barley forage. However, there is no relevant GAP in barley involving application at or before the forage stage.

*Oat forage*

The Australian GAP for application of diquat to oats at the forage stage is 1 × 140 g ai/ha application, with a 1-day grazing interval. Trials conducted in Australia in oats included forage sampling; however these trials did not match GAP.

*Wheat forage*

The Australian GAP for application of diquat to wheat at the forage stage is 1 × 140 g ai/ha application, with a 1-day grazing interval. Trials conducted in Australia in wheat included forage sampling; however these trials did not match GAP.



*Barley, rye and triticale straw*

The GAP for barley, rye and triticale straw in Australia is a single application at 600 g ai/ha made shortly before harvest for weed control.

Considering that decline data were available for all trial sites, the Meeting noted that for many of the trial sites, the interpolated residue level at 4 days after application differed by less than  $\pm 25\%$  from the measured level at 2 or 3 days after application.

The Meeting considered that straws of cereal crops are not distinguished in trade and considered that data for barley, oat and wheat straw matching the GAPs for barley, rye and triticale could be combined for the purpose of obtaining more robust estimates for maximum residue levels.

Residues of diquat cation in barley straw at 2–4 days after application (at trial sites where values consistent with those expected from use in accordance with GAP were obtained) were (n = 5): 2.8, 6.2, 6.9, 23, and 26 mg/kg (on a dry weight basis). Residues of diquat cation in oat straw at 2–4 days after application (at trial sites where values consistent with those expected from use in accordance with GAP were obtained) were (n = 4): 0.27, 1.8, 2.8, and 3.1 mg/kg.

Residues of diquat cation in wheat straw at 2–4 days after application (at trial sites where values consistent with those expected from use in accordance with GAP were obtained) were (n = 8): 1.2, 2.0, 2.4, 2.8, 3.3, 4.3, 5.6 and 6.1 mg/kg.

The Meeting further noted that the median residues of the barley, oat and wheat data sets differed by  $< 5\times$ , and that the datasets were statistically similar (Kruskal-Wallis), and agreed to combine them for the purpose of estimating maximum residue levels.

The combined data set is (n = 17): 0.27, 1.2, 1.8, 2.0, 2.4, 2.8 (3), 3.1, 3.3, 4.3, 5.6, 6.1, 6.2, 6.9, 23, and 26 mg/kg.

The Meeting estimated maximum residue levels of 40 mg/kg for diquat in barley straw and fodder (dry), rye straw and fodder (dry), and triticale straw and fodder (dry), together with median and highest residues of 3.1 and 26 mg/kg respectively.

*Oat straw*

The GAP for oat straw in Australia is an early application for weed control at 140 g ai/ha made between the 4-leaf and early tillering stage (BBCH 14–22) plus a pre-harvest weed control application at 600 g ai/ha shortly before harvest.

Residue trials generated in Australia for oats were provided to the Meeting but did not match GAP.

*Wheat straw*

The GAP for wheat straw in Australia is an early application for weed control at 140 g ai/ha made between the 4-leaf and early tillering stage (BBCH 14–22) plus a pre-harvest weed control application at 600 g ai/ha shortly before harvest.

Residue trials generated in Australia for wheat were provided to the Meeting but did not match GAP.

*Fate of residues during processing*

No processing studies were provided to this Meeting. The 2013 JMPR considered a processing study in soya bean, and this was used to estimate updated values for processed soya commodities based on the increased STMR covering soya bean RAC estimated by the Meeting.

## Summary of selected processing factors for diquat

Raw commodity	Processed commodity	Individual PF	Best estimate PF	STMR <sub>RAC</sub> (mg/kg)	STMR <sub>RAC</sub> × PF (mg/kg)	RAC MRL (mg/kg)	Processed commodity MRL
Soya bean	Hulls	2.6 3.6	3.1	0.05	0.155	0.4	1.24
	Meal	0.7 1.0	0.85		0.0425		-
	Oil	< 0.04 < 0.07	< 0.055		< 0.00275		-

Based on the estimated maximum residue level for the RAC of the dry beans subgroup, and the processing factor, the Meeting estimated a maximum residue level of 1.5 mg/kg for soya bean hulls ( $3.1 \times 0.4 = 1.24$ , rounded up to nearest 'step').

**Residues in animal commodities***Farm animal feeding studies*

The 2013 JMPR received information on the residue levels arising in tissues and milk when dairy cows were fed a diet containing incurred residues of diquat at dietary levels of 18, 50 and 84 ppm for 30 consecutive days. There were no residues of diquat at or above the LOQ (0.001 mg/kg) in any of the milk samples or at or above the LOQ (0.01 mg/kg) in any of the tissue samples (liver, kidney, fat and muscle) from any of the dose groups throughout the duration of the study.

The 2013 JMPR also received information on the residue levels arising in tissues and eggs, when laying hens were fed a diet containing diquat at total dietary levels of 1, 5 and 10 ppm diquat for 21 or 28 consecutive days. No residues of diquat above the LOQ (< 0.01 mg/kg) were found in any of the egg, fat, muscle, skin, liver or heart samples.

*Livestock dietary burden*

Dietary burden calculations for beef cattle and dairy cattle and poultry are provided below. The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO Manual, are presented in Annex 6 and summarised below.

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

	US-Canada		EU		Australia		Japan	
	max	mean	Max	Mean	max	Mean	max	Mean
Beef cattle	4.0	1.33	17	6.3	29 <sup>①</sup>	18 <sup>③</sup>	1.27	1.27
Dairy cattle	6.7	3.0	18	7.2	29 <sup>②</sup>	14 <sup>④</sup>	2.25	0.95
Poultry Broiler	1.37	1.37	1.32	1.30	0.34	0.34	0.20	0.20
Poultry Layer	1.37	1.37	5.8 <sup>⑤</sup>	3.5 <sup>⑥</sup>	0.34	0.34	0.04	0.04

- ① Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimates for mammalian meat
- ② Highest maximum dairy cattle dietary burden suitable for maximum residue level estimates for mammalian milk
- ③ Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat.
- ④ Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.
- ⑤ Highest maximum poultry dietary burden suitable for maximum residue level estimates for poultry meat and eggs.
- ⑥ Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs.

***Animal commodity maximum residue levels***

The Meeting noted that at the estimated maximum dietary burdens of 29 and 5.8 ppm for cattle and poultry respectively, no residues are expected in tissues, milk, or eggs. Slight increases in the dietary burdens over those calculated by the 2013 JMPR were noted for dairy cattle and poultry.

The Meeting considered that the recommendations of the 2013 JMPR for maximum residue levels at the LOQ (0.01(\*) mg/kg; 0.001(\*) mg/kg for milk), together with nil STMR and HR values, for mammalian and poultry meat and offal, milk, and eggs remained appropriate.

The Meeting estimated maximum residue levels of 0.01(\*) mg/kg for mammalian and poultry fats, together with STMR and HR values of 0.

**RECOMMENDATIONS**

On the basis of the data obtained from supervised residue trials the Meeting concluded that the maximum 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 MRL and for estimation of dietary intake (for animal and plant commodities): *Diquat ion*

The residue is not fat-soluble.

**DIETARY RISK ASSESSMENT*****Long-term dietary exposure***

The ADI for diquat is 0–0.006 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for diquat were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the 2013 and 2018 JMPR. The results are shown in Annex 3 of the 2018 JMPR Report. The IEDIs ranged from 2–30% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of diquat from uses considered by the JMPR is unlikely to present a public health concern.

***Acute dietary exposure***

The ARfD for diquat is 0.8 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for diquat 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 2018 JMPR Report. The IESTIs varied from 0–7% of the ARfD for children and 0–10% for the general population.

The Meeting concluded that acute dietary exposure to residues of diquat from uses considered by the present Meeting is unlikely to present a public health concern.



## 5.7 ETHIPROLE (304)

### TOXICOLOGY

Ethiprole is the common name approved by the International Organization for Standardization (ISO) for 5-amino-1-(2,6-dichloro- $\alpha,\alpha,\alpha$ -trifluoro-*p*-tolyl)-4-ethylsulfinylpyrazole-3-carbonitrile (International Union of Pure and Applied Chemistry [IUPAC]), with the Chemical Abstracts Service (CAS) number 181587-01-9.

Ethiprole is a non-systemic insecticide of the fiproles (phenylpyrazoles) group. It acts by interfering with the flow of chloride ions through the  $\gamma$ -aminobutyric acid-regulated chloride channel, thereby disrupting the central nervous system activity of insects.

Ethiprole 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 metabolism studies conducted in rats, ethiprole was rapidly excreted (up to 86% at 48 hours) after administration of a single or repeated low dose of 5 mg/kg bw; at a single high dose of 1000 mg/kg bw, excretion (up to 77%) was slightly lower. After a single low dose, the majority of administered radioactivity was excreted in the faeces, with urinary excretion being 24–36% after 168 hours. Similar results were obtained after repeated low doses. At the high dose, faecal excretion was again the major route of excretion, and urine accounted for only 3–5% of excretion after 168 hours. After bile duct cannulation, the urinary excretion and biliary excretion were, respectively, approximately 11% and 67% in males and 30% and 52% in females at the low dose, and approximately 1% and 9% in males and 1.5% and 7% in females at the high dose. Times to reach maximum concentrations ( $T_{\max}$  values) in whole blood and tissues were 8 and 48 hours at the low and high doses (5 and 1000 mg/kg bw, respectively). Tissue distribution was independent of sex, dose and duration of dosing. The highest radioactive residues were present in the liver and kidney (up to 12% and 1%, respectively, at the low dose, and up to 1% for both at the high dose) and glandular tissues, including thyroid.

Ethiprole is extensively metabolized. The pattern of metabolites in urine was independent of sex, dose and duration of dosing. The major components were the polar glucuronide conjugate of hydroxy-MB 45897, the sulfinic acid RPA 104615, as well as the less polar (non-conjugated) MB 45897 and, in female urine, the carboxylic acid RPA 112705. Three primary parallel metabolic pathways could be derived from the metabolites observed: 1) hydrolysis of the nitrile group to form the amide RPA 112916; 2) reduction of the sulfoxide group to form the sulfide RPA 107566, with subsequent alkyl oxidation; and 3) oxidation of the sulfoxide group to form the major metabolite (i.e. the sulfone RPA 097973), followed by further metabolic reactions, including conjugate formation.

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

The oral acute  $LD_{50}$  for ethiprole in rats was greater than 7080 mg/kg bw.

In a 28-day toxicity study, mice were fed diets containing ethiprole at a concentration of 0, 50, 250, 1000 or 2500 parts per million (ppm) (equal to 0, 9.3, 47.4, 186.2 and 458.0 mg/kg bw per day for males and 0, 11.8, 57.9, 234.4 and 513.0 mg/kg bw per day for females, respectively). The no-observed-adverse-

effect level (NOAEL) was 50 ppm (equal to 9.3 mg/kg bw per day), based on increased liver weights and histopathological changes in the liver at 250 ppm (equal to 47.4 mg/kg bw per day).

In a 28-day toxicity study, rats were fed diets containing ethiprole at a concentration of 0, 20, 100, 500 or 2500 ppm (equal to 0, 1.8, 9.2, 46.1 and 219.3 mg/kg bw per day for males and 0, 2.0, 9.6, 46.3 and 220.2 mg/kg bw per day for females, respectively). The NOAEL was 20 ppm (equal to 1.8 mg/kg bw per day), based on adrenal effects (increased weight with slight increase in vacuolation) and slight effects on thyroid hormones at 100 ppm (equal to 9.2 mg/kg bw per day).

In a 90-day toxicity study, rats were fed diets containing ethiprole at a concentration of 0, 5, 20, 500 or 2500 ppm (equal to 0, 0.296, 1.17, 30.5 and 155 mg/kg bw per day for males and 0, 0.373, 1.50, 37.6 and 188 mg/kg bw per day for females, respectively). The NOAEL was 20 ppm (equal to 1.17 mg/kg bw per day), based on mortality, changes in thyroid hormone levels, changes in clinical chemistry parameters, and increased liver and thyroid weights associated with microscopic changes in these target organs at 500 ppm (equal to 30.5 mg/kg bw per day).

In a 90-day toxicity study, dogs received ethiprole at a dietary concentration of 0, 30, 90 or 200 ppm (equal to 0, 1.0, 3.2 and 7.6 mg/kg bw per day for males and 0, 1.1, 3.6 and 8.5 mg/kg bw per day for females, respectively). The NOAEL was 30 ppm (equal to 1.0 mg/kg bw per day), based on reduced body weight gain and decreased thymus weight with atrophy at 90 ppm (equal to 3.2 mg/kg bw per day).

In a 1-year toxicity study, dogs received ethiprole at a dietary concentration of 0, 9, 30 or 90 ppm (equal to 0, 0.27, 0.70 and 2.73 mg/kg bw per day for males and 0, 0.22, 0.76 and 2.51 mg/kg bw per day for females, respectively). The NOAEL was 30 ppm (equal to 0.70 mg/kg bw per day), based on overall reduced body weight gain at 90 ppm (equal to 2.51 mg/kg bw per day).

The overall NOAEL for oral toxicity in dogs was 30 ppm (equal to 1.0 mg/kg bw per day), based on reduced body weight gain at 90 ppm (equal to 2.51 mg/kg bw per day).

In a 78-week carcinogenicity study in mice, ethiprole was administered in the diet at a concentration of 0, 10, 50, 150 or 300 ppm (equal to 0, 1.7, 8.6, 25.6 and 50.8 mg/kg bw per day for males and 0, 1.7, 12.5, 36.3 and 73.5 mg/kg bw per day for females, respectively). The NOAEL for toxicity was 150 ppm (equal to 36.3 mg/kg bw per day), based on a decrease in survival rate in females at 300 ppm (equal to 73.5 mg/kg bw per day). The NOAEL for carcinogenicity was 150 ppm (equal to 36.3 mg/kg bw per day), based on an increase in the incidence of hepatocellular adenomas in females at 300 ppm (equal to 73.5 mg/kg bw per day).

In a 104-week combined chronic toxicity and carcinogenicity study in rats, ethiprole was administered in the diet at 0, 5, 20, 75 or 250 ppm (equal to 0, 0.22, 0.85, 3.21 and 10.8 mg/kg bw per day for males and 0, 0.29, 1.17, 4.40 and 14.7 mg/kg bw per day for females, respectively). The NOAEL for toxicity was 20 ppm (equal to 0.85 mg/kg bw per day), based on effects in the thyroid and/or liver (histopathological changes, increased organ weights and/or altered thyroid hormone or bilirubin levels) at 75 ppm (equal to 3.21 mg/kg bw per day). At 250 ppm (equal to 14.7 mg/kg bw per day), increased incidences of tumours (subcutaneous lipoma in males, hepatocellular adenoma in males and thyroid adenoma in males and females) were noted, and the slight increase in ovary sex cord tumours was considered equivocal. The NOAEL for carcinogenicity was 75 ppm (equal to 3.21 mg/kg bw per day).

The Meeting concluded that ethiprole is carcinogenic in mice and rats.

Ethiprole 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 ethiprole 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, the Meeting concluded that ethiprole is unlikely to pose a carcinogenic risk to humans via exposure from the diet.

In a two-generation reproductive toxicity study, ethiprole was administered to rats in the diet at a concentration of 0, 10, 75 or 500 ppm (equal to 0, 0.66, 4.8 and 32 mg/kg bw per day for males and 0, 0.78, 5.8 and 37 mg/kg bw per day for females, respectively, based on the 10-week pre-mating feed intake in F<sub>0</sub>-generation animals). The NOAEL for parental toxicity was 75 ppm (equal to 4.8 mg/kg bw per day), based on decreased body weight and body weight gain and effects on liver and thyroid (histopathological effects and increased organ weights) at 500 ppm (equal to 32 mg/kg bw per day). The NOAEL for offspring toxicity was 75 ppm (equal to 4.8 mg/kg bw per day), based on reduced body weight with associated delays in acquisition of puberty at 500 ppm (equal to 32 mg/kg bw per day). The NOAEL for reproductive toxicity was 500 ppm (equal to 32 mg/kg bw per day), the highest dose tested.

In a developmental toxicity study in rats, ethiprole was administered by oral gavage at a dose of 0, 3, 10 or 30 mg/kg bw per day on days 6–20 of gestation. The NOAEL for maternal toxicity was 10 mg/kg bw per day, based on the slight decrease in body weight at gestation days 6–8, decreased feed consumption and liver effects at 30 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 10 mg/kg bw per day, based on the increased incidence of enlarged thymus and ossification delays in several bones at 30 mg/kg bw per day.

In a developmental toxicity study in rabbits, ethiprole was administered orally by gavage from gestation days 6 through 28 at a dose of 0, 0.25, 0.5, 2.0 or 4.0 mg/kg bw per day. The NOAEL for maternal toxicity was 0.5 mg/kg bw per day, based on excessive maternal toxicity (abortion, decreased body weight and reduced feed consumption) at 2.0 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 0.5 mg/kg bw per day, based on increased incidences of ossification delays in several bones (metacarpal, phalanges, pubis), enlarged fontanelles and the presence of 27 presacral vertebrae (variation) at 2.0 mg/kg bw per day.

The Meeting concluded that ethiprole is not teratogenic in rats or rabbits.

In an acute neurotoxicity study in rats, ethiprole was administered orally by gavage at a dose of 0, 100, 500 or 2000 mg/kg bw. No NOAEL was identified. The lowest-observed-adverse-effect level (LOAEL) was 100 mg/kg bw, the lowest dose tested, based on decreased landing foot splay (both sexes) and a lower level of activity compared with controls (females only) on the day of dosing only. There was no evidence of neuropathology after 14 days.

In a second acute neurotoxicity study in rats, ethiprole was administered orally by gavage at a dose of 0, 10, 25, 35 or 250 mg/kg bw. The NOAEL for acute neurotoxicity was 25 mg/kg bw, based on the lower level of arousal and a higher incidence of closure of the eyes at 35 mg/kg bw on the day of dosing only. There was no evidence of neuropathology after 14 days.

In a 90-day dietary neurotoxicity study, rats were fed ethiprole at a concentration of 0, 20, 100 or 400 ppm (equal to 0, 1.4, 7.2 and 28.7 mg/kg bw per day for males and 0, 1.7, 8.4 and 33.0 mg/kg bw per day for females, respectively). The NOAEL for systemic toxicity was 20 ppm (equal to 1.4 mg/kg bw per day), based on an increase in thyroid weight in males at 100 ppm (equal to 7.2 mg/kg bw per day). No signs of neurotoxicity were observed at 400 ppm (equal to 28.7 mg/kg bw per day), the highest dose tested. There was no evidence of neuropathology at any dose.

The Meeting concluded that ethiprole induces transient neurobehavioural effects.

No studies on immunotoxic effects were submitted.

***Toxicological data on metabolites and/or degradates******RPA 112916 (plant and rat metabolite)***

The acute oral LD<sub>50</sub> for the amide metabolite of ethiprole (RPA 112916) in rats was greater than 5000 mg/kg bw. In a 28-day dietary toxicity study, rats were fed RPA 112916 at a concentration of 0, 50, 500, 5000 or 10 000 ppm (equal to 0, 5.2, 51.4, 515 and 983 mg/kg bw per day for males and 0, 5.2, 53.5, 512 and 993 mg/kg bw per day for females, respectively). The NOAEL was 50 ppm (equal to 5.2 mg/kg bw per day), based on increased thyroid stimulating hormone (TSH) and increased liver weight with associated histopathological changes at 500 ppm (equal to 51.4 mg/kg bw per day). RPA 112916 was not mutagenic in an Ames test.

RPA 112916 is found in bile of rats in low amounts (2–3% of total radioactive residues) and is structurally very similar to its parent compound.

These findings indicate that the toxicological profile of RPA 112916 is very similar to that of its parent, ethiprole. It is concluded that RPA 112916 is not more potent than ethiprole.

***RPA 097973 (plant metabolite)***

The acute oral LD<sub>50</sub> for the sulfone metabolite of ethiprole (RPA 097973) in rats was greater than 5000 mg/kg bw. RPA 097973 was not mutagenic in an Ames test.

RPA 097973 is found in urine at over 10% of the dose, and its toxicity is considered to be covered by the parent compound.

***N-Glucuronide of RPA 107566 (goat metabolite)***

The *N*-glucuronide of RPA 107566 is not found in the rat. RPA 107566 is a minor metabolite in rat, found in faeces at less than 5%. The acute oral LD<sub>50</sub> for RPA 107566 is greater than 2000 mg/kg bw, and RPA 107566 is negative in a screening Ames test. The *N*-glucuronide of RPA 107566 is expected to be less toxic than RPA 107566.

For chronic toxicity, the TTC approach (Cramer class III) could be applied to the *N*-glucuronide of RPA 107566.

***Human data***

In reports on manufacturing plant personnel, no adverse health effects were noted. No information on accidental or intentional poisoning in humans was identified.

The Meeting concluded that the existing database on ethiprole was adequate to characterise 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, based on the NOAEL of 0.5 mg/kg bw per day for maternal (abortion, decreased body weight and reduced feed consumption) and embryo/fetal toxicity (ossification delays in several bones, enlarged fontanelles and the presence of 27 presacral vertebrae) in the developmental toxicity study in rabbits and using a safety factor of 100. The margin between the upper bound of the ADI and the LOAEL for liver, thyroid and skin tumours in rats is approximately 2000.

The Meeting established an ARfD of 0.005 mg/kg bw, based on the NOAEL of 0.5 mg/kg bw per day for maternal toxicity (decreased body weight and reduced feed consumption) in the developmental toxicity study in rabbits and using a safety factor of 100.



The Meeting concluded that the metabolites ethiprole amide (RPA 112916) and ethiprole sulfone (RPA 097973) would be covered under the ADI and the ARfD for ethiprole.

A toxicological monograph was prepared.

**Levels relevant to risk assessment of ethiprole**

Species	Study	Effect	NOAEL	LOAEL
Mouse	Seventy-eight-week study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	150 ppm, equal to 36.3 mg/kg bw per day	300 ppm, equal to 73.5 mg/kg bw per day
		Carcinogenicity	150 ppm, equal to 36.3 mg/kg bw per day	300 ppm, equal to 73.5 mg/kg bw per day
Rat	Acute neurotoxicity study <sup>b</sup>	Neurotoxicity	25 mg/kg bw	35 mg/kg bw
	Two-year studies of toxicity and carcinogenicity <sup>a,c</sup>	Toxicity	20 ppm, equal to 0.85 mg/kg bw per day	75 ppm, equal to 3.21 mg/kg bw per day
		Carcinogenicity	75 ppm, equal to 3.21 mg/kg bw per day	250 ppm, equal to 10.8 mg/kg bw per day
	Two-generation study of reproductive toxicity <sup>a</sup>	Reproductive toxicity	500 ppm, equal to 32 mg/kg bw per day <sup>d</sup>	–
		Parental toxicity	75 ppm, equal to 4.8 mg/kg bw per day	500 ppm, equal to 32 mg/kg bw per day
		Offspring toxicity	75 ppm, equal to 4.8 mg/kg bw per day	500 ppm, equal to 32 mg/kg bw per day
	Developmental toxicity study <sup>b</sup>	Maternal toxicity	10 mg/kg bw per day	30 mg/kg bw per day
		Embryo and fetal toxicity	10 mg/kg bw per day	30 mg/kg bw per day
Rabbit	Developmental toxicity study <sup>b</sup>	Maternal toxicity	0.5 mg/kg bw per day	2.0 mg/kg bw per day
		Embryo and fetal toxicity	0.5 mg/kg bw per day	2.0 mg/kg bw per day
Dog	Thirteen-week and 1-year studies of toxicity <sup>a,d</sup>	Toxicity	30 ppm, equal to 1.0 mg/kg bw per day	90 ppm, equal to 2.51 mg/kg bw per day

<sup>a</sup> Dietary administration.

<sup>b</sup> Gavage administration.

<sup>c</sup> Two or more studies combined.

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

*Acceptable daily intake (ADI) (applies to ethiprole, ethiprole-amide and ethiprole-sulfone, expressed as ethiprole)*

0–0.005 mg/kg bw

*Acute reference dose (ARfD) (applies to ethiprole, ethiprole-amide and ethiprole-sulfone, expressed as ethiprole)*

0.005 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 ethiprole***

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

Rate and extent of oral absorption	Rapid; extensive (>80%) at 5 mg/kg bw; low (~10%) at 1 000 mg/kg bw
Dermal absorption	No data
Distribution	Highest residues in liver and kidney
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Largely complete within 48 hours, primarily in bile and faeces
Metabolism in animals	Extensive, independent of sex, dose and length of dosing; hydrolysis of nitrile group, reduction of sulfoxide group, oxidation of sulfoxide group
Toxicologically significant compounds in animals and plants	Ethiprole

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#### *Acute toxicity*

Rat, LD <sub>50</sub> , oral	>7 080 mg/kg bw
Rat, LD <sub>50</sub> , dermal	No data
Rat, LC <sub>50</sub> , inhalation	No data
Rabbit, dermal irritation	No data
Rabbit, ocular irritation	No data
Guinea-pig, dermal sensitization	No data

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

Target/critical effect	Body weight gain
Lowest relevant oral NOAEL	1.0 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEC	No data

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#### *Long-term studies of toxicity and carcinogenicity*

Target/critical effect	Thyroid and liver
Lowest relevant NOAEL	0.85 mg/kg bw per day (rat)
Carcinogenicity	Carcinogenic in mice and rats <sup>a</sup>
<i>Genotoxicity</i>	
	No evidence of genotoxicity in vitro or in vivo <sup>a</sup>
<i>Reproductive toxicity</i>	
Target/critical effect	Body weight, liver, thyroid
Lowest relevant parental NOAEL	4.8 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	4.8 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	32 mg/kg bw per day (rat)
<i>Developmental toxicity</i>	
Target/critical effect	Abortion, body weight, feed consumption, ossification delays, several skeletal variations
Lowest relevant maternal NOAEL	0.5 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	0.5 mg/kg bw per day (rabbit)
<i>Neurotoxicity</i>	
Acute neurotoxicity NOAEL	25 mg/kg bw
Subchronic neurotoxicity NOAEL	28.7 mg/kg bw per day, highest dose tested
Developmental neurotoxicity NOAEL	No data
<i>Other toxicological studies</i>	
Immunotoxicity	No data
<i>Studies on toxicologically relevant metabolites</i>	
RPA 112916	Acute oral LD <sub>50</sub> : >5 000 mg/kg bw (rat) 28-day dietary toxicity NOAEL: 5.2 mg/kg bw per day (rat) Ames: Not mutagenic
RPA 097973	Acute oral LD <sub>50</sub> : >5 000 mg/kg bw (rat) Ames: Not mutagenic
<i>Human data</i>	
	No adverse effects in manufacturing personnel

<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>	Developmental toxicity study in rabbits	100
ARfD	0.005 mg/kg bw <sup>a</sup>	Developmental toxicity study in rabbits	100

<sup>a</sup> Applies to ethiprole, ethiprole-amide and ethiprole-sulfone, expressed as ethiprole.

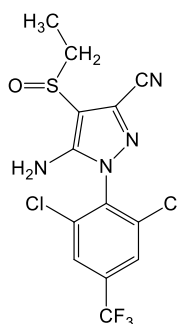
### RESIDUE AND ANALYTICAL ASPECTS

Ethiprole is an insecticide belonging to the chemical class of phenylpyrazoles. Ethiprole acts by interfering with the passage of chloride ions through the  $\gamma$ -aminobutyric acid GABA regulated chloride channel, thereby disrupting an insect's central nervous system activity and causing death.

It was scheduled for evaluation as a new compound by the 2018 JMPR at the Forty-ninth Session of the CCPR (2017).

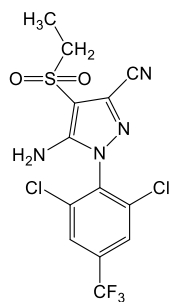
The manufacturer supplied information on identity, metabolism and environmental fate, methods of residue analysis, freezer storage stability, registered use patterns, supervised residue trials, fate of residues in processing and farm animal feeding studies.

The IUPAC name is 5-Amino-1-(2,6-dichloro- $\alpha,\alpha,\alpha$ -trifluoro-p-tolyl)-4-ethylsulfinylpyrazole-3-carbonitrile.

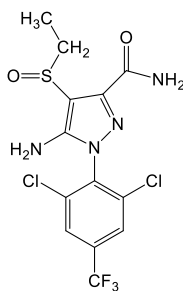


Ethiprole

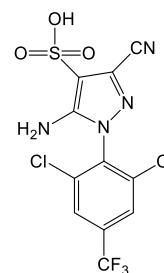
The structures of the key metabolites discussed are shown below:



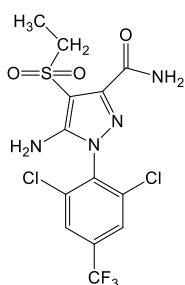
ethiprole-sulfone  
(097973)



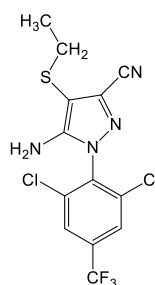
(RPA ethiprole-amide  
122916)



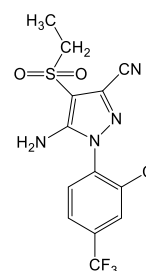
ethiprole-sulfonic acid  
(RPA 104615)



ethiprole-sulfone-amide

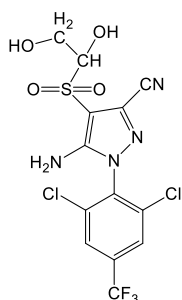


ethiprole-sulfide

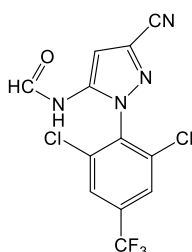


ethiprole-deschloro-sulfone

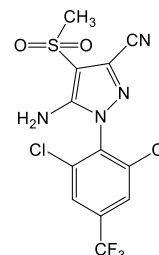
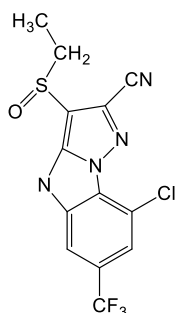
(RPA 112917)

ethiprole-dihydroxy-sulfone  
(dihydroxy-RPA 097973)

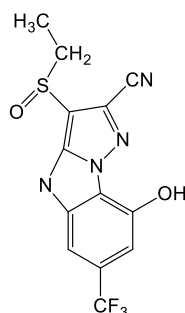
(RPA 107566)

ethiprole-formamide  
103343)

(RPA 115369)

ethiprole-methyl-sulfone  
(RPA 094569)

RPA 157925



AE 0764815

### Physical and chemical properties of ethiprole

Ethiprole 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 2.9 at 20 °C, suggesting that the parent has the potential to partition into fat. Ethiprole was shown to be hydrolytically stable at pH 4, 5 and 7, but slowly degrades at pH 9, with ethiprole-amide the only detected hydrolysis product. Ethiprole is photolytically unstable in aqueous media.

### Plant metabolism

Ethiprole metabolism in primary crops was investigated following either foliar applications (rice, sweet pepper and cotton), or by soil application (rice) using  $^{14}\text{C}$ -ethiprole labelled on the phenyl moiety.

Two different methods of application to rice were described. In one, the metabolism of  $^{14}\text{C}$ -ethiprole was investigated following foliar application of ethiprole to greenhouse grown rice at a total seasonal rate of 670 g ai/ha. Separate rice plants were treated at 5× that rate. The first application was made 25 days prior to crop maturity, with the second application 11 days later, 14 days prior to harvest. In another study, soil application of ethiprole was performed, in order to simulate application of a granule formulation to water in paddy rice.  $^{14}\text{C}$ -ethiprole was applied twice by soil drench applications to paddy rice at 600g ai/ha at BBCH 65 (= full flowering) and BBCH 69–89 (= between milk stage and ripening). Harvest was 30 days after the last application.

TRRs from foliar application were 6.3 mg eq/kg for rice straw, 2.1 mg eq/kg for rice grain, 0.15 mg eq/kg for brown rice and 4.0 mg eq/kg for rice hulls, TRRs from soil application were 24.0 mg eq/kg for rice straw, 5.7 mg eq/kg for rice husks and 0.28 mg eq/kg for hulled rice grain.

Acetonitrile and water extraction of rice, resulted in extraction efficiencies of 87–113% for rice straw, 85–100% for paddy rice grain and hulled (brown) rice grain and 62–100% for rice hulls/husks.

The main compound was parent in all rice matrices [67–75% of the TRR for foliar application (0.10–4.7 mg eq/kg) and 42–62% of the TRR for soil application (0.18–10.1 mg eq/kg)]. The major metabolite was ethiprole-sulfone which was found at significant levels in all matrices [20–35% TRR for foliar application (0.03–2.2 mg eq/kg) and 18–23% TRR for soil application (0.051–5.6 mg eq/kg)]. Ethiprole-amide was observed at 11% TRR in rice straw from soil application, while it was observed in husks and brown rice grain at 8% TRR. It was present in rice matrices after foliar application at < 1% TRR. No other metabolites were present at > 5% TRR in any rice matrices.

The metabolism of  $^{14}\text{C}$ -ethiprole in greenhouse sweet peppers was investigated following foliar application at a total seasonal rate of 670 g ai/ha. The two applications (450 and 220 g ai/ha) were made 26 and 14 days prior to harvest. In addition separate fruit were treated at 5× this seasonal rate. Plant samples treated at the 1× rate were collected 2–4 hours after the first application (foliage only), prior to the second application (fruit and foliage), 2–4 hours after the second application (fruit and foliage), and at final harvest (fruit and foliage). Samples treated at the 5× rate were collected only at final harvest.

TRRs in foliage were 184 mg eq/kg after the first application, 36.0 mg eq/kg before the second application, 118 mg eq/kg after the second application, and 44.6 mg eq/kg at harvest for the 1× application. TRRs were 0.45–0.68 mg eq/kg in green pepper fruit and 0.31–0.55 mg eq/kg in red peppers for the 1× application.

Acetonitrile and water extraction resulted in extraction efficiencies of 77–100% for pepper foliage and 85–101% for green and red pepper fruit.

Ethiprole accounted for the majority of the TRR in the foliage (83–99% TRR, 30.8–171 mg eq/kg) at each time point (after the first application, before and after the second application and at harvest) for the 1× application. More extensive metabolism was observed in sweet peppers, with ethiprole present at 22–92% TRR. In green (immature) peppers, ethiprole-amide and ethiprole-sulfone were both present at levels >10% TRR. Ethiprole-amide and ethiprole-sulfone were observed at up to 15% TRR and 13% TRR, respectively at harvest after two applications. Ethiprole-amide was also observed at 18% TRR after application of 1 spray at 220 g ai/ha to new fruit formed after the first treatment. In red (mature) fruits, ethiprole-sulfone accounted for up to 16% TRR with ethiprole-amide observed at 5% TRR. No other metabolites were present at >4% TRR in either foliage or fruit.

The metabolism of  $^{14}\text{C}$ -ethiprole in field grown cotton was investigated following two foliar applications at a total seasonal rate of 670 g a.i./ha. The first application, representing two-thirds of the seasonal rate, was made 61 days prior to harvest and the second application was made 48 days prior to harvest. Further cotton plants were treated at 10× that seasonal use rate (*i.e.* two applications for a total of 6.7 kg a.i./ha). Plant samples were collected just before the second application [foliage [TRR = 55 (1×)–348 (10×) mg eq/kg], old [TRR = 15.9 (1×)–256 (10×) mg eq/kg] and new growth [TRR = 5.0 (1×)–136 (10×) mg eq/kg], after the second application [foliage, TRR = 46.7 (1×)–484 (10×) mg eq/kg] and at harvest 48 days after the second application [bolls and gin trash (TRR = 4.6 (1×)–60 (10×) mg eq/kg)]. The cotton bolls were ginned to yield lint [TRR = 0.12 (1×)–2.5 (10×) mg eq/kg] and seed [TRR = 0.07 (1×)–0.57 (10×) mg eq/kg].

Acetonitrile and water extraction resulted in extraction efficiencies of 85% for cotton foliage, 76% for cotton gin trash and 41–54% for cotton seed. Triton X-100 was added to release loosely bound residues followed by harsher techniques.

In cottonseed, ethiprole and the sulfone were identified at very low levels in the 1× and 10× samples (1–7% TRR,  $\leq 0.04$  mg eq/kg). Minor levels of ethiprole-deschloro-sulfone and ethiprole-formamide (1% TRR, 0.001 mg eq/kg) were observed in the 1× seed samples but not in the 10× samples. Ethiprole-sulfonic acid was only observed in the cottonseed 10× samples at a low level (< 3% TRR, 0.014 mg eq/kg)

Parent ethiprole (16–21% TRR, 0.74–3.3 mg eq/kg) and ethiprole-sulfone (15–26% TRR, 1.2–2.4 mg eq/kg) were the main residue components in foliage and gin trash. Minor levels of ethiprole-sulfonic acid, ethiprole-deschloro-sulfone and ethiprole-formamide were observed at < 10% TRR total in foliage and gin trash. A large number of unidentified polar and non-polar compounds were characterised in all matrices.

As photolysis studies in water indicate that significant photodegradation may occur, the Meeting discussed whether the metabolism studies conducted in a greenhouse (two rice studies and one pepper study) were representative for uses in the field. In all three studies, artificial light was supplied to mimic sunlight. In particular, the light spectrum used in the rice study carried out in a climatic chamber to simulate application of a granule formulation to water in paddy rice, was similar to that used in the photolysis studies. The Meeting therefore decided that the supplied metabolism studies were adequate to demonstrate metabolism under field and glasshouse conditions.

#### *Summary of plant metabolism*

The metabolism of ethiprole is comparable in all crops investigated. Most of the radioactivity was recovered in the organosoluble extraction, with the majority of this being identified as parent and ethiprole-sulfone. The metabolic pathway of ethiprole in plants proceeds *via* oxidation to the sulfone and hydrolysis to ethiprole-amide. Significant plant metabolites, including ethiprole-sulfone and ethiprole-amide were also observed in the rat metabolism studies.

#### *Environmental fate*

The Meeting received information on soil photolysis, the route and rate of aerobic metabolism (degradation) of ethiprole and ethiprole-sulfone, field dissipation, hydrolysis, phototransformation in sterile and natural water, phototransformation of ethiprole-sulfone and ethiprole-sulfide in sterile water, degradation in aerobic and anaerobic water sediment systems and fate in paddy soil under field conditions. Only those studies relevant to the current evaluation are reported here.

#### *Confined rotational crops*

A study was undertaken to investigate the metabolism of ethiprole in the representative crops lettuce, radish, wheat and sorghum from four consecutive rotations using [ $^{14}\text{C}$ ]-ethiprole sprayed onto the soil at a total seasonal rate of 740 g ai/ha. Lettuce and radish were each sown at 30, 90, 150 and 365 days after the soil application, wheat at 30, 90 and 365 days and sorghum at 150 days after the soil application. Radish tops (TRRs = 0.026–0.23 mg eq/kg), radish roots (TRRs = 0.023–0.098 mg eq/kg), lettuce (TRRs = 0.032–0.29 mg eq/kg), sorghum straw (TRR = 0.30 mg eq/kg), sorghum grain (TRR = 0.027 mg eq/kg), wheat straw (TRRs = 0.20–0.76 mg eq/kg), and wheat grain (TRRs = 0.013–0.053 mg eq/kg) were harvested at maturity. Sorghum (0.058 mg eq/kg) and wheat forage (0.036–0.30 mg eq/kg) were collected approximately at half-maturity.

Acetonitrile and water extraction or acetonitrile/water/acetic acid extraction resulted in extraction efficiencies of 82–104% for lettuce, 77–100% for radish leaves, 52–69% for radish root, 65–88% for wheat/sorghum forage, 66–88% for wheat/sorghum straw and 61–86% in wheat/sorghum grain.

Parent ethiprole was extensively metabolised as it could be detected only at low levels in lettuce, radish and wheat forage of the first rotation (PBI 30 days) amounting to 5–19% TRR (0.015–0.043 mg/kg). At later PBIs, its residue level was < 0.01 mg/kg.

Ethiprole-sulfone was the main residue component in almost all crop commodities and all PBIs amounting to 36–57% TRR in lettuce (0.012–0.13 mg eq/kg), 14–31% TRR in radish leaves (0.004–0.071 mg eq/kg), 27–36% TRR in radish roots (0.007–0.036 mg eq/kg, except PBI 90 days), 34–46% of TRR in wheat/sorghum forage (0.016–0.10 mg eq/kg) and 18–54% of TRR in wheat/sorghum straw (0.082–0.17 mg eq/kg) but only 4–12% of TRR in wheat/sorghum grain ( $\leq$  0.004 mg eq/kg, not observed at PBI 365 days).

The main residue component in wheat and sorghum grain was ethiprole-sulfonic acid accounting for 8–40% of TRR at PBIs 30, 90 and 150 days (up to 0.016 mg eq/kg). It was also a significant metabolite in radish leaves (10–22% TRR, 0.005–0.023 mg eq/kg), radish roots (8–29% TRR, 0.002–0.013 mg eq/kg), wheat/sorghum forage (2–15% TRR, up to 0.016 mg eq/kg) and wheat/sorghum straw (5–17% TRR, 0.015–0.12 mg eq/kg). Ethiprole-sulfone amide was present in lettuce at 5–21% TRR (0.004–0.031 mg eq/kg), radish leaves at 4–15% TRR (up to 0.013 mg eq/kg), radish roots at 3–4% TRR (up to 0.002 mg eq/kg), wheat forage at 3–19% TRR (up to 0.026 mg eq/kg) and wheat/sorghum straw at 3–11% TRR (0.016–0.065 mg eq/kg).

#### *Hydrolysis*

Ethiprole was shown to be hydrolytically stable at pH 4, 5 and 7 over 31 days at 25 °C in the dark. Ethiprole degrades slowly at pH 9, with ethiprole-amide the only detected hydrolysis product. The  $DT_{50}$  is 121 days by extrapolation.

#### *Phototransformation in sterile water*

An aqueous phototransformation study showed ethiprole is quickly photodegraded in an aqueous medium. Its half-life ( $DT_{50}$ ) = 6.46 hours for irradiation under a Xenon lamp. Except for the benzimidazole of ethiprole (RPA 157925), all metabolites in the sterile water system were only tentatively identified.

#### *Phototransformation in natural water*

The aqueous phototransformation of ethiprole was studied in natural (pond) water collected from a pond system. The experimental photolytic  $DT_{50}$  of  $^{14}C$ -ethiprole was calculated to be 0.2 days. Up to 21 photodegradation products were formed. The major photolysis products, RPA 157925 and AE 0764815, rapidly degraded after reaching maxima after 8 hours and 1 day respectively.

#### *Phototransformation of ethiprole-sulfone and ethiprole-sulfide in natural water*

The photochemical breakdown of the ethiprole metabolites  $^{14}C$ -ethiprole-sulfone and  $^{14}C$ -ethiprole-sulfide was investigated in buffered aqueous solution (pH 5) during irradiation with artificial sunlight. The  $DT_{50}$  values for  $^{14}C$ -ethiprole-sulfone and  $^{14}C$ -ethiprole-sulfide were approximately 15 hours and 5 hours respectively.

#### *Degradation in water-sediment systems (aerobic and anaerobic conditions)*

The degradation of ethiprole was studied under aerobic conditions in water-sediment systems in the UK (two) and the USA (one). Under aerobic aquatic conditions, ethiprole is rapidly transferred from the water to the sediment where it is reduced *via* the sulfoxide group to one major metabolite ethiprole-sulfide, which is primarily present in the sediment together with minor amounts of ethiprole-sulfone.  $DT_{50}$  values for ethiprole were 4–14 days in water and 5–16 days in the total system. It was concluded that ethiprole is not



likely to persist in an aerobic aquatic environment.

The degradation of ethiprole was also studied in water-sediment systems under anaerobic conditions. Ethiprole was degraded to only one major product, ethiprole-sulfide. In water and the total system, ethiprole had a DT<sub>50</sub> value of 2 days. It was concluded that ethiprole is unlikely to persist in an anaerobic aquatic environment.

#### *Fate in paddy field under field conditions*

Four terrestrial rice field studies conducted in Japan indicated that ethiprole and the major metabolites ethiprole-sulfone and ethiprole-sulfide, potentially formed under the conditions of paddy rice growing, are not persistent. The degradation half-life of ethiprole and ethiprole-sulfide in paddy soil ranged from 2–4 and 30–63 days respectively under rice paddy field conditions. In the paddy water, the dissipation half-lives of ethiprole and its metabolites ethiprole-sulfone and ethiprole-sulfide did not exceed 5 days. Ethiprole benzimidazole and AE 0764815, were seen to dissipate quickly with DT<sub>50</sub> values of 2–5 days in water and 26 days (ethiprole benzimidazole) in paddy soil. Potential accumulation of ethiprole and its major metabolites ethiprole-sulfone and ethiprole-sulfide in paddy water and soil, following repeated application of ethiprole in successive seasons, can be excluded.

Based on the findings of the confined rotational study, the terrestrial rice field studies, and the other environmental fate studies, the Meeting concluded that the uptake of quantifiable residues of ethiprole and its associated metabolites in secondary crops is unlikely.

#### ***Animal metabolism***

The Meeting received animal metabolism studies with ethiprole in hens and goats. Evaluation of the metabolism studies in rats was carried out by the WHO Core Assessment Group.

##### *Goats*

A study on the metabolism of [phenyl-<sup>14</sup>C]ethiprole was conducted with two lactating goats orally dosed twice daily for 7 consecutive days at 14.2 ppm feed (high dose) or 1.2 ppm feed (low dose) of daily feed consumption. The goats were milked in the morning immediately prior to each administration, and then twice daily throughout the study period. Urine and faeces were collected during the day prior to the first dose and at 24 hour intervals thereafter. Each animal was sacrificed approximately 23 hours after the last dose and selected tissues collected.

The total recovery of radioactivity was 87% for both doses. The majority of the radioactivity was excreted with the faeces, accounting for 62–69% of the total dose, while excretion *via* urine accounted for 8–15%.

The radioactivity levels and concentrations measured in the milk ranged from 0.013 mg eq/kg at 8 hours after the first dose to the plateau level of 0.070 mg eq/kg at 152 hours for the high-dose level, and 0.002 mg eq/kg at 8 hours after the first dose to the plateau level of 0.009 mg eq/kg at 152 (and 168) hours for the low-dose level. The total recovery of radioactivity in milk at 175 hours post first dose, accounted for < 1% of the administered doses.

The highest TRR values in tissues were found in liver, renal fat and omental fat (0.612–0.685 mg eq/kg at the high dose and 0.081–0.094 mg eq/kg at the low dose). TRRs in muscle and kidney were 0.086–0.21 mg eq/kg for the high dose and 0.010–0.033 mg eq/kg for the low dose.

Extraction of residues with methanol at ambient temperature ranged from 88% of the TRR (liver) to 99% TRR (milk).

Ethiprole was extensively metabolised in the goat. Analysis of extracts from liver, kidney, muscle, renal and omental fat and milk showed ethiprole-sulfone to be the major residue component, representing 32–79% of TRR. Parent ethiprole was identified in kidney (4% TRR in high dose only), muscle (10–17% TRR), renal (9–17% TRR) and omental fat (10–15% TRR) and milk (18–29% TRR). A major metabolite in liver and kidney was thought to be ethiprole-sulfonic acid which co-chromatographed with the N-glucuronide of ethiprole-sulfide (total 13–26% TRR, 0.041–0.090 mg eq/kg high dose and 0.009–0.017 mg eq/kg low dose). All other identified metabolites in milk and tissues were present at <6% TRR.

#### *Laying hens*

A study on the metabolism of ethiprole in laying hens was conducted with the test compound <sup>14</sup>C-labelled in the phenyl position.

Two dose groups of five laying hens each were dosed orally once daily for 14 consecutive days at nominal levels of 10 ppm and 1 ppm of daily food consumption. The animals were sacrificed 23 hours after the last administration.

The total recovery of radioactivity was 94% for the high-dose group and 91% for the low-dose group. The majority of the administered dose was eliminated in the excreta, accounting for 91% and 88% of the total dose for the high and low-dose hen groups respectively. Low levels of radioactivity were detected in eggs in both dose groups, with the residues in egg white reaching a plateau level approximately 4 days after the first administration and in egg yolk 10 days after the first administration. The residue plateau in egg white and egg yolk accounted for approximately 0.22 and 3.7 mg eq/kg at the high dose and approximately 0.015 and 0.30 mg eq/kg at the low dose. A total of 2.2–2.3% of the dose was recovered in the eggs.

Highest tissue residues were observed in abdominal fat, liver and combined skin and fat (0.90–1.4 mg eq/kg at the high dose and 0.088–0.131 mg eq/kg at the low dose).

Extraction of residues with methanol ranged from 82% (liver and breast muscle) to 99% (abdominal fat).

Ethiprole-sulfone was the major residue component in tissues, representing 35–93% of TRR. Parent ethiprole was only identified at a very low level (2–3% of TRR) in muscle of the low-dose hens. As observed in the goat, ethiprole-sulfonic acid, which co-chromatographed with a N-glucuronide of ethiprole-sulfide, was observed in the liver at a total 11–12% TRR (0.014–0.14 mg eq/kg). All other identified metabolites in tissues were observed at < 7% TRR.

Egg yolk samples contained predominantly the sulfone metabolite (49–72% TRR). Parent ethiprole was present at 3–8% TRR as well as a number of minor metabolites, all of them accounting for < 6% of TRR. In egg whites, the main residue component was ethiprole-dihydroxy-sulfone (38–53% TRR, 0.006–0.009 mg eq/kg at the low-dose and 0.11–0.12 mg eq/kg at the high dose), followed by ethiprole-sulfone (12% TRR, high dose) and ethiprole-amide (19% TRR, low dose). All other identified metabolites in egg whites were observed at < 8% TRR.

#### *Summary of animal metabolism*

In rats, laying hens and lactating goats the majority of the administered dose is rapidly excreted. Ethiprole was extensively metabolised in each, and proceeds *via* oxidation, reduction, and hydrolysis followed by additional metabolism pathways such as conjugation. Most of the major metabolites identified in goat and hen metabolism studies were also observed in the rat.

### ***Methods of analysis***

The Meeting received information on LC-MS/MS analytical methods suitable for the determination of residues of parent, ethiprole-sulfone, ethiprole-deschloro-sulfone, ethiprole-amide, ethiprole-sulfide and ethiprole-formamide in plant matrices. LOQs for plant commodities are generally 0.001–0.002 mg/kg (up to 0.02 mg/kg). No extraction efficiency study was submitted for plant matrices, but the solvent system used for extraction is acetonitrile/water, as was used in the metabolism studies, and is acceptable.

LC-MS/MS and GC/ECD analytical methods are available for the determination of residues of parent, ethiprole-sulfone, ethiprole-methyl sulfone, ethiprole-deschloro-sulfone, ethiprole-sulfonic acid and ethiprole-sulfide in animal matrices. LOQs for animal commodities range from 0.001–0.2 mg/kg. Methods involve extraction with methanol or acetonitrile/water. One method involved an oxidation step, converting the parent to sulfone. Satisfactory extraction efficiencies were obtained for ethiprole, ethiprole-sulfone and ethiprole-sulfide in animal commodities using Method 01431, which was used in the feeding studies.

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

The Meeting received information on the freezer storage stability of ethiprole, ethiprole-sulfone and ethiprole-amide in plant commodities. The residues are stable for at least 24 months in sugarcane stalks (high water), citrus fruit (high acid), soya bean seeds (high oil content), dry bean seed (high protein) and wheat grain (high starch content) matrices, when stored frozen at approximately -18 °C.

Additional storage stability data showed that residues of ethiprole and ethiprole-sulfone are stable frozen for at least 12 months in rice grain and tea leaves (-23 °C), while ethiprole, ethiprole-sulfone, ethiprole-amide and ethiprole-deschloro-sulfone are stable under frozen storage for at least 12 months in cotton seed, gin trash, hulls, meal and oil and at least 16 months in orange fruit, juice, dry pulp and oil (≤ -10 °C). The storage periods in the storage stability studies cover the sample storage intervals in the residue trials.

All samples in the ethiprole dairy cow and laying hen feeding studies were analysed within thirty days of collection. Therefore there was no necessity for freezer storage stability data.

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

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

Following application of ethiprole to crops, the parent compound and the sulfone were the major residues. Parent ethiprole was the major identified residue found in all rice commodities from foliar and soil application (42–75% TRR), in peppers (22–92% TRR), in cottonseed from 10× application (7% TRR) and in cotton foliage (21% TRR). Ethiprole-sulfone was found in rice grain and straw (18–35% TRR), peppers (4–16% TRR), and gin trash (26% TRR), and was the major residue detected in all matrices of all rotations in the confined rotation study, with the exception of radish leaves at 365 days, radish root at 90 days and wheat/sorghum grain.

With the exception of ethiprole-amide in green pepper fruit (15–18% TRR, 0.074–0.12 mg eq/kg) and in rice straw from soil application (11% TRR, 2.68 mg eq/kg), other metabolites were observed at less than 10% TRR or less than 0.01 mg eq/kg in primary crop metabolism studies.

Residues of ethiprole were consistently greater than the sulfone and much greater than the amide across all foods for human consumption in the metabolism studies. Similarly, parent was usually the dominant residue in the crop trials.

A suitable analytical method to determine parent compound in plant matrices is available.

The Meeting therefore considered that a residue definition of "*Ethiprole*" is appropriate for plant commodities for compliance with MRLs (enforcement).

In deciding if additional 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 those compounds.

Ethiprole-sulfone is found in plant metabolism and secondary crops studies and crop field trials at levels that are significant relative to the parent compound in most samples and is considered to have no greater toxicity than the parent ethiprole. The Meeting therefore considered that ethiprole-sulfone should be included for risk assessment.

Ethiprole-amide was observed in the pepper and rice plant metabolism studies. The amide was observed in the coffee field trials and in significant levels compared to parent, and has no greater toxicity than the parent. The Meeting decided that ethiprole-amide contributes significantly to the total exposure of ethiprole through the diet.

The Meeting therefore considered that a residue definition of "*Sum of ethiprole, ethiprole-amide and ethiprole-sulfone expressed as parent equivalents*" is appropriate for plant commodities for dietary risk assessment.

#### *Animal commodities*

Ethiprole was extensively metabolised in goat and poultry. Ethiprole-sulfone was observed as a major residue across all goat matrices (52–69% of TRR in milk, 59–66% of TRR in muscle, 76–79% of TRR in fat, 35–55% of TRR in liver, and 32–42% of TRR in kidney) and was observed in hen liver (35–54% TRR), hen muscle (58–77% TRR), hen fat (91–93% TRR), hen skin and fat (78–88% TRR), egg yolks (49–72% TRR) and egg whites (up to 12% TRR). Parent ethiprole was identified in goat muscle (10–17% TRR), fat (9–17% TRR), milk (18–29% TRR) and kidney (up to 4% TRR), and at levels <10% of TRR in hen muscle and eggs.

In the dairy cattle feeding study, residues of ethiprole above the LOQ were found in fat samples of the highest dose group while ethiprole-sulfone was present in muscle of the highest group, milk and kidney samples of the two highest dose groups, and in liver and fat samples from all dose groups. Residues of parent and ethiprole-sulfone were observed in cream samples. Ethiprole was found at 0.01 mg/kg in egg samples from the highest dose group of the laying hen feeding study, while ethiprole-sulfone was present above the LOQ in muscle of hens fed from the highest dose group and fat, liver and eggs of hens from the two highest dose groups.

A suitable analytical method to determine parent compound and ethiprole-sulfone in animal matrices is available.

The Meeting decided that a residue definition of the "*Sum of ethiprole and ethiprole-sulfone, expressed as ethiprole*", is a suitable marker for compliance in livestock commodities.

In addition to the residues for compliance, dietary exposure from consumption of livestock commodities may occur for ethiprole-sulfonic acid, the N-glucuronide of ethiprole-sulfide and ethiprole-dihydroxy-sulfone.

A fraction observed in both liver (13–18% of the TRR) and kidney (20–26% of the TRR) of goats, and in the liver (11–12% of the TRR) of hens, was thought to be due to ethiprole-sulfonic acid which co-chromatographed with the N-glucuronide of ethiprole-sulfide. The proportion of the two compounds was not determined in each matrix.

Since ethiprole-sulfonic acid was not observed in the lactating dairy cattle and laying hen feeding studies, it will not be included in the risk assessment definition for animal commodities.

The N-glucuronide of ethiprole-sulfide was detected in considerable amounts in liver and kidney. As no specific data were available on the toxicity of the metabolite the TTC approach was applied<sup>22</sup>. The estimated exposure based on potential animal commodities (0.3 µg/kg bw) was below the applicable threshold of toxicological concern. The Meeting concluded that dietary exposure to the N-glucuronide of ethiprole-sulfide from the uses considered by the current Meeting is unlikely to present a public health concern.

In egg white, the main residue component was ethiprole-dihydroxy-sulfone (38–53% TRR). The latter compound was not detected in any other matrix. Although not a rat metabolite, it was considered to be of no greater toxicity than the parent due to structural similarity. As the residue concentration observed in egg white, in comparison with the whole egg, are insignificant, the Meeting decided that the overall contribution to the dietary burden is negligible, so it will not be included in the definition for risk assessment.

No additional metabolites were observed in animal matrices at greater than 10% TRR.

It is therefore considered that a residue definition of “*Sum of ethiprole and ethiprole-sulfone, expressed as parent equivalents*” is appropriate for animal commodities for dietary risk assessment.

The log K<sub>ow</sub> of ethiprole (log K<sub>ow</sub> 2.9) suggests that parent ethiprole has the potential to partition into fat. The ratio of ethiprole + ethiprole-sulfone residues in muscle/fat and milk/cream in the dairy cattle feeding study and muscle/fat in the laying hen feeding study, and muscle/fat in the goat and hen metabolism studies, support the conclusion that the components of the compliance definition are fat-soluble.

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

Definition of the residue for dietary risk assessment for plant commodities: *sum of ethiprole, 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-(ethylsulfinyl)-1H-pyrazole-3-carboxamide (ethiprole-amide) and 5-amino-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-ethylsulfonylpyrazole-3-carbonitrile (ethiprole-sulfone), expressed as parent equivalents*.

Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: *sum of ethiprole and 5-amino-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-ethylsulfonylpyrazole-3-carbonitrile (ethiprole-sulfone), expressed as parent equivalents*.

The Meeting agreed that the residue be designated as fat-soluble.

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

Supervised trials were available for the use of ethiprole on rice and coffee.

Product labels were available from Brazil, India, Indonesia, Japan and Thailand for rice and Brazil, El Salvador, Guatemala and Honduras for coffee.

For dietary risk assessment the residues are expressed as the sum of ethiprole, ethiprole-amide and ethiprole-sulfone expressed as ethiprole (referred to as “total”).

### **Rice**

The Japanese GAPs were the critical GAPs for rice. None of the submitted trial data matched the Japanese

<sup>22</sup> See Toxicology section for further details

GAPs for rice, so these will not be referred to further.

GAP for ethiprole in Thailand is for foliar applications (number not indicated on the registered label) at 94 g ai/ ha with a 14-day PHI.

Twelve trials were conducted in China, India and Thailand approximating this GAP [four applications (three in one trial) were made at 91–110g ai/ha, with samples harvested 14 to 16 days after treatment]. Although the number of spray applications made in Thailand could be higher than four, it is considered that any applications made earlier in the crop cycle, i.e. further away from harvest, would not significantly increase the residues, noting the short half-life of ethiprole and ethiprole-sulfone in soil and water.

Although rice samples were not analysed for ethiprole-amide, one of the components of the residue definition, the Meeting considered this to be acceptable, as the results of the foliar rice metabolism study showed that significant residues of the amide, in comparison with parent and ethiprole-sulfone, are not expected.

Residues of ethiprole in rice grains from 12 supervised trials conducted in China, India and Thailand in ranked order were (n = 12): 0.11, 0.12, 0.14 (2), 0.17, 0.20, 0.31, 0.41, 0.42, 0.43 and 1.3 (2) mg/kg.

Total residues in ranked order were (n = 12): 0.18, 0.22, 0.25 (2), 0.30, 0.34, 0.53, 0.69, 0.76, 0.80, 1.6 and 1.7 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg and a STMR of 0.44 mg/kg for ethiprole in rice grain (paddy rice).

### *Coffee*

GAP for ethiprole in coffee in Brazil is 2 foliar applications at 500 g ai/ ha, with a 60-day PHI.

Ten residue trials were conducted according to established local practices in Brazil, Colombia, Costa Rica and Mexico according to the Brazilian GAP, giving residues of ethiprole in green coffee beans in ranked order of (n = 10): 0.004, 0.005, 0.006, 0.008, 0.013, 0.014, 0.016, 0.018, 0.022 and 0.044 mg/kg.

Total residues were in ranked order (n = 10): 0.011, 0.015 (2), 0.020, 0.024, 0.025, 0.029 (2), 0.043 and 0.060 mg/kg.

The Meeting estimated a maximum residue level of 0.07 mg/kg, and a STMR of 0.0245 mg/kg for ethiprole in coffee beans.

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

The Meeting received data which showed that ethiprole and ethiprole-sulfone were not degraded during the simulation of pasteurisation (pH 4, 90 °C, 20 minutes), and baking, boiling and brewing (pH 5, 100 °C, 60 minutes). Minor degradation was observed under the conditions of sterilisation (pH 6, 120 °C, 20 minutes) and infusing tea/cooking of rice (pH 7, 100 °C, 40 minutes). Ethiprole-amide (5–6%) and ethiprole-sulfone-amide (3–4%) were detected as minor degradation products of ethiprole and ethiprole-sulfone respectively, under those conditions. These residues are either addressed by the residue definition (ethiprole-amide) or considered to be minor (ethiprole-sulfone-amide).

The Meeting also received processing studies for rice and coffee. The table below summarises maximum residue levels calculated on the determined processing factors for parent and STMR-Ps calculated on the determined processing factors for parent ethiprole, ethiprole-amide and ethiprole-sulfone.

Processing Factors from the Processing of Raw Agricultural Commodities (RACs) with Field-Incurred

## Residues from Foliar Treatment with Ethiprole

RAC	Processed Commodity	Best Estimate Processing Factor (parent)	RAC Maximum residue level	Processed Commodity Maximum residue level	Best Estimate Processing Factor (parent + ethiprole-sulfone + ethiprole-amide) <sup>b</sup>	RAC STMR	Processed Commodity STMR-P
Rice <sup>a</sup>	Husked (brown) rice	0.36	3	1.5	0.32	0.44	0.14
	Polished rice	0.11		0.4	0.09		0.040
	Hulls	-		-	1.4		0.62
	Bran	-		-	1.2		0.53
Coffee	Roasted coffee	1.95	0.07	0.2	1.8	0.0245	0.044
	Instant coffee	-		-	1.95		0.048

<sup>a</sup> Cleaned paddy rice taken as the RAC. As previous experience of the JMPR shows this does not have a significant effect on observed residues, this is considered to be acceptable.

<sup>b</sup> The amide metabolite was not measured in rice as it was not found in significant amounts in the corresponding metabolism study.

**Residues in animal commodities***Estimated maximum and mean dietary burdens of farm animals*

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry. 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.

Potential cattle feed items include rice bran, rice grain and rice hulls. Potential poultry feed items include rice grain. The dietary burden was calculated from total residues of ethiprole, ethiprole-amide and ethiprole-sulfone.

## Summary of livestock dietary burden for ethiprole (ppm of dry matter diet)

	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.188	0.188	-	-	0.441 <sup>a</sup>	0.441 <sup>c</sup>	0.118	0.118
Dairy cattle	0.188	0.188	0.118	0.118	0.346 <sup>b</sup>	0.346 <sup>d</sup>	0.059	0.059
Poultry Broiler	0.159	0.159	0.059	0.059	0.368	0.368	0.029	0.029
Poultry Layer	0.159	0.159	0.029	0.029	0.368 <sup>e</sup>	0.368 <sup>f</sup>	0.118	0.118

<sup>a</sup> Highest maximum beef or dairy cattle dietary burden suitable for HR and maximum residue level estimates for mammalian tissues

<sup>b</sup> Highest maximum dairy cattle dietary burden suitable for HR and maximum residue level 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 mammalian milk

<sup>e</sup> Highest maximum poultry dietary burden suitable for HR and maximum residue level estimates for poultry tissues and eggs

<sup>f</sup> Highest maximum poultry dietary burden suitable for STMR estimates for poultry tissues and eggs

*Farm animal feeding studies*

The Meeting received a lactating dairy cow feeding study which provided information on residues of

ethiprole arising in tissues and milk when dairy cows were dosed for 28 days, at feeding levels equivalent to 0, 0.14, 0.41, 1.31 and 1.38 (depuration group) ppm ethiprole in the diet. Residues of parent, ethiprole-sulfone, ethiprole-sulfonic acid and ethiprole-sulfide were determined.

Total ethiprole (parent + ethiprole-sulfone) residues in milk from the 1.31 ppm feed group reached plateau levels within approximately 14 days of consecutive dosing and declined rapidly, from 0.042 mg/kg to < 0.01 mg/kg, at 15 days after cessation of dosing. The residue in milk was ethiprole-sulfone only, but residues of parent + ethiprole-sulfone did concentrate in cream.

Residues of ethiprole-sulfone were observed in fat and liver samples at every feeding level and in kidney and muscle samples at higher feeding levels and it was the dominant residue. Parent was only observed in fat samples at the highest feeding level. Residues of parent + ethiprole-sulfone in all tissues were <LOQ within 15 days of cessation of dosing.

The Meeting also received information on residues arising in tissues and eggs when laying hens were dosed with ethiprole for 28 days, at feeding levels equivalent to 0, 0.084, 0.50, 2.51 and 2.46 (depuration group) ppm in the diet. Residues of parent, ethiprole-sulfone, ethiprole-sulfonic acid and ethiprole-sulfide were determined.

Total ethiprole residues in eggs from the 2.51 ppm feed group reached plateau levels within approximately 14 days of consecutive dosing and declined rapidly, from approximately 0.16 mg/kg to < 0.02 mg/kg, at 15 days after cessation of dosing. Ethiprole-sulfone was again the dominant residue (residues up to 0.178 mg eq/kg) with residues of parent (maximum 0.01 mg/kg) observed in eggs at the highest feeding level only. Total residues in egg yolk were approximately 10× the residues in egg white.

Residues of parent were <LOQ in all tissue samples of all dose groups. Ethiprole-sulfone was observed at the highest feeding level in muscle and in the two highest feeding levels in fat and liver (residues up to 0.168 mg eq/kg). Residues of ethiprole-sulfone in all tissues were <LOQ within 5 days of cessation of dosing.

No quantifiable residues of ethiprole-sulfonic acid were observed in any milk, cream or skimmed milk or tissue (subcutaneous, mesenteric and perirenal fat, muscle, liver and kidney) samples at any feeding level in the dairy cattle transfer study or in any eggs, muscle, fat and liver samples at any feeding level in the laying hen transfer study.

No quantifiable residues of ethiprole-sulfide were observed in milk or tissues in the dairy cattle study or in any eggs or tissues samples in the laying hen transfer study. Residues were observed in cream (0.007 mg eq/kg) after feeding at the 1.38 ppm feeding level.

#### *Animal commodity maximum residue levels*

##### *Cattle- STMR, HR and maximum residue levels*

For highest residue level estimation, the high residues in the cattle tissues were calculated by interpolating the maximum dietary burden for beef cattle (0.441 ppm) between the relevant feeding levels (0.41 and 1.31 ppm) in the dairy cow feeding study and using the highest tissue concentrations from individual animals within those feeding groups. For highest residue level estimation, the high residues in the cattle milk were calculated by interpolating the maximum dietary burden for dairy cattle (0.346 ppm) between the relevant feeding levels (0.14 and 0.41 ppm) in the dairy cow feeding study and using the highest mean milk concentrations from those feeding groups.

The STMR values for the tissues were calculated by interpolating the mean dietary burden for beef cattle (0.441 ppm) with the 0.41 and 1.31 ppm feeding levels from the dairy cow feeding study and using the mean tissue concentrations from those feeding groups. The STMR values for the milk were calculated



by interpolating the mean dietary burden for dairy cattle (0.346 ppm) with the 0.14 and 0.41 ppm feeding levels from the dairy cow feeding study and using the mean milk concentrations from those feeding groups.

Ethiprole 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 <sup>a</sup>
HR Determination (beef or dairy cattle)							
Feeding Study	0.14 0.41	< 0.01 0.0129	0.41 1.31	< 0.02 0.046	0.0726 0.252	0.0282 0.089	0.0907 0.459
Dietary burden and estimate of highest residue	0.346	0.012	0.441	0.021	0.079	0.030	0.10
STMR Determination (beef or dairy cattle)							
Feeding Study	0.14 0.41	< 0.01 0.0112	0.41 1.31	< 0.02 0.041	0.0701 0.228	0.0274 0.080	0.0852 0.331
Dietary burden and estimate of STMR	0.346	0.011	0.441	0.021	0.076	0.029	0.094

<sup>a</sup> Mesenteric fat

The Meeting estimated the following STMR values: milk 0.011 mg/kg; muscle 0.021 mg/kg; edible offal (based on liver) 0.076 mg/kg, kidney 0.029 mg/kg and fat 0.094 mg/kg.

The Meeting estimated the following HR values: muscle 0.021 mg/kg; edible offal (based on liver) 0.079 mg/kg, kidney 0.030 mg/kg and fat 0.10 mg/kg.

The Meeting estimated the following maximum residue levels: milk 0.015 mg/kg; meat (mammalian except marine mammals) 0.15 mg/kg (fat), edible offal (based on liver) 0.1 mg/kg and mammalian fats (except milk fats) 0.15 mg/kg.

In the Day 30 sample the mean residues observed in cream were 12.2 times the residues in milk. It is therefore calculated that the estimated STMR in cream will be 0.13 mg/kg. It is assumed that cream is 40% fat, therefore the Meeting estimated a maximum residue level for milk fats of 0.5 mg/kg.

#### *Poultry- STMR, HR and maximum residue levels*

For highest residue level estimation, the high residues in the hen tissues and eggs were calculated by interpolating the maximum dietary burden (0.368 ppm) with the 0.084 and 0.50 ppm feeding levels in the laying hen feeding study and using the highest tissue concentrations from individual animals within that feeding group and using the highest mean egg concentration from those feeding groups.

The STMR values for the tissues and eggs were calculated by interpolating the mean dietary burden (0.368 ppm) with the 0.084 and 0.50 ppm feeding levels from the poultry feeding study and using the mean tissue and egg concentrations from those feeding groups.

Ethiprole Feeding Study	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)						
Feeding Study	0.084	< 0.02	0.084	< 0.02	< 0.02	< 0.02
	0.50	0.0470	0.50	< 0.02	0.0390	0.048
Dietary burden and estimate of highest residue	0.368	0.038	0.368	< 0.02	0.033	0.039
STMR Determination (poultry broiler or layer)						
Feeding Study	0.084	< 0.02	0.084	< 0.02	< 0.02	< 0.02
	0.50	0.0342	0.50	< 0.02	0.0360	0.0447
Dietary burden and estimate of STMR	0.368	0.030	0.368	< 0.02	0.031	0.037

The Meeting estimated the following STMR values: egg 0.030 mg/kg; muscle 0.02 mg/kg; edible offal (based on liver) 0.031 mg/kg and fat 0.037 mg/kg.

The Meeting estimated the following HR values: egg 0.038 mg/kg; muscle 0.02 mg/kg; edible offal (based on liver) 0.033 mg/kg and fat 0.039 mg/kg.

The Meeting estimated the following maximum residue levels: eggs 0.05 mg/kg; poultry fats 0.05 mg/kg; poultry meat 0.05 mg/kg (fat) and poultry edible offal (based on liver) 0.05 mg/kg.

## 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.

The Meeting recommended the following residue definitions for ethiprole:

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

Definition of the residue for dietary risk assessment for plant commodities: *sum of ethiprole, 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-(ethylsulfinyl)-1H-pyrazole-3-carboxamide (ethiprole-amide) and 5-amino-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-ethylsulfonylpyrazole-3-carbonitrile (ethiprole-sulfone), expressed as parent equivalents.*

Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: *sum of ethiprole and 5-amino-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-ethylsulfonylpyrazole-3-carbonitrile (ethiprole-sulfone), expressed as parent equivalents.*

The Meeting considers the residue to be fat-soluble.

## DIETARY RISK ASSESSMENT

### Long-term dietary exposure

The ADI for ethiprole is 0–0.005 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for ethiprole 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 2018 JMPR Report. The IEDIs ranged from

1–6% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of ethiprole from uses considered by the JMPR is unlikely to present a public health concern.

***Acute dietary exposure***

The ARfD for ethiprole is 0.005 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for ethiprole 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 2018 JMPR Report. The IESTIs varied from 0–80% of the ARfD for children and 0–40% for the general population.

The Meeting concluded that acute dietary exposure to residues of ethiprole from uses considered by the present Meeting is unlikely to present a public health concern



## 5.8 FENPICOXAMID (305)

### TOXICOLOGY

Fenpicoxamid is the ISO-approved common name for [2-[[[(3*R*,7*R*,8*R*,9*S*)-7-benzyl-9-methyl-8-(2-methylpropanoyloxy)-2,6-dioxo-1,5-dioxonan-3-yl]carbamoyl]-4-methoxypyridin-3-yl]oxymethyl 2-methylpropanoate, with the CAS number 517875-34-2.

Fenpicoxamid is a foliar fungicide whose mode of action is by the inhibition of mitochondrial complex III to disrupt spore germination and germ tube elongation.

Fenpicoxamid 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 metabolism studies conducted in rats using fenpicoxamid labelled with  $^{14}\text{C}$  at the phenyl-UL (uniformly labelled) and 2-pyrimidine positions, the absorption of fenpicoxamid was rapid ( $T_{\max}$  2–4 hours), but low (5–20%). Values for the area under the plasma concentration–time curve from 0 to 48 hours ( $\text{AUC}_{0-48\text{ h}}$  values) ranged from 13 to 24  $\mu\text{g}\cdot\text{h/g}$  at the low dose (10 mg/kg bw) and from 73 to 74  $\mu\text{g}\cdot\text{h/g}$  at the high dose (300 mg/kg bw), indicating a lack of dose proportionality. Elimination was rapid (58–90% of the administered dose within 24 hours) and predominately via the faeces. Biliary excretion of radiolabel was higher than urinary excretion and accounted for only a small fraction of the faecal excretion. Absorbed fenpicoxamid was completely metabolized, with no parent found in the urine. A significant portion of radioactivity was found bound within the faeces (~56% at the single low dose and ~34% at the single high dose), which may account for the lack of absorption. However, following repeated exposure, the portion bound in the faeces was reduced to approximately 14%, suggesting saturation of the binding sites in faecal material.

Tissue distribution was measured at the maximum concentration ( $C_{\max}$ ) and  $\frac{1}{2}C_{\max}$  (2 and 6 hours post-dosing, respectively). At those time points, the highest concentrations of radioactivity were in the gastrointestinal tract, urinary bladder, kidneys and liver. One hundred and sixty-eight hours following dosing, concentrations of radioactivity in all tissues were at or below 0.01% of the administered dose.

The principal routes of metabolism of fenpicoxamid involved hydrolysis of various ester groups, as well as *O*-dealkylation of the hydroxymethoxy side-chain of the pyridine ring. The primary metabolites were X12326349 and X696872; however, X12326349 also occurs as an impurity.

Toxicokinetics were determined in all the short- and long-term studies of toxicity referenced below under “Toxicological data”. Overall, there was a low internal exposure to fenpicoxamid, as evidenced by low levels of parent compound and major metabolites in the urine and blood samples; saturation of absorption led to small increases in internal dose, even with large increases in the administered dose. Therefore, a proportionate dose–response relationship would not be expected.

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

In rats, fenpicoxamid had an acute oral  $\text{LD}_{50}$  greater than 2000 mg/kg bw, an acute dermal  $\text{LD}_{50}$  greater than 5000 mg/kg bw and an acute inhalation median lethal concentration ( $\text{LC}_{50}$ ) greater than 0.53 mg/L.

Fenpicoxamid was non-irritating to the skin and minimally irritating to the eyes of rabbits. It was not a dermal sensitizer in mice. Fenpicoxamid did not cause phototoxicity in vitro.

The main toxic effects of fenpicoxamid in short- and long-term studies were liver changes, including adenomas and carcinomas, in the mouse; liver and thyroid changes in the rat; and body weight effects and liver changes in the dog.

In a 90-day study, mice received a dietary concentration of fenpicoxamid of 0, 300, 1500, 3000 or 6000/9000 ppm (males, increased at day 57) or 6000 ppm (females) (equal to 0, 40, 192, 399 and 921 mg/kg bw per day for males and 0, 49, 303, 566 and 1107 mg/kg bw per day for females, respectively), with recovery groups of 0 and 3000 ppm. The NOAEL was 300 ppm (equal to 40 mg/kg bw per day), based on increased liver weights and hepatocellular hypertrophy in males and females, decreased serum triglycerides, hepatocyte fatty change and multifocal single-cell necrosis in males and decreased serum albumin in females at 1500 ppm (equal to 192 mg/kg bw per day).

In a 29-day study in which rats received a dietary concentration of fenpicoxamid of 0, 2300, 4500 or 9000 ppm (equal to 0, 196, 395 and 788 mg/kg bw per day for males and 0, 197, 377 and 764 mg/kg bw per day for females, respectively), the NOAEL was 9000 ppm (equal to 764 mg/kg bw per day), the highest dose tested.

In a 90-day study in which rats received a dietary concentration of fenpicoxamid of 0, 3000, 6000 or 11 500/14 000 ppm (dose increased at day 71; equal to 0, 180, 365 and 732 mg/kg bw per day for males and 0, 205, 413 and 834 mg/kg bw per day for females, respectively), the NOAEL was 11 500/14 000 ppm (equal to 732 mg/kg bw per day), the highest dose tested.

In a 90-day study in which dogs received a dietary concentration of fenpicoxamid of 0, 3000, 10 000 or 30 000 ppm (equal to 0, 100, 408 and 939 mg/kg bw per day for males and 0, 122, 353 and 1115 mg/kg bw per day for females, respectively), the NOAEL was 30 000 ppm (equal to 939 mg/kg bw per day), the highest dose tested.

In a 1-year study in which dogs received a dietary concentration of fenpicoxamid of 0, 3000, 10 000 or 30 000 ppm (equal to 0, 84, 300 and 981 mg/kg bw per day for males and 0, 80, 273 and 1011 mg/kg bw per day for females, respectively), the NOAEL was 3000 ppm (equal to 80 mg/kg bw per day), based on an increased incidence of thin appearance and increased total bilirubin in males and females and decreased body weight and increased liver changes in males at 10 000 ppm (equal to 273 mg/kg bw per day).

In an 18-month toxicity study in which mice received a dietary concentration of fenpicoxamid of 0, 50, 300 or 1500/3000 ppm (equal to 0, 5.3, 32 and 156 mg/kg bw per day for males and 0, 6.8, 40 and 388 mg/kg bw per day for females, respectively), the NOAEL for toxicity was 50 ppm (equal to 5.3 mg/kg bw per day), based on altered liver metabolism and increased hepatocellular hypertrophy in males at 300 ppm (equal to 32 mg/kg bw per day). The NOAEL for carcinogenicity was 50 ppm (equal to 5.3 mg/kg bw per day), based on an equivocal increase in the incidence of liver adenomas in males at 300 ppm (equal to 32 mg/kg bw per day).

In a 2-year toxicity study in which rats received a dietary concentration of fenpicoxamid adjusted to achieve intakes of 0, 101, 302 and 1009 mg/kg bw per day, a NOAEL for toxicity could not be identified, as increased thyroid weight, histopathological changes in the thyroid and increased blood iodide were observed at 101 mg/kg bw per day, the lowest dose tested. The NOAEL for carcinogenicity was 302 mg/kg bw per day, based on an increased incidence of ovarian adenocarcinomas at 1009 mg/kg bw per day.

The Meeting concluded that fenpicoxamid is carcinogenic in male mice and female rats, but not in female mice or male rats.

Fenpicoxamid was tested for genotoxicity in an adequate range of in vitro and in vivo assays. It was not mutagenic in bacterial or mammalian cells in vitro. It caused chromosomal aberrations in rat lymphocytes in vitro, but it gave negative results in vivo in a mouse micronucleus test and unscheduled DNA synthesis assay.

The Meeting concluded that fenpicoxamid is unlikely to be genotoxic in vivo.

As fenpicoxamid is unlikely to be genotoxic in vivo and there is a clear threshold for liver adenomas in male mice and ovarian adenocarcinomas in female rats, the Meeting concluded that fenpicoxamid is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation reproductive toxicity study in which rats received a dietary concentration of fenpicoxamid adjusted to provide achieved intakes of 0, 107, 322 and 1066 mg/kg bw per day for males and 0, 105, 315 and 1052 mg/kg bw per day for females, the NOAEL for parental toxicity, reproductive toxicity and offspring toxicity was 1052 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in which female rats received fenpicoxamid in the diet at a concentration of 0, 1350, 4050 or 13 500 ppm (equal to 0, 103, 311 and 1036 mg/kg bw per day, respectively) from gestational days 6 to 21, the NOAEL for maternal and embryo/fetal toxicity was 13 500 ppm (equal to 1036 mg/kg bw per day), the highest dose tested.

In a developmental toxicity study in which female rabbits received fenpicoxamid in the diet at a concentration of 0, 1500, 5000 or 15 000 ppm (equal to 0, 52.8, 177 and 495 mg/kg bw per day, respectively) from gestational days 7 to 28, the NOAEL for maternal toxicity was 1500 ppm (equal to 52.8 mg/kg bw per day), based on decreased body weight gain, feed consumption and faecal output at 5000 ppm (equal to 177 mg/kg bw per day). The NOAEL for embryo and fetal toxicity was 15 000 ppm (equal to 495 mg/kg bw per day), the highest dose tested.

No neurotoxicity or immunotoxicity studies were available, but there was no indication of neurotoxic or immunotoxic effects in the short- or long-term toxicity studies.

No information on the potential effects of fenpicoxamid on the microbiome of the human gastrointestinal tract is available.

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

The acute oral LD<sub>50</sub> of X642188, a rat and crop metabolite, was greater than 2000 mg/kg bw. X642188 was negative in the Ames test. For chronic toxicity, the TTC approach (Cramer class III) could be applied.

No toxicity information was available for any other metabolites and/or degradates. However, based on structure–activity considerations, the TTC approach (Cramer class III) could be applied to X12264475 (animal metabolite and processing product), X12314005 (crop metabolite and processing product) and X12335723 (processing product) for the assessment of chronic toxicity.

Insufficient information was available to evaluate the toxicological relevance of the metabolites X12326349 (animal metabolite), X696872 (animal metabolite) and X12019520 (simulated processing product).

#### ***Human data***

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

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

### Toxicological evaluation

The Meeting established an ADI of 0–0.05 mg/kg bw, on the basis of the NOAEL of 5.3 mg/kg bw per day from the 18-month mouse carcinogenicity study for liver changes and an equivocal increase in the incidence of adenomas at 32 mg/kg bw per day. A safety factor of 100 was applied. The Meeting noted that there was a margin of 600 between the upper bound of the ADI and the LOAEL for adenomas in mice and a margin of 2000 relative to the LOAEL (the lowest dose tested) for non-neoplastic effects on the thyroid in the 2-year study in rats.

The Meeting concluded that it was not necessary to establish an ARfD for fenpicoxamid in view of its low acute oral toxicity and the absence of any other toxicological effects, including developmental toxicity, that would be likely to be elicited by a single dose.

A toxicological monograph was prepared.

### Levels relevant to risk assessment of fenpicoxamid

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	50 ppm, equal to 5.3 mg/kg bw per day	300 ppm, equal to 32 mg/kg bw per day
		Carcinogenicity	50 ppm, equal to 5.3 mg/kg bw per day	300 ppm, equal to 32 mg/kg bw per day
Rat	Two-year study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	–	101 mg/kg bw per day <sup>b</sup>
		Carcinogenicity	302 mg/kg bw per day	1 009 mg/kg bw per day
	Two-generation study of reproductive toxicity <sup>a</sup>	Reproductive toxicity	1 052 mg/kg bw per day <sup>c</sup>	–
		Parental toxicity	1 052 mg/kg bw per day <sup>c</sup>	–
		Offspring toxicity	1 052 mg/kg bw per day <sup>c</sup>	–
	Developmental toxicity study <sup>a</sup>	Maternal toxicity	13 500 ppm, equal to 1 036 mg/kg bw per day <sup>c</sup>	–
		Embryo and fetal toxicity	13 500 ppm, equal to 1 036 mg/kg bw per day <sup>c</sup>	–
	Developmental toxicity study <sup>a</sup>	Maternal toxicity	1 500 ppm, equal to 52.8 mg/kg bw per day	5 000 ppm, equal to 177 mg/kg bw per day
		Embryo and fetal toxicity	15 000 ppm, equal to 495 mg/kg bw per day <sup>c</sup>	–



Species	Study	Effect	NOAEL	LOAEL
Dog	One-year study of toxicity <sup>a</sup>	Toxicity	3 000 ppm, equal to 80 mg/kg bw per day	10 000 ppm, equal to 273 mg/kg bw per day

<sup>a</sup> Dietary administration.

<sup>b</sup> Lowest dose tested.

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

#### *Acceptable daily intake (ADI)*

0–0.05 mg/kg bw

#### *Acute reference dose (ARfD)*

Unnecessary

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

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

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

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

Rate and extent of oral absorption	Rapid, but low
Dermal absorption	No data
Distribution	Wide; higher concentrations in plasma, liver, kidney and urinary bladder
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapid and complete; primarily via the faeces; 58–90% eliminated within 24 hours
Metabolism in animals	Large percentage not absorbed and bound within faeces; otherwise, extensively metabolized
Toxicologically significant compounds in animals and plants	Fenpicoxamid

##### *Acute toxicity*

Rat, LD <sub>50</sub> , oral	>2 000 mg/kg bw
Rat, LD <sub>50</sub> , dermal	>5 000 mg/kg bw
Rat, LC <sub>50</sub> , inhalation	>0.53 mg/L
Rabbit, dermal irritation	Non-irritating
Rabbit, ocular irritation	Minimally irritating
Mouse, dermal sensitization	Not sensitizing

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

Target/critical effect	Thin appearance, decreased body weight and liver changes
------------------------	--

Lowest relevant oral NOAEL	80 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEC	No data
<i>Long-term studies of toxicity and carcinogenicity</i>	
Target/critical effect	Liver changes and adenomas
Lowest relevant NOAEL	5.3 mg/kg bw per day (male mouse)
Carcinogenicity	Carcinogenic in male mice and female rats; not carcinogenic in female mice or male rats <sup>a</sup>
<i>Genotoxicity</i>	
	No evidence of genotoxicity in vivo <sup>a</sup>
<i>Reproductive toxicity</i>	
Target/critical effect	None
Lowest relevant parental NOAEL	1 052 mg/kg bw per day, highest dose tested (rat)
Lowest relevant offspring NOAEL	1 052 mg/kg bw per day, highest dose tested (rat)
Lowest relevant reproductive NOAEL	1 052 mg/kg bw per day, highest dose tested (rat)
<i>Developmental toxicity</i>	
Target/critical effect	Decreased feed consumption, body weight gain and faeces
Lowest relevant maternal NOAEL	52.8 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	495 mg/kg bw per day, highest dose tested (rabbit)
<i>Neurotoxicity</i>	
Acute neurotoxicity NOAEL	No data
Subchronic neurotoxicity NOAEL	No data
Developmental neurotoxicity NOAEL	No data
<i>Other toxicological studies</i>	
Immunotoxicity	No data
<i>Studies on toxicologically relevant metabolites</i>	
X642188	LD <sub>50</sub> > 2 000 mg/kg bw No evidence of genotoxicity
<i>Human data</i>	
	No adverse health effects noted in manufacturing plant personnel

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

### Summary

	Value	Study	Safety factor
ADI	0–0.05 mg/kg bw	Eighteen-month carcinogenicity study in mice	100

ARfD

Unnecessary

–

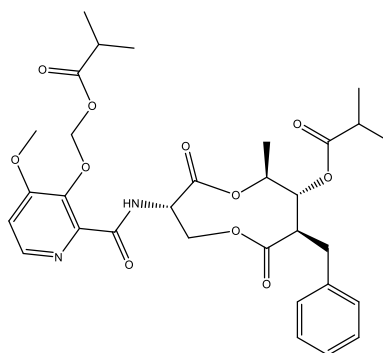
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## RESIDUE AND ANALYTICAL ASPECTS

Fenpicoxamid is a picolinamide fungicide for the control of foliar diseases. It acts as a contact and residual protectant with limited systemic activity but some translaminar activity. The representative uses in Europe were for cereals for control of Septoria leaf blotch (*Zymoseptoria tritici*, syn: *Septoria tritici*). Fenpicoxamid is also registered for use on banana for the control of Black sigatoka (*Mycosphaerella fijiensis*).

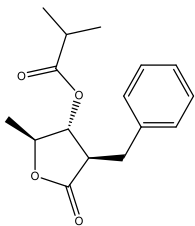
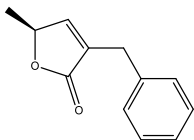
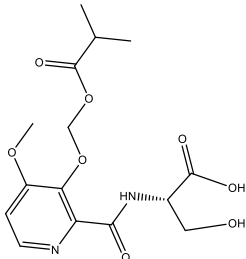
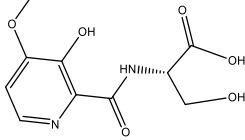
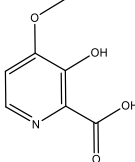
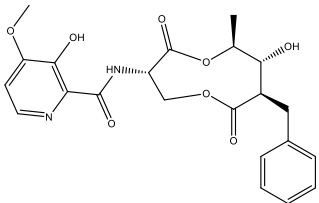
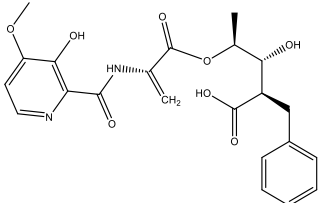
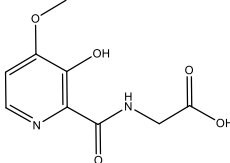
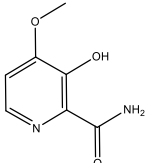
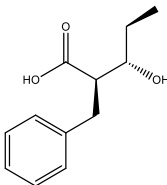
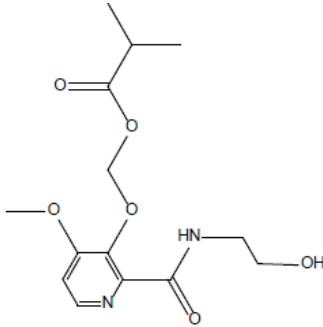
Fenpicoxamid was scheduled at the Forty-ninth Session of the CCPR for the evaluation of toxicology and residues for the first time by the 2018 JMPR. The Meeting received information on plant and animal metabolism, a confined rotational crop study, methods of residue analysis, storage stability, environmental fate, and supervised trials and GAP information on banana.

The IUPAC name of fenpicoxamid is (3*S*,6*S*,7*R*,8*R*)-8-benzyl-3-{3-[(isobutyryloxy)methoxy]-4-methoxypyridine-2-carboxamido}-6-methyl-4,9-dioxo-1,5-dioxonan-7-yl isobutyrate. The structural formula is:



Some metabolites referred to in the appraisal are addressed by their company codes:

Code	Structure	Code	Structure
X642188 (MW: 514.5)		X12326349 (MW: 462.5)	
Open-ring fenpicoxamid isomer (MW: 632.7)		X11963422 (MW: 206.2)	

Code	Structure	Code	Structure
X12314005 (MW: 276.3)		X12019520 (MW: 188.2)	
X12335723 (MW: 356.3)		X12264475 (MW: 256.1)	
X696476 (MW: 169.1)		X696872 (MW: 444.4)	
13495S-3S (MW: 444.4)		X763024 (MW: 226.2)	
X12313581 (MW: 168.2)		PH-met 208 (MW: 208.3)	
X12446477 (MW: 312.32)			

Fenpicoxamid is not volatile. The log  $K_{OW}$  value (4.2 at pH 5) indicates that the compound may be partitioned into fat. Hydrolysis is likely to be a significant route of degradation. Aqueous photolysis is also likely to be a significant route of degradation, but at a less extent than hydrolysis.

### ***Plant metabolism***

The Meeting received information on the fate of fenpicoxamid following foliar application on fruits (tomato), leafy vegetables (cabbage) and cereals (wheat).

#### ***Tomato***

The metabolism of  $^{14}\text{C}$ -fenpicoxamid (phenyl- and pyridine-radiolabelled) was studied in greenhouse grown tomatoes following two foliar applications at a rate equivalent to 300 g ai/ha at a 30-day re-treatment interval. Mature fruits were collected 1, 7 and 14 days after the last application (DALA).

TRR levels in mature fruits (1, 7 and 14 DALA) were in the range of 0.057–0.13 mg eq/kg and greater than 99% of the radioactivity was extracted with acetonitrile and aqueous acetonitrile, with the majority of residues recovered in the surface rinse (80–90%). No significant differences in TRR levels of fruits were observed for either  $^{14}\text{C}$ -label at all harvest intervals.

Parent was the major component in tomato fruit, accounting for 90–97% (0.051–0.12 mg/kg) of the total radioactivity. Minor metabolites X642188, an open-ring fenpicoxamid isomer, and phenyl-label specific X12314005 were found at very low levels up to 0.7% TRR and present at 0.001 mg/kg each. There were 2 to 5 unidentified metabolites, but no single component was present at concentrations greater than 0.001 mg eq/kg. A similar trend was observed in the vines.

#### ***Cabbage***

The metabolism of  $^{14}\text{C}$ -fenpicoxamid (phenyl- and pyridine-radiolabelled) was studied in outdoor grown cabbage following two foliar applications at a rate of 300 g ai/ha with a 30-day re-treatment interval. Immature cabbage samples were collected 14 days after the first application and mature cabbage samples were collected 7 DALA.

For both labels, TRR levels in immature cabbage were in the range of 0.93–1.3 mg eq/kg. In mature cabbage heads with wrapper leaves, TRRs for both labels were 0.42–0.51 mg eq/kg, while those in mature cabbage heads without wrapper leaves were approximately one-fifth of the residue in intact cabbage. Greater than 98% of the total residue in cabbage samples could be extracted with acetonitrile and aqueous acetonitrile, containing 0.1% phosphoric acid.

In all cabbage samples (immature cabbage, cabbage head with or without wrapper leaves, and wrapper leaves), parent was a major component accounting for 68–96% of the TRR and present at levels of 0.054–1.5 mg/kg. In cabbage heads with wrapper leaves, X12314005 (13% TRR, 0.030 mg/kg) was also present in amounts approximately 10-fold less than the parent compound and showed much lower levels in the edible portion of the commodity (cabbage head without wrapper leaves: 3.4% TRR, 0.002 mg/kg). Two metabolites, X642188 and an open-ring fenpicoxamid isomer, were found at low levels, up to 5.4% and 5.0% TRR, respectively and present at up to 0.013 and 0.058 mg/kg, respectively. Additionally, 3 to 10 unidentified metabolites were present, none of which were greater than 4.8% TRR and 0.028 mg eq/kg.

#### ***Wheat***

Metabolism of  $^{14}\text{C}$ -fenpicoxamid (phenyl- and pyridine-radiolabelled) was studied in outdoor grown wheat following two foliar applications at a rate of 133 g ai/ha. Immature wheat forage samples were collected at 28 days after the first application. Immature wheat hay samples were collected at 24 DALA and dried. Mature grain and straw were collected at 78 DALA.

TRR levels in wheat samples (both labels) were 0.54–0.99 mg eq/kg in forage, 3.0–7.8 mg eq/kg in hay, 4.2–4.9 mg eq/kg in straw and 0.016–0.019 mg eq/kg in grain. 90–110% of the TRR in forage, hay,

and straw were extracted using acetonitrile/H<sub>3</sub>PO<sub>4</sub> solvent system at elevated temperatures. In grain, 50–97% of the TRR was extracted, with 34–37% TRR (0.005–0.007 mg eq/kg) remaining in the PES.

For grain (both labels), parent represented 21–38% of the TRR (0.004–0.006 mg/kg). Metabolite X642188 was found at 0.8% TRR (< 0.001 mg/kg). Two other minor metabolites were present at 2.9–5.5% TRR (< 0.001 mg/kg). No unidentified single component accounted for more than 4% TRR (0.001 mg eq/kg).

In forage, hay and straw (both labels), the majority of the residue remained as the parent, representing 76–98% TRR. Seven minor metabolites were found at 0.5–3.4% TRR each (up to 0.12 mg/kg). No unidentified single component accounted for more than 3.5% TRR (0.15 mg eq/kg). Unextracted residues in straw (1.9–4.0% TRR, 0.078–0.19 mg eq/kg) were incorporated into natural plant constituents characterised as pectin, lignin, hemicellulose and cellulose.

In summary, fenpicoxamid is not extensively metabolised in tomato, cabbage and wheat following foliar application. Parent fenpicoxamid constitutes the large majority of residues in wheat, cabbage and tomato, with low levels of several metabolites observed. A similar metabolite profile was observed across the three crop groups investigated. The metabolism proceeds through loss of the oxymethylisobutyrate group from the pyridine ring or through opening and cleavage of the bislactone ring to ultimately produce low levels of several postulated pyridine-label or phenyl-label specific metabolites.

Plant metabolite X642188 was identified as a metabolite in rats.

### ***Confined rotational crops***

A confined study was conducted to investigate the metabolism of fenpicoxamid in the representative crops wheat, lettuce, and radish. <sup>14</sup>C- fenpicoxamid (phenyl- and pyridine-radiolabelled) was applied to sandy loam soil at 260 g ai/ha. The crops were planted at 30, 180 and 270 days plant-back intervals (PBI) and harvested. Residues in lettuce (immature and mature), radish (tops and roots), wheat (forage, hay, straw and grain) were analysed.

Residues in crops consistently declined with longer PBIs. In food commodities TRR levels (both labels) were 0.006–0.020 mg eq/kg and 0.001–0.009 mg eq/kg at 30 and 180 days PBI, respectively. For feed (both labels), residues were 0.008–0.13 mg eq/kg and 0.001–0.032 mg eq/kg at 30 and 180 days PBI, respectively.

In immature lettuce and radish tops (TRR, ≥ 0.01 mg eq/kg only at 30 day PBI), residues consisted of more than 30 individual components at concentrations of up to 0.004 mg eq/kg. Parent was not detected. In wheat grain, the recovered residue consisted of multiple polar components present at less than 0.01 mg eq/kg each. Parent was considered present at less than a quantifiable level, 0.01 mg/kg.

In feed commodities, residues consisted of multiple components up to 0.01 mg/kg observed in PH-labelled hay (30 days PBI). Parent was detected only in straw present at less than 0.01 mg eq/kg.

The Meeting concluded that significant transfer of residues into rotated crops is not expected following an application of up to 260 g ai/ha.

### ***Animal metabolism***

The Meeting received information on metabolism of fenpicoxamid in rats, goat and hens.

#### ***Rat***

Metabolism studies on laboratory animals including rats were reviewed in the framework of toxicological evaluation by the current JMPR.

### *Lactating goats*

Metabolism of  $^{14}\text{C}$ - fenpicoxamid (phenyl- and pyridine-radiolabelled) was investigated in lactating goats. Goats were dosed orally once daily for five consecutive days at ca. 20 ppm in the diet. Milk was collected twice daily. Animals were sacrificed 6–7 hours after the last dose.

The majority of the administered dose was excreted in faeces (54–63%) and in urine (5–14%) for both labels. The total radioactivity (both labels) was near or below 0.005 mg eq/kg in muscle and fat, 0.026–0.065 mg eq/kg in liver and 0.033–0.041 mg eq/kg in kidney. During the dosing period the residue levels in milk reached a plateau quickly with a maximum of 0.008 mg eq/kg (day 2, PH-label) or 0.005 mg eq/kg (day 3, PY-label). Milk, muscle, and fat were not characterised further due to the low residue levels.

Organic solvent (25% aqueous acetonitrile) extracted 89% and 64% of the total radioactivity in kidney and liver, respectively, in both labels. For liver (PY-label), acid extraction after organic extraction released an additional 34% of the total radioactivity.

In kidney (both labels), the largest components were X12326349 and 13495S-3S, accounting for 17–33% TRR (0.004–0.01 mg/kg) and 8.3–11% TRR (0.002–0.003 mg/kg), respectively. Nine other metabolites found did not exceed each 10% TRR (up to 0.001 mg/kg). A polar peak with 32% TRR (0.013 mg eq/kg) was found in the PY-labelled kidney, but further characterisation and identification for the polar peak was not achieved. Parent compound was observed in only PH-label at a very low level, 0.2% TRR (< 0.001 mg/kg).

In liver (both labels), the largest components were metabolites X12326349 and X12264475. X12326349 was found at up to 16% TRR (0.007 mg/kg): 10–13% TRR (0.002–0.006 mg/kg) from neutral extraction and 2.6% TRR (0.001 mg/kg) by additional acid hydrolysis. X12264475 was found at up to 21% TRR (0.006 mg/kg): 2.1% TRR (0.001 mg/kg) from neutral extraction and 19% TRR (0.005 mg/kg) by additional acid hydrolysis. A polar peak with 21% TRR (0.014 mg eq/kg) was found in the PY-labelled liver, but further characterisation and identification was not achieved. Parent was not observed in liver.

In goats (liver and kidney), metabolites X12326349, 13495S-3S and X12264475 were the main components. Parent and any metabolites were not present at levels greater than 0.01 mg/kg.

### *Laying hens*

Metabolism of  $^{14}\text{C}$ -fenpicoxamid (phenyl- and pyridine-radiolabelled) was investigated in laying hens. Separate groups of animals were orally dosed for 7 days at ca. 10 ppm in the diet. Eggs were collected twice daily. The animals were sacrificed 6–8 hours after the last dose.

The majority (ca. 88% in both labels) of the total administered dose was eliminated in the excreta. Total residue levels (both labels) were 0.006–0.009 mg eq/kg in muscle, 0.005–0.010 mg eq/kg in fat, 0.008–0.016 mg eq/kg in skin with fat, 0.039–0.15 mg eq/kg in liver and 0.001–0.007 mg eq/kg in eggs. Residue levels in PY-labelled eggs plateaued by day 5, while no plateau was reached by day 7 in PH-labelled eggs.

Aqueous acetonitrile solvent extracted 61–64% TRR in eggs, 45–46% TRR in liver, 84% TRR in fat and 95% TRR in skin with fat, in both labels. In liver, acid extraction after organic extraction further released 17–37% TRR in both labels, leaving unextracted residues of 12% TRR (0.018 mg eq/kg) in PH-label and 14% TRR (0.005 mg eq/kg) in PY-label.

In liver (both labels), fat (PH-label) and skin with fat (PH-label) the residue consisted of multiple low-level components. The largest component co-elute X11963422/MW208 accounted for 12–28% TRR (or 0.001–0.006 mg/kg) in the all tissues. X696872 was found at 17% TRR (0.001 mg/kg) in fat and 15% TRR

(0.002 mg/kg) in skin with fat. X129300 was found at 14% TRR (< 0.001 mg/kg). Parent was not detected in liver and fat, but at a very low level (5.2% TRR, < 0.001 mg/kg) in skin with fat. No other single component exceeded 5.9% TRR and 0.004 mg/kg.

In eggs (both labels), the largest components were the co-elute 11963422/MW208 and X12264475, accounting for 32% TRR (< 0.001 mg/kg) and 14% TRR (< 0.001 mg/kg), respectively. Other metabolites were present at up to 6.4% TRR (< 0.001 mg/kg) except a polar component at up to 27% TRR (0.002 mg eq/kg). No parent was found in eggs.

In summary for animal metabolism (goats and hens), metabolism of fenpicoxamid was extensive, proceeding through loss of either or both of the oxymethylisobutyrate side chains (O-dealkylation of the ester side chains) and opening of the bislactone ring at one of two possible positions. Further metabolism resulted in complete cleavage of the bislactone ring to give a variety of phenyl-ring and pyridine-ring specific metabolites.

Goat metabolite X12326349 was identified as a metabolite in rats.

### ***Environmental fate***

The Meeting received information on hydrolysis, aqueous photolysis, aerobic degradation in soil and soil photolysis.

#### ***Hydrolysis***

Hydrolytic degradation of <sup>14</sup>C-fenpicoxamid (phenyl- and pyridine-radiolabelled) in the dark sterile aqueous buffered solution was rapid and extensive. The degradation rate increased with increasing pH and temperature. The DT<sub>50</sub> values of fenpicoxamid at pH 7 were 4.1 days at 10 °C, 0.92 days at 25 °C and 0.38 days at 35 °C. Hydrolysis products X12314005, X12019520, X12264475, X12335723, X12386481, X12433979, isomer of X11963422, open-ring fenpicoxamid isomer and X12393285 were observed.

In a separate study, the hydrolysis of X642188 in the dark sterile aqueous buffered solutions was rapid and extensive. Degradation rate increased with increasing pH and temperature. The DT<sub>50</sub> values of X642188 at pH 7 were 1.3 days at 10 °C, 0.22 days at 25 °C and 0.075 days at 35 °C.

Hydrolysis is likely to be a significant route of degradation.

#### ***Aqueous photolysis***

<sup>14</sup>C-fenpicoxamid (phenyl- and pyridine-radiolabelled) in the sterile aqueous buffered solution under irradiation conditions at 25 °C of summer sunlight at 40 °N latitude was degraded with the photolytic DT<sub>50</sub> value of 3.1 days. The degradate X12446477 and a multi-component peak were observed only in the irradiated sample; otherwise, identical degradation products were found under both the irradiation and non-irradiation conditions. Given that the DT<sub>50</sub> of fenpicoxamid in the dark control sample was 1.3 days, the Meeting concluded that hydrolysis is likely to be a more prominent dissipation pathway than photolysis.

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

Soils were treated with <sup>14</sup>C-fenpicoxamid (phenyl- and pyridine-radiolabelled) at 133 g ai/ha and incubated under aerobic conditions in the dark at 20 °C, with 50% maximum water holding capacity.

In both labels, parent degraded rapidly and extensively in all four tested soils. The geometric mean DT<sub>50</sub> and DT<sub>90</sub> values of parent were 1.2 days and 15.6 days, respectively. Major metabolites X642188, X696872, X12264475, X763024, X696476, X12313581 and X11963422 were observed.

Fenpicoxamid was not considered to be persistent in soil.



### *Soil photolysis*

In a soil photolysis study, fenpicoxamid was significantly degraded in dark (13–17% applied radioactivity (AR) remaining) and irradiated (26–32% AR remaining) moist soils and less degradation occurred in irradiated dry soil (64–76% AR remaining). Phototransformation was not a major pathway of degradation of fenpicoxamid.

### *Methods of analysis*

Three methods involving aqueous acetonitrile extraction and determination by LC-MS/MS were fully validated for analysis of fenpicoxamid and its metabolites in plant (X642188) and animal (X642188 and X12326349) commodities. In one method for plant commodities, LOQs of fenpicoxamid and X642188 were 0.01 mg/kg in matrices of high water, high acid, high oil and high starch content. In two methods for animal commodities, LOQs for parent, X642188 and X12326349, where measured, were 0.01 mg/kg.

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

In a storage stability study on fenpicoxamid and X642188, the compounds were stable for at least 24 months in banana whole fruit and pulp when stored frozen at -18 °C.

No storage stability data were available for animal commodities.

### *Definition of the residue*

The fate of fenpicoxamid was investigated after foliar application to tomato, cabbage and wheat plants. In plant metabolism studies, the parent compound was a major component of radioactive residues, accounting for 90–97% TRR in tomato, 68–96% TRR in cabbage, 21–38% TRR in wheat grain and 76–98% TRR in wheat feed commodities. All metabolites identified were present at less than 10% TRR.

The confined rotational crop study indicated very limited transfer of radioactivity into food or feed commodities. The Meeting concluded that it is unlikely to find parent and the metabolites in succeeding crops.

A validated analytical method for parent compound in plant matrices is available.

The Meeting therefore considered that fenpicoxamid is a suitable marker for enforcement of maximum residue levels and for dietary risk assessment for plant commodities.

In establishing the residue definition for assessing dietary exposure from plants, the Meeting considered that metabolite levels in plants were much lower than residue levels of parent compound and would be unlikely to contribute significantly to dietary exposure. While significant levels of the degradates X12314005, X12016520, X12335723, and X12264475 were observed in the simulated processing study, the Meeting noted that there were no quantifiable residues of fenpicoxamid in banana pulp. Therefore, based on the uses considered by the Meeting, there are no concerns regarding the formation of these metabolites. Should the Meeting evaluate future uses involving commodities subject to high-temperature conditions, these compounds may need to be considered for assessing dietary risk.

For all animal species investigated, no quantified residues of the parent compound were found.

In goat liver and kidney matrices, X12326349 was the predominant residue with TRR levels of 16–33%. The kidney and liver samples also showed residues of 13495S-3S at 8.3–11% TRR and X12264475 at up to 21% TRR. However, the concentrations of all metabolites found were < 0.01 mg/kg, except for X12326349 in kidney (0.01 mg/kg).

In hens, the co-elute X11963422/MW208 was the predominant residue in all matrices (12–32% TRR). Further metabolites exceeding 10% TRR were X696872 (fat: 17% TRR, skin with fat: 15% TRR), X12264475 (eggs: 14% TRR) and X129300 (skin with fat: 14% TRR). However, the concentrations of all metabolites found were very low, not exceeding 0.01 mg/kg.

Metabolism studies with lactating goat and laying hen demonstrated that residues above 0.01 mg/kg are not expected in animal commodities at feeding levels up to 20 ppm and 10 ppm, respectively. Provided dietary burdens do not exceed these feeding levels, the Meeting decided that residues definitions for enforcement and dietary risk assessment for animal commodities are not necessary.

Based on the above, the Meeting recommended the following residue definitions.

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

The Meeting did not recommend residue definitions for animal commodities (compliance with the MRL and dietary risk assessment) as they are not necessary for the uses considered by the current Meeting.

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

The Meeting received supervised trial data for banana.

#### ***Banana***

Fenpicoxamid is registered for foliar use on banana in Central and South America (Costa Rica, Ecuador, El Salvador, Guatemala, Honduras, Nicaragua and Panama). A total of eleven independent trials were conducted in Colombia, Costa Rica, Ecuador, Guatemala and Honduras during 2014 and 2015, approximating the GAP (three foliar applications at 0.050 kg ai/ha with 8 day re-treatment intervals and no restriction on PHI; aerial application only).

Fenpicoxamid residues in un-bagged banana (whole fruit) were (n = 11): 0.012, 0.014, 0.014, 0.023, 0.024, 0.034, 0.034, 0.038, 0.046, 0.058 and 0.066 mg/kg.

Fenpicoxamid residues in un-bagged banana (pulp) were (n = 11): < 0.01 mg/kg (11).

The Meeting estimated a maximum residue level of 0.15 mg/kg and a STMR of 0.01 mg/kg for banana.

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

#### ***High temperature hydrolysis***

Buffered water samples, dosed at approximately 0.03 µg/mL with either phenyl- or pyridine-radiolabelled fenpicoxamid, were heated at 90 °C for 20 minutes (pH 4), boiled at 100 °C for 60 minutes (pH 5), and steamed at 120 °C for 20 minutes (pH 6), to simulate industrial or household preparation.

At pH 4, 5 and 6 respectively, the following hydrolysis products were found:

- Fenpicoxamid (PH- and PY-label): 80–87% (pH 4), 19–28% (pH 5) and not detected (pH 6);
- X12314005 (PH-label): 10%, 48% and not detected;
- X12019520 (PH-label): 2.9%, 12% and 87%;
- X12335723 (PY-label): 15%, 77% and 65% ;
- X12264475 (PY-label): not detected, not detected and 18%.

Should the Meeting evaluate future uses involving commodities subject to high-temperature conditions, these compounds may need to be considered for assessing dietary risk.

***Fate of residues during processing***

No information was provided.

***Farm animal feeding studies***

No information was provided.

***Farm animal dietary burden***

There are no relevant feed items from the use on banana.

## RECOMMENDATIONS

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

The Meeting recommended the following residue definitions for fenpicoxamid.

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

The Meeting concluded that if future uses of fenpicoxamid result in an increase of the exposure for the goat metabolite X12326349 and the hydrolysis products X12314005, X12019520, X12335723 and X12264475, reconsideration of the residue definitions may become necessary.

## DIETARY RISK ASSESSMENT

***Long-term dietary exposure***

The ADI for fenpicoxamid is 0–0.05 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for fenpicoxamid 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 2018 JMPR Report. The IEDIs were 0% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of fenpicoxamid 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 fenpicoxamid was unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of fenpicoxamid from the use considered is unlikely to present a public health concern.



## 5.9 FENPYROXIMATE (193)

### RESIDUE AND ANALYTICAL ASPECTS

The current Meeting identified an error in a table in the 2017 evaluation of fenpyroximate that was relied upon in setting the residue definitions for livestock commodities by the 2017 JMPR. Columns in Table 39 on lactating goat metabolism were incorrectly labelled leading the 2017 JMPR to include (*E*)-4-[(1,3-dimethyl-5-(4-hydroxyphenoxy)pyrazol-4-yl)methyleneaminooxymethyl]benzoic acid (M-5) and its conjugates in the residue definition for risk assessment for animal commodities. The current Meeting re-evaluated the lactating goat metabolism studies and the residue definitions for livestock commodities.

In goats, the residue profile varied by matrix. The Fen-OH metabolite was consistently observed as a major residue in milk, muscle and fat (27% TRR milk, 74% TRR muscle, 35% TRR fat) and detected in liver and kidney (5% TRR liver, and 3% TRR kidney). Additional residues observed across multiple matrices at greater than 10% TRR were fenpyroximate (26% TRR milk, 36% TRR fat), N-desmethyl M-3 (20% TRR liver, 26% TRR kidney), M-3 (33% TRR muscle, 14% TRR fat, 59% TRR liver, 47% TRR kidney) and M-21 (26–55% TRR in milk). A QuEChERS method was validated for analysis of fenpyroximate and M-3 in milk, fat, muscle, and offal. Based on structural similarities between fenpyroximate, M-3 and Fen-OH, the Meeting noted that the method is likely to be suitable for analysis of Fen-OH. The Meeting confirmed that the sum of fenpyroximate, Fen-OH and M-3, expressed as fenpyroximate is a suitable marker for compliance in livestock commodities.

In addition to the residues for compliance, dietary exposure from consumption of livestock commodities may occur for the sum of M-5 and M-5-glucuronide for liver (6% TRR, 0.065 mg eq/kg) and kidney (10% TRR, 0.213 mg eq/kg), for M-21 in milk (55% TRR, 0.015 mg eq/kg), and M-22 in liver and kidney (4–9% TRR, 0.053–0.14 mg eq/kg). The toxicity of M-5, M-5-glucuronide, M-21 and M-22 are covered by parent fenpyroximate. M-5 and its conjugates were only detected in liver and kidney and only at ≤ 10% TRR. As such M-5 and its conjugates are expected to make a negligible contribution to overall long-term dietary exposure. Since M-21, M-22 and desmethyl-M3 were not detected in the dairy cow feeding study, the Meeting decided that they do not need to be included for assessing dietary exposure. There was no evidence in the goat metabolism study of significant levels of Z-isomers and it is not necessary to include Z-isomers in the residue definition. The Meeting decided that definition for dietary risk assessment should be revised to the sum of fenpyroximate, Fen-OH and M-3, expressed as fenpyroximate, in livestock commodities.

In summary, the fenpyroximate residue definition, for compliance with the MRL and dietary risk assessment, for animal commodities is: *sum of fenpyroximate, 2-hydroxymethyl-2-propyl (E)-4-[(1,3-dimethyl-5-phenoxy)pyrazol-4-yl]-methylenaminooxymethyl]benzoate (Fen-OH), and (E)-4-[(1,3-dimethyl-5-phenoxy)pyrazol-4-yl]methylenaminooxymethyl]benzoic acid (M-3), expressed as fenpyroximate.*

Maximum residue levels for livestock commodities needed to be revised in light of the amended residue definitions. The dietary burdens are the same as reported by the 2017 JMPR.

#### ***Animal commodity maximum residue levels***

The calculation used to estimate highest total residues for use in estimating maximum residue levels, STMR and HR values for cattle matrices is shown below.

	Feed level (ppm) for milk residues	Residues (mg/kg) in milk	Feed level (ppm) for tissue residues	Residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
maximum residue level beef or dairy cattle							
Feeding study <sup>a</sup>	3	0.005	3	0.017	0.42	0.36	0.083
	10	0.013	10	0.059	0.91	0.459	0.169
Dietary burden and high residue	3.503	0.0056	3.503	0.02	0.455	0.367	0.089
STMR beef or dairy cattle							
Feeding study <sup>b</sup>	1	0	1	< 0.01	0.19	0.20	0.015
	3	0.005	3	0.015	0.37	0.29	0.063
Dietary burden and median residue	1.595	0.0015	1.595	0.011	0.247	0.229	0.029

<sup>a</sup> Highest residues for tissues and mean residues for milk

<sup>b</sup> Mean residues for tissues and milk

For liver and kidney, the compounds measured in the feeding study and reported as the residue were the sum of fenpyroximate and M-3 while the residue definition for dietary risk assessment also includes Fen-OH. The lactating goat metabolism studies can be used to calculate scaling factors for conversion of residues measured as the sum of fenpyroximate and M-3 to the sum of fenpyroximate, Fen-OH and M-3. The scaling factors, calculated as the mean factors from the benzyl and pyrazole label experiments, are kidney 1.04 and liver 1.08. A conservative scaling factor of 1.1 is applied to the estimates for liver and kidney to give highest residues of 0.501 and 0.404 mg/kg for liver and kidney respectively and median residues of 0.272 and 0.252 mg/kg respectively.

The Meeting estimated a maximum residue level of 0.01 mg/kg for fenpyroximate for milk, of 0.1 mg/kg for mammalian meat (fat), of 0.5 mg/kg for edible offal (mammalian) and 0.1 mg/kg for mammalian fats confirming its previous recommendations. The Meeting estimated STMRs of 0.0015 mg/kg for milk, of 0.011 mg/kg for mammalian meat, 0.272 mg/kg for edible offal (mammalian) and 0.029 mg/kg for mammalian fat.

There were no changes to the conclusions of the dietary risk assessment. A corrigenda was prepared for the monograph.

## 5.10 FLUAZINAM (306)

### TOXICOLOGY

Fluazinam is the ISO-approved common name for 3-chloro-*N*-(3-chloro-5-trifluoromethyl-2-pyridyl)- $\alpha,\alpha,\alpha$ -trifluoro-2,6-dinitro-*p*-toluidine (IUPAC), with the CAS number 79622-59-6.

Fluazinam is used as a fungicide. The fungicidal mode of action is uncoupling of mitochondrial oxidative phosphorylation.

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

A toxicity data package on fluazinam was received by the Meeting, and a draft toxicological monograph was prepared.

In a number of the repeated-dose toxicity studies in mice, rats and dogs, vacuolation of white matter of the brain was observed, a potentially severe effect that appears to be associated with one of the impurities found at relatively low levels in fluazinam technical material (i.e. impurity B-1457: 5-chloro-*N*-(3-chloro-5-trifluoromethyl-2-pyridyl)- $\alpha,\alpha,\alpha$ -trifluoro-4,6-dinitro-*o*-toluidine). The sponsor did not provide any information on the level of this impurity in any of the batches tested in the toxicity studies, even though such information has been made available to regulatory authorities for registration purposes. The current FAO specification for fluazinam limits the level of this impurity to 0.3%.

The Meeting concluded that information on the level of impurity B-1457 in the batches tested for toxicity was required to conclude that any proposed health-based guidance values cover the level of this toxicologically relevant impurity present in commercial batches of technical-grade fluazinam, and therefore completion of the evaluation of fluazinam was not possible.

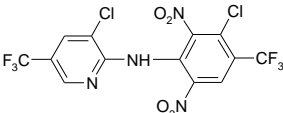
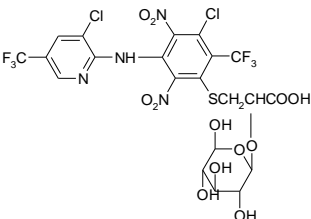
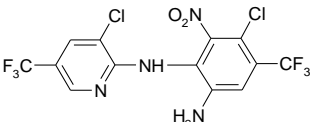
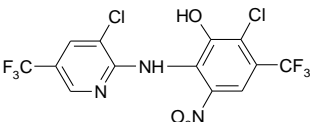
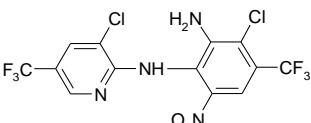
The Meeting re-emphasized the importance of a timely and complete submission of all relevant data to enable JMPR to perform a state-of-knowledge risk assessment.

### RESIDUE AND ANALYTICAL ASPECTS

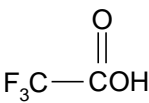
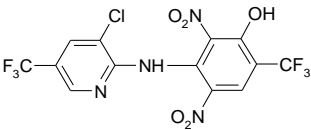
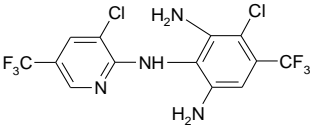
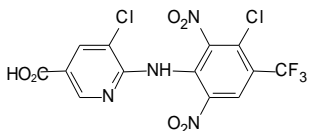
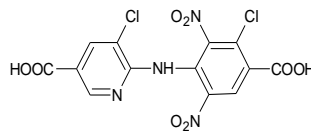
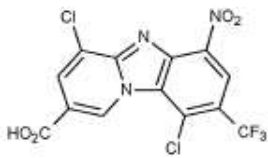
Fluazinam acts as a fungicide with activity against fungus from the class of *Oomycetes*, especially against *Phytophthora infestans*. It works protectively and needs to be applied before the disease attacks. At the Forty-eighth Session of the CCPR (2016), it was scheduled for evaluation as a new compound by the 2018 JMPR.

The Meeting received information on the identity, physical chemical properties, metabolism (plants, rotational crops and animals), environmental data, methods of analysis, freezer storage data, GAP information, supervised residue trials, fate of residues on processing and animal transfer studies.

In this document, the common names, chemical structures and chemical names of the compounds are as follows:

Chemical name (IUPAC)	Compound Name/Code	Structure	Occurrence in metabolism studies
3-Chloro- <i>N</i> -(3-chloro-5-trifluoromethyl-2-pyridyl)- <i>a,a,a</i> -trifluoro-2,6-dinitro- <i>p</i> -toluidine	Fluazinam, IKF-1216		Potatoes, peanut (foliage), grapes, apples, laying hen (liver, kidney, muscle, fat, egg yolk), RAT
3-[[4-amino-3-[[3-chloro-5-(trifluoromethyl)-2-pyridyl]amino]- <i>a,a,a</i> -trifluoro-6-nitro- <i>o</i> -tolyl]thio]-2-( $\beta$ -D-glucopyranosyloxy) propionic acid	AMGT		Potatoes grapes, wine, apples
2-(6-amino-3-chloro- <i>a,a,a</i> -trifluoro-2-nitro- <i>p</i> -toluidino)-3-chloro-5-(trifluoromethyl) pyridine	AMPA		Potatoes, peanut (foliage), wine goat (liver, kidney, muscle, fat, milk), laying hen (liver, kidney, muscle, fat, egg yolk and white), RAT
2-chloro-6-[(3-chloro-5-(trifluoromethyl)-2-pyridyl)amino]- <i>a,a,a</i> -trifluoro-5-nitro- <i>m</i> -cresol	SDS-67230		Grapes, apples
2-(2-amino-3-chloro- <i>a,a,a</i> -trifluoro-6-nitro- <i>p</i> -toluidino)-3-chloro-5-(trifluoromethyl) pyridine	MAPA		Laying hen (liver, kidney, muscle, fat, egg yolk and white)



Chemical name (IUPAC)	Compound Name/Code	Structure	Occurrence in metabolism studies
Trifluoroacetic acid	TFAA		<p>Potatoes, peanut (foliage), apples</p> <p>rotational crops: lettuce (DAT 30) carrots (DAT 30) barley grain: DAT 120 DAT 365</p>
5-[(3-chloro-5-(trifluoromethyl)-2-pyridyl)amino]- <i>a,a,a</i> -trifluoro-4,6-dinitro- <i>o</i> -cresol	HYP A		Laying hen (liver, kidney, muscle, fat, egg yolk and white); SOIL (major)
3-chloro-2-(2,6-diamino-3-chloro- <i>a,a,a</i> -trifluoromethyl- <i>p</i> -toluidino)-3-chloro-5-(trifluoromethyl)pyridine	DAPA		<p>goat (liver, kidney, muscle, fat, bile, urine, milk)</p> <p>laying hen (liver, kidney, muscle, fat egg yolk and white), RAT</p>
5-Chloro-6-(3-chloro-2,6-dinitro-4-trifluoromethylanilino)nicotinic acid	CAPA		Potato Hydrolysis
6-(4-Carboxy-3-chloro-2,6-dinitroanilino)-5-chloronicotinic acid	DCPA		Hydrolysis
4,9-dichloro-6-nitro-8-(trifluoromethyl)-pyrido-[1,2- <i>a</i> ]benzimidazole-2-carboxylic acid	G-504		Hydrolysis

With respect to the physical and chemical properties that may impact on residues in crops, fluazinam is not regarded as volatile, it has a higher solubility in organic solvents compared to its solubility in water, the partition coefficient indicates its potential to sequester in fat, and aqueous photolysis and hydrolysis may play an important role in its degradation.

### ***Plant metabolism***

The Meeting noted that TFAA was identified in the plant metabolism studies (primary and rotational) formed as a result of ring cleavage and fragmentation. The plant metabolism studies were conducted with phenyl or pyridyl labelled fluazinam. The Meeting noted that it would not be possible to identify and quantify residues of TFAA that may have arisen from the pyridyl radiolabelled studies.

### ***Potato***

#### ***Study 1***

Potatoes, grown outdoors, were treated with foliar applications of  $^{14}\text{C}$ -fluazinam labelled in the phenyl or pyridyl ring. Two application regimes were investigated; in the low-dose regime potatoes received four applications of 0.6 kg ai/ha and in the high-dose regime potatoes received four applications at 1.8 kg ai/ha. The applications were performed 55, 76, 99 and 105 days after sowing.

Potato tubers were sampled 7 and 22 days after the last application, with the latter time period representing crop maturity. Potato tubers were separated into pulp and peel.

At 7/22 DALA the TRR for whole potato were: low dose-phenyl label (0.065/0.069 mg eq/kg), low dose-pyridyl label (0.055/0.072 mg eq/kg), high dose-phenyl label (0.11/0.11 mg eq/kg) and high dose-pyridyl label (0.105/0.10 mg eq/kg).

Initial solvent extractions were conducted with acetonitrile, acetonitrile: water (80: 20, v/v) and methanol: water (80: 20, v/v). Solvent extractable residues, in terms of whole potatoes, ranged from 30–51% TRR. Owing to the low radioactivity limited identification work was undertaken. In the peel samples (low dose, 22 DALA) all identified components, including fluazinam, were  $\leq 0.004$  mg eq/kg. A number of unidentified metabolites were found with the highest metabolite, unknown M3, occurring at a level of 0.011 mg eq/kg (0.002 mg eq/kg in terms of whole potato).

#### ***Study 2***

Potatoes (variety *Kennebec*), grown outdoor, were treated four times, with a foliar spray, either with phenyl-labelled  $^{14}\text{C}$ -fluazinam at a rate of 0.505 kg ai/ha or pyridyl-labelled  $^{14}\text{C}$ -fluazinam at a rate of 0.43 kg ai/ha. Applications were made 40–41, 26–27, 15–16 and 6–7 days before harvest.

Total radioactive residues in potato were low: 0.0097 mg eq/kg (phenyl label) and 0.0236 mg eq/kg (pyridyl label).

Initial residues were extracted with acetonitrile. The extractable residue were 36% TRR for the phenyl label and 47% TRR for the pyridyl label. Owing to the low radioactivity, limited identification work was undertaken. TFAA was identified at a level of  $< 0.001$  mg eq/kg, AMGT ( $< 0.001$  mg eq/kg), AMPA ( $< 0.001$  mg eq/kg) and fluazinam (0.001 mg /kg).

The PES, accounting for 48–51% TRR, was found to be almost entirely composed of starch.

### ***Grapes***

Field grown grapevines (variety *Pinot Noir*) were treated twice, with a foliar spray, with  $^{14}\text{C}$ -phenyl-fluazinam

or  $^{14}\text{C}$ -pyridyl-fluazinam at the rate of 0.75 kg ai/ha. The first application was made at 80% of petal fall and the second at bunch closure (35 days after the first application). Samples were harvested 71 days after the last application. The TRR was 1.7 mg eq/kg from grapes treated with phenyl-label and 1.7 mg eq/kg in grapes treated with pyridyl-label.

Solvent extraction (acetonitrile: water, 90: 10, v/v) extracted 57% TRR (phenyl label) and 49% TRR (pyridyl label). In the extractable residue fluazinam (max 0.36 mg/kg, 21.3% TRR) was the major component. All other identified metabolites occurred at levels of < 4% TRR.

A large portion of the radioactivity present in the solids (PES) after the initial solvent extractions was found to be associated with natural products: 52% TRR for the phenyl label and 45% TRR for the pyridyl label.

The radioactivity in wine produced from the treated grapes was also investigated. The TRR residues in wine were: 0.73 mg eq/kg (vin de presse, both labels), 0.41 mg eq/kg (vin de goutte, phenyl label) and 0.54 mg eq/kg (vin de goutte, pyridyl label). The solvent (hexane and ethyl acetate) extractable residue ranged from 24–36% TRR. The aqueous phase accounted for 45% TRR for both the phenyl and pyridyl labels. The only two metabolites identified were AMPA (0.038 mg eq/kg, 5.2% TRR) and AMGT (0.076 mg eq/kg, 10% TRR). The ethanol, produced from the fermentation process, was found to contain radioactive residues (maximum 0.043 mg eq/kg, 5.9% TRR).

### Apple

Apple trees (variety *Golden delicious*) grown outdoors were treated with a foliar spray with either phenyl or pyridyl-labelled fluazinam. A total of six applications of approximately 0.93 kg ai/ha per application were made. The first application was applied 161 days before harvest. The following five applications were made at intervals of 9, 22, 34, 34, and 30 days.

Samples were harvested 32 days after the last application.

The total radioactive residue levels in apples were 1.9 mg eq/kg and 2.8 mg eq/kg for the phenyl and pyridyl labels respectively. The apples were surface washed with acetonitrile which accounted for 36% TRR for the phenyl label and 46% TRR for the pyridyl label. Fluazinam (max 1.2 mg/kg, 42% TRR) and SDS-67230 (max 0.07 mg eq/kg, 2.5% TRR) were identified in the surface wash.

In terms of whole apple, including the surface wash, acetonitrile extracted 56% TRR for the phenyl label, and 64%TRR for the pyridyl label.

The whole apples were separated into pomace and juice.

For pomace the extraction with acetonitrile gave an extractability of 20–24% TRR (in terms of whole apple) for both labels. None of the identified metabolites (fluazinam, SDS-37230, AMGT and sugars) occurred at levels above 3% TRR in the solvent extract.

Enzymatic and acid hydrolysis of the PES of the pomace demonstrated a significant portion of the solids were associated with natural products: 26% TRR (phenyl label) and 30% TRR (pyridyl label).

In the juice, the metabolites identified (fluazinam, AMGT and sugars) were all at levels  $\leq$  5% TRR.

In summary, the main residue identified in apples was fluazinam, ranging from 37 to 45% of the TRR (0.69–1.2 mg/kg). The two metabolites of fluazinam that retained the basic structural form of the parent molecule, SDS-67230 and AMGT, were present at levels below 3% of the TRR (< 0.08 mg eq/kg). Radiolabelled sugars, formed by incorporation of radioactivity, accounted for 6–9% of the TRR (0.16–0.17 mg eq/kg), while structural polymeric compounds such as hemicellulose, pectin. Lignin and cellulose

accounted for another 26–30% of the TRR (0.49–0.839 mg eq/kg). TFAA comprised < 1% of the TRR (0.003 mg eq/kg).

### *Peanut*

Peanut plants, initially grown outdoors and then grown under protection, were treated four times with a foliar spray with either phenyl-labelled or pyridyl-labelled fluazinam at a rate of 0.56 kg ai/ha per application. The first application was made 56 days after planting and then at intervals of 21, 22 and 23 days.

Peanut nutmeat, shells and foliage were collected 90 days after the last application.

The TRR distributions for the phenyl/pyridyl labels were: foliage (25 mg eq/kg/32 mg eq/kg), shells (0.87 mg eq/kg/ 4.7 mg eq/kg) and nutmeats (0.85 mg eq/kg/ 1.2 mg eq/kg).

Initial solvent extraction was performed with acetonitrile: water (80: 20, v/v) for foliage and shells, and with hexane, acetonitrile and water for the nutmeats. The extractabilities for the phenyl/pyridyl labels were: foliage (37%/ 47% TRR), shells (55% / 44% TRR) and nutmeats (51%/ 54% TRR).

In nutmeats, neither fluazinam nor any metabolites containing the phenyl-pyridyl ring structure were present in detectable amounts ( $\geq 0.01$  mg eq/kg). The major metabolites were TFAA (0.28 mg eq/kg, 38% TRR and fatty acids (0.23–0.58 mg eq/kg, 31–49% TRR).

Foliage contained detectable levels of fluazinam (1.8–2.3 mg/kg, 7.4–7.5% TRR) and the metabolite AMPA (0.24–0.4 mg eq/kg, 0.8–1.6% TRR). TFAA was also identified indicating that extensive metabolism of fluazinam had occurred.

In peanut shells, only fluazinam was identified.

The enzymatic, acid and base hydrolysis of the PES demonstrated that a significant portion of the radioactive residue was associated with natural products for the foliage and shells: foliage (49–53% TRR) and shells (40–52% TRR).

For nutmeats half of the radioactivity in the PES were found to be associated with natural products: 23–28% of the TRR.

In summary, the metabolism of fluazinam in peanuts was found to consist of extensive degradation and incorporation of the radioactivity into natural products

### ***Summary of plant metabolism***

In summary, the metabolism of fluazinam in primary crops of grapes, apples, potatoes and peanuts has been investigated. The metabolism of fluazinam proceeds through the reduction of one or both nitro groups to form AMPA and then replacement of the phenyl chlorine with a sulphur-containing side chain, followed by attachment of glucose to form AMGT. The metabolite SDS-67230 was also identified in apples and grapes.

Fluazinam is the main residue on plant parts such as foliage or fruit that are exposed to the spray application. However, fluazinam was not found in peanut nutmeats and only at low levels in potato tubers.

The appearance of radiolabelled natural products provides evidence that fluazinam is extensively metabolised. The presence of TFAA also supports the extensive metabolism of fluazinam and the incorporation into natural products. In potatoes, the fact that radioactivity from both phenyl ring- and pyridyl ring-labelled fluazinam appeared in starch indicated that both rings were broken down into fragments that could enter the carbon pool.

For the plant metabolites identified, only AMPA was observed in the rat metabolism studies.

### ***Animal metabolism***

The Meeting received animal metabolism studies with fluazinam in goats and hens. Evaluation of the metabolism studies in rats was carried out by the WHO core assessment group.

The tissues, milk and egg from the metabolism studies were stored at  $\leq -18^{\circ}\text{C}$  for up to 6 months, negating the need to generate storage stability data. However, the Meeting noted that the storage stability data, generated using fortified samples, demonstrated that fluazinam, AMPA and DAPA were unstable in a number of animal matrices.

Within the livestock metabolism studies the metabolic profiles of various samples after different storage periods were compared. The metabolic profiles of ruminant liver, time zero compared to 4 months of storage, and milk, time zero compared to 7 month of storage, were comparable. For the hen liver and egg samples, metabolic profile changes were observed from the time zero compared to 4 months of storage. The changes were most prominent for three unidentified metabolites in egg yolk.

A comparison of the metabolic profiles for stored radiolabelled muscle (hen and goat) samples, for which the greatest instability was observed for the fortified samples, were not undertaken.

The meeting decided that owing to the instability observed in the fortified samples, in particular for muscle (goat), the lack of information on the stability of radiolabelled muscle samples (hen and goat) and the changes observed in the HPLC profiles for hen liver and egg, not to use the livestock metabolism studies to recommend residue definitions for animal commodities.

### ***Environmental fate***

The Meeting received information on the environmental fate and behaviour of fluazinam, including aerobic soil degradation, soil photolysis, aqueous photolysis and aqueous hydrolysis. Studies were also received on the behaviour of [ $^{14}\text{C}$ ]-fluazinam in rotational crops.

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

Soil degradation studies were conducted on two soil types at application rates ranging from 0.75–5 kg ai/ha. The primary degradates observed were MAPA (maximum 2.2% applied radioactivity (AR), 30 DAT), HYPA (maximum 14% AR, 48 DAT) and DAPA (1.9% AR, 14 DAT). The mineralisation of fluazinam into  $\text{CO}_2$  accounted for up to a maximum 6% of the AR and soil bound residues accounted for up to 46% of the AR.

The  $\text{DT}_{50}$  values calculated for fluazinam ranged from 17–56 days for the sandy loam soil. A  $\text{DT}_{50}$  value of 212 days was calculated for the loamy sand soil.

For HYPA the  $\text{DT}_{50}$  value calculated for the sandy loam soil ranged from 166–257 days.

The Meeting considered that fluazinam was moderately – medium persistent in soil under aerobic conditions.

#### ***Soil photolysis***

A photo-degradation study on a loamy sand soil was conducted with [ $^{14}\text{C}$ ]-fluazinam at a dose rate of approximately 3 mg/kg. The samples were exposed to simulated sunlight for a 12 hour light/12 hour dark cycle for 30 days.

The DT<sub>50</sub> values for the net photodegradation of fluazinam were 32 and 21 days for the phenyl and pyridyl labels respectively.

Fluazinam degraded moderately in light and represented an average of 35% of the AR after 30 days. After 30 days CO<sub>2</sub> accounted for an average of 2.4% of the AR and bound residues accounted for an average of 22% of the AR. The only metabolites identified were AMPA and HYPA, and after 30 days these metabolites accounted for an average of 4.7% and 6.2% of the AR respectively.

The Meeting considered that fluazinam was stable in soil when exposed to light.

#### *Aqueous photolysis*

The aqueous photolysis of fluazinam was investigated for [<sup>14</sup>C]-fluazinam in sterile buffer at pH 5. The samples were exposed to simulated sunlight for a 12 hour light/12 hour dark cycle for 30 days. The only major analytes identified were G-504 (maximum 17% TRR, at day 10) and CO<sub>2</sub> (maximum 18% TRR after 30 days). The DT<sub>50</sub> value for fluazinam was 2.5 days.

The Meeting concluded that photolysis may play an important role in the degradation of fluazinam.

#### *Aqueous hydrolysis*

Fluazinam was found to be hydrolytically stable at pH 4 for 5 days at 50 °C.

At pH 7 and 9 (stored for 29 days at 25 °C and 56 days at 50 °C) fluazinam was hydrolytically unstable.

At pH 7 and 25 °C fluazinam was hydrolysed to CAPA which was present at > 90% of the AR at the end of the incubation period. At pH 7 and 50 °C fluazinam was hydrolysed to CAPA and DCPA. At the end of the incubation period DCPA accounted for up to 71% of the AR and CAPA accounted for up to 29% of the AR.

At pH 9 hydrolysis of fluazinam was comparable to that observed at pH 7.

The DT<sub>50</sub> values calculated at pH 7 and 25 °C ranged from 2.7–4.5 days. At pH 9 and 25 °C the DT<sub>50</sub> values ranged from 3.5–3.9 days.

The Meeting concluded that hydrolysis may play an important role in the degradation of fluazinam.

#### *Confined rotational crop studies*

A confined rotational crop study was undertaken with the application of either phenyl or pyridyl labelled fluazinam to the bare soil at an application rate of 2 × 1.12 kg ai/ha with an interval of 28 days between applications. Rotational crops of barley, carrots and lettuce were planted 30, 120 and 365 days after the last application.

The TRR in the mature crops tested were 0.04–0.30 mg eq/kg (lettuce), < 0.01–0.07 mg eq/kg (carrot roots), 0.034–0.35 mg eq/kg (carrot tops), 0.075–0.93 mg eq/kg (barley forage), 0.054–0.30 mg eq/kg (barley grain) and 0.093–1.2 mg eq/kg (barley straw).

The initial extraction was undertaken with methanol: acetone (1:1, v/v). The extractabilities were 51–95% TRR (mature lettuce), 69–92% TRR (mature carrot root), 45–91% TRR (mature carrot top), 8.8–78% TRR (barley grain), 68–96% TRR (barley forage) and 41–85% TRR (barley straw).

TFAA was found in the solvent extracts from all crops and all plant back intervals. The levels ranged from 0.004 mg eq/kg (35% TRR) for carrot roots for a PBI of 365 days to 0.88 mg eq/kg (94% TRR) for barely forage from a PBI of 120 days.

HPLC analysis of the solvent extracts resulted in several distinct regions being identified. The HPLC profiles indicated each region contained multiple components. In addition, the HPLC profiles of the extracts were different for the phenyl and pyridyl labels. These two pieces of information, along with the presence of TFAA in the rotational crops indicates cleavage of the two rings and extensive fragmentation.

Cellulase hydrolysis of the PES succeeded in releasing 11% TRR. Analyses of the aqueous fractions from enzyme hydrolysis indicated two regions of radioactivity. Subsequent mild acid and strong base hydrolysis succeeded in releasing most of the radioactivity from the PES. After base hydrolysis the resulting PES-fractions were all < 10% of the TRR and < 0.01 mg eq/kg, with the exception of phenyl-label barley straw where a TRR of 0.011 mg eq/kg was obtained.

Amylase hydrolysis of the grain PES demonstrated that up to 29% TRR was associated with starch.

In summary, in rotational crops no residues of fluazinam or related compounds based on the two-ring structure of fluazinam were found. Differences in the HPLC profiles from the phenyl and pyridyl labels indicate extensive metabolism of fluazinam. The only metabolite identified was TFAA. This occurred in significant amounts in lettuce (0.45 mg eq/kg, 120 day PBI), barley grains (0.18 mg eq/kg, 365 day PBI) and carrots (0.07 mg eq/kg, 30 day PBI). Enzymatic, base and acid hydrolysis did not release fluazinam or any other structurally related two ring structures. The incorporation into natural plant products, such as starch, was demonstrated.

Overall the metabolic pattern in rotational crops is more extensive than observed in primary crops.

The Meeting agreed that residues of TFAA could occur at significant levels in rotational crops.

The meeting noted that the rotational crop metabolism study was underdosed by a factor of 2.3 when considering the crops that can be rotated and the maximum application rates considered in this Meeting. In addition, since the position of the pyridyl –radiolabel does not address formation of the TFAA, no information on its presence in the raw agricultural commodities is available for the representative samples. For the phenyl-label, the meeting noted that TFAA was quantified using LSC-detection. It remains unclear if the lower radioactivity in TFAA compared to the full phenyl-label (1 vs 6 <sup>14</sup>C-atoms) was taken into account for the quantification of residues. The Meeting concluded that the data submitted are insufficient to estimate TFAA concentrations under field conditions.

## ***Methods of analysis***

### ***Plant commodities***

Residues were determined in crops using several different analytical methods. Following solvent extraction, using various solvents, and sample clean up, the majority of the methods employed GC-ECD to determine fluazinam. LC-MS/MS was also employed. An LOQ of 0.01 mg/kg was supported for fluazinam. The Meeting concluded that suitable methods are available for the determination of fluazinam in the crops under consideration.

An LC-MS/MS enforcement method was also validated for the determination of fluazinam in crops of high starch, high acid, high water, high protein and high oil content. Two ion transitions were validated and an LOQ of 0.01 mg/kg was supported for fluazinam in all five crop matrices. The method was successfully validated by an independent laboratory. The extraction efficiency of the method was not

investigated. The method employed methanol: acetic acid (98: 2, v/v) as the extraction solvent compared to aqueous acetonitrile extractions employed in the plant metabolism studies.

The applicability of previous versions of FDA PAM methods for the determination of fluazinam in crops of high water content and high fat content was demonstrated.

#### *Animal commodities*

A method was investigated for the determination of fluazinam, AMPA and DAPA in animal matrices. This method was used in the ruminant feeding study.

In this method, milk and tissues were extracted with various solvents and then concentrated and partitioned in hexane. Following evaporation to near dryness and dissolving the residue in acetonitrile: water (1:1, v/v) final determination was achieved by GC-MS (DAPA/milk only) and LC-MS/MS (fluazinam, AMPA and DAPA).

For the determination of conjugates in liver and kidney, samples were also extracted with aqueous acetonitrile followed by an additional hydrolysis step (HCl at 37 °C for 1 hour).

Only three replicates were undertaken at each fortification level. However, the Meeting agreed the data were sufficient to conclude on the accuracy and repeatability of the method.

The Meeting agreed that the method had not been validated for all analyte/matrix combinations and in particular the recoveries were poor for fluazinam/ kidney, AMPA/kidney and DAPA/liver.

The extraction efficiency of this method was not investigated.

The applicability of the hydrolysis step was investigated with analytical standards of the free form of the analytes only, standards of the conjugates were not employed. The Meeting concluded that the validation data were not acceptable for the determination of AMPA in kidney and DAPA in liver and kidney. In addition, the Meeting concluded that as the validation data were not generated using standards of the conjugates, or using samples with incurred residues (e.g. if standards of the conjugates are unstable), then the efficiency of the hydrolysis step had not been investigated.

It was noted by the Meeting that validation data had been generated for only one ion transition.

The initial ILV of the method was unsuccessful. Owing to the poor reproducibility observed in the ILV, the extraction procedure (non-hydrolysis method) was modified and a second ILV undertaken. Overall the reproducibility of the modified extraction procedure was demonstrated for the determination of fluazinam, AMPA and DAPA in liver only.

The meeting concluded that the method employed in the ruminant feeding study was not suitable and therefore the results from the ruminant feeding study could not be relied on. With respect to enforcement, reproducibility has only been demonstrated for a modified extraction procedure for the determination of fluazinam, AMPA and DAPA in liver.

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

##### *Plant commodities*

The freezer storage stability of fluazinam in homogenised plant samples fortified with fluazinam was investigated in a number of matrices. Fluazinam was found to be stable on storage in crops with high water content for at least 915 days, crops of a high acid content for at least 1144 days, crops of high starch content for at least 1096 days and crops of high oil content for at least 790 days.



Additional stability investigations were undertaken as part of a number of residue trials. In the majority of these studies both the stored samples and the residue trial samples were subjected to significant temperature variations throughout the study (maximum 0 to -40 °C). As a result of the instability of fluazinam observed in these crops (broccoli, mustard greens, snap beans, lima beans and ginseng) the Meeting concluded the trials could not be used to estimate maximum residue levels, STMRs or HR for fluazinam.

Data generated specifically on soya bean, alongside the residue trial samples, demonstrated that fluazinam was stable in soya bean under the storage conditions ( $\leq -10$  °C for 153 days) employed in the residue trial.

#### *Animal commodities*

The stability of fluazinam, AMPA and DAPA in tissues and milk was investigated as part of the ruminant feeding study. Fluazinam, AMPA and DAPA were stable in milk, and fluazinam and AMPA were stable in fat, for the duration of the study. DAPA was not stable in fat, and fluazinam, AMPA and DAPA were not stable in liver and muscle. The Meeting concluded that as a result of the poor stability observed and the poor recoveries for the analytical method, the results of the ruminant feeding study could not be relied on.

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

##### *Plant commodities*

The nature of the residue was investigated in apple, grape, potato and peanut following foliar applications. The metabolic pathway is generally similar in all crops investigated but the extent of metabolism in the edible parts investigated differs.

In potatoes the TRR levels were low and significant residues were not identified.

In grapes, fluazinam was identified to be the main component of the residue accounting for up to 21% of the TRR. Fluazinam was also the main component of the residue identified in apple accounting for up to 45% of the TRR. In peanut the major compound identified was TFAA accounting for 38% of the TRR).

The nature of the residue in rotational crops was investigated in barley, carrots and lettuce. TFAA was found in significant amounts in lettuce (96% TRR), barley grains (59% of the TRR) and carrots (70% of the TRR). Concentrations were reported up to 0.45 mg eq/kg in lettuce. However, the Meeting concluded that the radio-label addressed only a portion of the total TFAA present.

The nature of the residue under simulated processing conditions was investigated. Under conditions representative of pasteurization (pH4, 90 °C, 20 minutes) fluazinam was found to be stable. However, under conditions representative of baking/brewing/boiling (pH5, 100 °C, 60 minutes) and sterilization (pH 6, 120 °C, 20 minutes) fluazinam was found to be unstable. Under conditions representative of baking/brewing/boiling fluazinam was 34–39% AR and CAPA was 51–56% AR. Under conditions representative of sterilization DCPA was 36–37% AR, G-504 was 11% AR and CAPA was 43–45% AR.

In summary, fluazinam and TFAA are the major compounds present in crops, and DCPA, G-504 and CAPA are the major degradates on processing.

TFAA can occur from several sources including other pesticides (e.g. flurtamone and saflufenacil) and as such would not be a suitable marker.

The Meeting considered that fluazinam was a suitable marker for the enforcement of MRLs for all crops.

Suitable analytical methods are available to determine fluazinam.

From a dietary risk perspective, as the WHO Core Assessment Group could not conclude on toxicological reference values for fluazinam, the Meeting was unable to consider a residue definition for dietary risk assessment.

In summary, based on the above, the Meeting recommended the following residue definitions for compliance with the MRL.

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

The Meeting was unable to conclude on a residue definition for dietary risk assessment.

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

The Meeting received residue trials data for fluazinam on apple, grape, blueberries, bulb onion, cabbage, mustard greens, broccoli, melon, cucumber, summer squashes, peppers, lettuce, beans with pods, beans without pods, soya beans, carrot, potato, ginseng, peanuts and tea.

Due to the storage stability issues observed in the residue trials for broccoli, mustard greens, snap beans, lima beans and ginseng the Meeting concluded that maximum residue levels, STMRs and HRs could not be estimated for these crops.

TFAA was not included in the analysis of the samples from the residue trials considered in this Meeting.

#### ***Apples***

The critical GAP in the USA is for ten foliar applications of 0.504 kg ai/ha with a re-treatment interval of 7 days and a PHI of 28 days. Trials conducted in Canada and the USA were provided.

Residues of fluazinam in apple approximating the GAP in rank order were (n = 13): 0.03, 0.03, 0.04, 0.12, 0.13, 0.14, 0.14, 0.14, 0.15, 0.16, 0.18, 1.4 and 1.5 mg/kg with the highest analytical result reported as 1.7 mg/kg.

For fluazinam the Meeting estimated a maximum residue level of 3 mg/kg for apples.

#### ***Grapes***

GAP information was provided from Chile, Hungary and Italy. None of the trials matched the GAP for these countries. The Meeting concluded that a maximum residue level, a STMR and HR could not be estimated for grapes.

#### ***Subgroup of Bush berries***

The critical GAP in the USA (Subgroup of Blueberries) is for a maximum of six foliar applications at a rate of 0.73 kg ai/ha. The re-treatment interval between applications is 7 days with a PHI of 30 days. Trials conducted in the USA were provided.

Residues of fluazinam in blueberries in rank order were (n = 9): 0.19, 0.25, 0.47, 0.53, 0.67, 1.1, 1.4, 1.7 and 1.8 mg/kg with the highest analytical result reported as 2 mg/kg.

For fluazinam the Meeting estimated a maximum residue level of 4 mg/kg. The maximum residue level applies to the Subgroup of Bushberries.

#### ***Subgroup of Bulb Onion***

The critical GAP in the USA (Subgroup Bulb Onion) is for 6 foliar applications at 0.583 kg ai/ha with a re-treatment interval of 7 days and a PHI of 7 days. Trials conducted in the USA matching GAP were provided.

Residues of fluazinam in bulb onion in rank order were (n = 9): < 0.01, < 0.01, < 0.01, 0.012, 0.016, 0.017, 0.032, 0.04 and 0.098 mg/kg with the highest analytical result reported as 0.10 mg/kg.

For fluazinam the Meeting estimated a maximum residue level of 0.15 mg/kg. The maximum residue level applies to the Subgroup of Bulb Onions.

### *Cabbage*

The critical GAP in the USA is for a soil drench followed by foliar treatment. The soil drench treatment is 0.025 kg ai/hL with 100 mL of this solution being applied per plant (i.e. 0.025 kg ai/1000 plants) applied at or just after transplantation. The foliar use has a maximum individual application rate of 0.561 kg ai/ha with a total application rate of 3.36 kg ai/ha. The interval between applications is 7 days with a PHI of 7 days. Trials conducted in the USA were provided.

Residues of fluazinam in cabbage in rank order were (n = 8): 0.13, 0.23, 0.28, 0.39, 0.53, 0.67, 1.5 and 1.5 mg/kg with the highest analytical result reported as 1.7 mg/kg.

For fluazinam the Meeting estimated a maximum residue level of 3 mg/kg for cabbage.

### *Lettuce*

The critical GAP in the USA is for one foliar application at 0.87 kg ai/ha with a PHI of 30 days. Six trials, conducted in the USA, can be regarded as supporting the GAP. These trials were all conducted on leaf lettuces. In addition, as the application rate in these trials were outside the 25% limit then the application rate and resulting residue levels needed to be scaled using the proportionality principle.

Residues of fluazinam in lettuce (unscaled) in rank order were (n = 6): < 0.01, 0.02, 0.02, 0.02, 0.16 and 1.6 mg/kg with the highest analytical result reported as 1.7 mg/kg.

Residues of fluazinam in lettuce were scaled using scaling factors ranging from 1.26–1.32.

Residues of fluazinam in lettuce (scaled) in rank order were (n = 6): < 0.01, 0.015, 0.015, 0.015, 0.12 and 1.2 mg/kg with the highest analytical result reported as 1.3 mg/kg.

For fluazinam the Meeting estimated a maximum residue level of 3 mg/kg for lettuce, leaf.

### *Subgroup of Fruiting Vegetables, Cucurbits – Melon, Pumpkins and Winter squashes*

The critical GAP in the USA (Subgroup of Fruiting vegetables, Cucurbits – Melon, Pumpkins and Winter squashes), is for a maximum foliar application rate of 0.876 kg ai/ha with a total application of 5.26 kg ai/ha. The interval between applications is 7 days with a PHI of 30 days. Trials conducted in the USA matching this GAP were provided.

Residues of fluazinam in melon in rank order were (n = 8): < 0.01, < 0.01, 0.011, 0.014, 0.02, 0.021, 0.024 and 0.048 mg/kg.

For fluazinam the Meeting estimated a maximum residue level of 0.07 mg/kg. The maximum residue level applies to the subgroup of Fruiting Vegetables, Cucurbits – Melons, Pumpkins and Winter squashes.

### *Subgroup of Fruiting Vegetables, Cucurbits –Cucumbers and Summer squashes*

The critical GAP is for the USA (Subgroup of Fruiting Vegetables, Cucurbits - Cucumber and Summer squashes), is for four foliar applications of 0.876 kg ai/ha, with an interval between applications of 7 days and a PHI of 7 days.

A total of six trials, conducted on cucumber, and six trials, conducted on summer squash, were provided. The trials were conducted in the USA. Two of the trials conducted on summer squash cannot be used as the storage interval from sampling to analysis is not supported. One trial in cucumber was regarded as an overdosed trial, but as the residue was < 0.01 mg/kg it is regarded as supporting the GAP. The remaining trials do not reflect the GAP as 5 applications were made. The first application was a drench treatment and the Meeting agreed that the contribution of this treatment to the overall residue would be low and therefore the trials could be used to support the GAP.

Residues of fluazinam in cucumber and summer squash approximating the GAP in rank order were (n = 10): < 0.01 (7), 0.012, 0.013 and 0.027 mg/kg

For fluazinam the Meeting estimated a maximum residue level of 0.04 mg/kg. The maximum residue level applies to the Subgroup of Fruiting Vegetables, Cucurbits – Cucumbers and Summer squashes.

#### *Subgroup of Peppers and Subgroup of Eggplant*

The critical GAP in the USA (subgroup of Peppers and Subgroup of Eggplant), is for a maximum individual foliar application of 0.876 kg ai/ha with a total application rate of 5.26 kg ai/ha. The interval between applications is 7 days with a PHI of 30 days. The first application may be a soil drench treatment. Trials conducted in the USA were provided.

The trials do not reflect the GAP as the first two applications were a soil drench treatment. The Meeting concluded that the drench treatments early in the growing season are unlikely to impact on the final residue level and therefore the trials can be regarded as supporting the GAP. In five of the trials the interval between two of the applications exceeded the range of 7 days and was up to 55 days. As the residues from all trials were comparable the Meeting concluded all trials could be used to support the GAP.

Residues of fluazinam in peppers approximating the GAP in rank order were (n = 12): < 0.01 (5), 0.011, 0.015, 0.015, 0.016, 0.019, 0.03 and 0.054 mg/kg.

For fluazinam the Meeting estimated a maximum residue level of 0.07 mg/kg for peppers. The maximum residue level applies to the subgroup of peppers, except martynia, okra and roselle, and the Subgroup of eggplant.

Based on a drying factor of 10 the Meeting estimated a maximum residue level of 0.7 mg/kg for dried chili peppers.

#### *Soya bean (dry)*

The critical GAP in the USA is for a maximum individual dose of 0.583 kg ai/ha, a total maximum application of 1.17 kg ai/ha, 10 days between applications and a latest time of application at early pod formation. Trials conducted in the USA were provided.

Residues of fluazinam in soya bean in rank order were (n = 16): < 0.01 (16) mg/kg.

For fluazinam the Meeting estimated a maximum residue level of 0.01 mg/kg for soya bean.

#### *Carrots*

The critical GAP in the USA, is for maximum individual treatment rate of 0.583 kg ai/ha, with a maximum yearly application total of 2.33 kg ai/ha, a 7 day re-treatment interval and a PHI of 7 days. The GAP also specifies that no more than 4 applications can be made. Trials conducted in the USA were provided.

Within the trials submitted, several were regarded as replicate trials and hence the highest residue from the replicates has been selected.

Residues of fluazinam in carrot in rank order were (n = 8): < 0.02, 0.09, 0.1, 0.13, 0.13, 0.23, 0.37 and 0.51 mg/kg with the highest analytical result reported as 0.56 mg/kg.

For fluazinam the Meeting estimated a maximum residue level of 0.9 mg/kg for carrot.

#### *Potato*

The critical GAP in the USA, is for a total seasonal maximum application amount of 2.04 kg ai/ha with a maximum individual application rate of 0.292 kg ai/ha, 7–10 days between applications and a PHI of 14 days. Trials conducted in the USA were provided.

In a majority of the trials two replicate trials were undertaken to investigate different application regimes. In terms of the GAP the Meeting concluded that there were 8 trials that support the GAP. There was one further trial that represented an overdosed trial compared to the GAP. However, as the residue in the potato tuber was < 0.01 mg/kg it was regarded as supporting the GAP.

Residues of fluazinam in potato approximating the GAP in rank order were (n = 9): < 0.01 (9) mg/kg.

For fluazinam the Meeting estimated a maximum residue level of 0.01 mg/kg for potatoes.

#### *Peanut*

The critical GAP in the USA, is for a seasonal maximum application total of 2.34 kg ai/ha with a maximum individual application rate of 0.874 kg ai/ha, 21–28 days between applications and a PHI of 30 days. Trials conducted in the USA were provided.

Six trials support the GAP. A further three trials are regarded as overdosed trials compared to the GAP. However, as residues in the nutmeats were < 0.01 mg/kg then the trials were regarded as supporting the GAP.

Residues of fluazinam in peanut approximating the GAP in rank order were (n = 9): < 0.01 (9) mg/kg.

For fluazinam the Meeting estimated a maximum residue level of 0.01 mg/kg for peanut.

#### *Tea, green, black (black, fermented and dried)*

The critical GAP in Japan is for one foliar application at a rate of 0.025 kg ai/hL with a PHI of 14 days. The trials were conducted in Japan.

The samples were stored frozen for up to 6 months prior to analysis. Storage stability data supports a storage period of 5 months. However, no degradation was observed at 5 months of storage and therefore the Meeting concluded that the data were sufficient to cover the 6 months of storage.

Residues of fluazinam in tea in rank order were (n = 7): 0.4, 0.64, 0.67, 2.4, 2.6, 3.1 and 9.0 mg/kg with the highest analytical result reported as 10 mg/kg.

For fluazinam the Meeting estimated a maximum residue level of 15 mg/kg for tea, green, black (black, fermented and dried).

### **Animal feeds**

#### *Soya bean forage and hay, and Peanut hay*

For soya bean and peanut the authorised label from the USA does not permit the feeding of animal feed items to livestock. Therefore the animal feed items from soya bean and peanut were not considered further.

### **Rotational crops**

The Meeting noted that significant residues of TFAA could occur in rotational crops. However, rotational crop field trial data for TFAA were not provided to the Meeting.

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

#### *High temperature hydrolysis*

In the high temperature hydrolysis study, fluazinam was found to be stable under conditions representative of pasteurisation (pH 4, 90 °C, 20 minutes). However, under conditions representative of baking/brewing/boiling (pH 5, 100 °C, 60 minutes) and sterilisation (pH 6, 120 °C and 20 minutes) fluazinam was degraded to CAPA (maximum 56% AR) , G-504 (maximum 11% AR) and DCPA (maximum 37% AR).

#### *Processing*

The Meeting received information on the effects of processing on the magnitude of fluazinam residue levels for apple, grape, soya beans, potato and peanuts. The major degradates identified on hydrolysis (CAPA, G-504 and DCPA) were not investigated.

Data on residue levels of TFAA in processed commodities was not provided to the Meeting.

As residues in the raw agricultural commodities of potato tubers and peanut were < 0.01 mg/kg no processing factors could be derived. The processing factors (PF) determined for the other commodities, the best estimate PF, and the STMR-P and HR-P values estimated by the Meeting for fluazinam are outlined below:

Commodity	Individual processing factors for fluazinam	Best estimate PF for fluazinam	STMR-P for fluazinam (mg/kg)	HR-P for fluazinam (mg/kg)	Comment
Apple, Juice (raw)	0.33	-	0.0462	0.55	-
Apple, Juice (pasteurised)	0.33	-	0.0462	0.55	-
Apple, wet pomace	2.33	-	0.33	-	-
Apple, dry pomace	3	-	-	-	-
Grape, wet pomace	6.9, 5.13	6	-	-	Median PF
Grape, dry pomace	12.8, 6.25	9.53	-	-	-
Grape, juice	< 0.01, 0.25	0.25	0.15	1.78	Highest PF as 10 fold difference between two values
Raisins	0.25, 0.25	0.25	0.15	1.78	Mean PF
Grape, wine	0.39, 0.55, 0.38, 0.39,	0.39	0.23	2.77	Median PF
Grape, red wine	< 0.02, 0.33, 0.5	0.33	0.20	2.34	-
Grape, white wine	< 0.05	-	-	-	-

***Residues in animal commodities***

The Meeting received a lactating dairy cow feeding study which provided information on residue levels of fluazinam arising in tissues and milk when dairy cows were fed at rates of 2.5, 7.5 and 25 ppm. The Meeting concluded that as residues were not stable in all analyte/matrix combinations and the recovery data for the analytical method were poor, the feeding study could not be relied on.

**RECOMMENDATIONS**

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

The Meeting was unable to conclude on a residue definition for dietary risk assessment for plant commodities.

**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 plant commodities. In addition, the Meeting could not reach a conclusion on the residue levels of TFAA in the crops considered in this Meeting.





## 5.11 FLUDIOXONIL (211)

### RESIDUE AND ANALYTICAL ASPECTS

Fludioxonil was evaluated for the first time by the JMPR in 2004 when an acceptable daily intake (ADI) of 0–0.4 mg/kg bw was established. An acute reference dose (ARfD) was considered unnecessary. In 2006, 2010, 2012 and 2013 the JMPR evaluated the compound for residues and recommended a number of maximum residue levels.

The definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities is parent *fludioxonil*. The definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities is the *sum of fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid and expressed as fludioxonil*. The residue is fat-soluble.

At the Forty-ninth Session of the CCPR, fludioxonil was scheduled for the evaluation of additional uses by the 2018 JMPR

The current Meeting received additional analytical methods, GAP information and residue trial data for uses on blueberries, currants, guava, avocado, pomegranate, pineapple, bulb onion, green onion, mustard greens, dry pea, dry soya bean, carrot and celery. In addition, processing data for carrots and a new dairy cow feeding study was received.

#### **Methods of analysis**

The Meeting received additional information on analytical methods for fludioxonil in soya bean.

Method POPIT MET.073.Rev11 and POPIT MET.073.Rev16 employ shaking of the sample material with methanol. The resulting extract is further diluted with methanol and 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 fludioxonil in soya beans.

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

##### *Blueberries*

Blueberries were previously evaluated by the 2004 JMPR where a maximum residue level of 2 mg/kg and a STMR of 0.60 mg/kg was estimated for fludioxonil based on a GAP from the USA using four foliar applications at a rate of 250 g ai/ha and a 0 day PHI. The residue levels from the trials considered by the 2004 JMPR in ranked order were (n = 8): < 0.05, 0.14, 0.26, 0.52, 0.68, 0.84, 0.90 and 1.4 mg/kg.

The 2018 Meeting considered the critical GAP for use on bush berries in Canada that allows three foliar applications at a rate of 244 g ai/ha with a 7 day re-treatment interval and 1 day PHI. Two new trials from Canada matching the GAP were submitted, resulting in residues of 0.88 and 1.7 mg/kg in the fruits.

The Meeting agreed that the existing maximum residue level accommodates for residues of fludioxonil according to the Canadian GAP.

##### *Currants, black, red, white*

The use of fludioxonil on currants was previously evaluated by the 2004 JMPR, but as no relevant label was provided, no recommendations could be made.

The current Meeting considered, the critical GAP for use on currants in Ireland that allows three foliar applications at a rate of 250 g ai/ha with a 10 day interval between the 1<sup>st</sup> and 2<sup>nd</sup> applications, a 28 day interval between the 2<sup>nd</sup> and 3<sup>rd</sup>, and a PHI of 7 days.

Field trials with black- and red currant from Germany, already submitted for the 2004 JMPR, were re-evaluated and residues of fludioxonil following GAP treatment ( $\pm 25\%$ ) were ( $n = 5$ ): 0.26, 0.60, 0.62, 0.63 and 1.4 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg and a STMR of 0.62 mg/kg for fludioxonil in currants, black, red, white.

#### *Guava*

The critical GAP for the use on guava in the USA allows for four foliar applications at a rate of 245 g ai/ha with a 7 day re-treatment interval and a PHI of 0 days.

In field trials on guava from the USA, residues of fludioxonil following GAP treatment ( $\pm 25\%$ ) were ( $n = 4$ ): 0.11, 0.12, 0.13 and 0.19 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg and a STMR of 0.125 mg/kg for fludioxonil in guava.

#### *Avocado*

The use of fludioxonil on avocado as foliar treatment was previously evaluated by the 2013 JMPR where a maximum residue level of 0.4 mg/kg and a STMR of 0.05 mg/kg were estimated, based on trials from the USA.

The current Meeting received GAP information for the use on avocado from Australia, which comprised one post-harvest dip/drench/flood spray application at a rate of 60 g ai/hL.

In trials performed in Australia on avocados receiving a dip treatment, residues of fludioxonil in whole fruits following GAP treatment ( $\pm 25\%$ ) were ( $n = 8$ ): 0.25, 0.26, 0.41, 0.43, 0.47, 0.52, 0.59 and 0.76 mg/kg.

Corresponding residues in the flesh were: < 0.01(2) and 0.01(6) mg/kg.

In two trials involving a flood spray treatment residues of fludioxonil found were: 0.62 and 0.80 mg/kg. Corresponding residues in the flesh were: < 0.01(2) mg/kg.

The Meeting noted that both treatment resulted in comparable residue levels and decided to combine both data sets ( $n = 10$ ): 0.25, 0.26, 0.41, 0.43, 0.47, 0.52, 0.59, 0.62, 0.76 and 0.80 mg/kg.

Corresponding combined residues in the flesh were: < 0.01(4), 0.01(6) mg/kg.

The Meeting estimated a STMR of 0.01 mg/kg, based on the flesh, and a maximum residue level of 1.5 mg/kg for fludioxonil in avocado. The Meeting withdrew its previous recommendation for avocado of 0.4 mg/kg.

#### *Pomegranate*

Pomegranate was previously evaluated by the JMPR in 2004 and 2010, where a maximum residue level of 2 mg/kg and a STMR of 1 mg/kg were estimated for fludioxonil based on a GAP from the USA of a single dip or drench application at 60 g ai/hL.

The current Meeting considered, the critical GAP for the use on pomegranate in the USA that allows for two post-harvest dip/drench applications at a rate of 36 g ai/hL.

In trials performed in the USA, pomegranates received either 2× dip applications or 1× dip plus 1× drench application at 36 g ai/hL for 30 seconds each. The samples were allowed to dry between treatments. Residues of fludioxonil following 2× dip treatments were (n = 4) 1.3, 1.7, 1.8 and 2.0 mg/kg, while residues after 1× dip plus 1× drench treatment were (n = 4) 0.72, 0.88, 0.92 and 1.0 mg/kg.

As the treatments resulted in appreciably different residues, the Meeting decided to only consider the double dip treatment for the estimation of maximum residue levels as it resulted in the higher residues.

On the basis that the variability of residues from post-harvest treatment is lower the Meeting decided that a lower maximum residue level was sufficient. Hence, the Meeting estimated a STMR of 1.75 mg/kg and a maximum residue level of 3 mg/kg (based on the mean + 4 SD) for fludioxonil in pomegranate (whole fruit). The Meeting withdraws its previous recommendation for pomegranate of 2 mg/kg.

### *Pineapple*

The use of fludioxonil on pineapple was previously evaluated by the 2013 JMPR, but no recommendations were made.

The current Meeting considered, the critical GAP for the post-harvest use on pineapples in the USA that allows one drench treatment and one spray treatment at a rate of 60 g ai/hL.

In trials conducted in the USA, residues of fludioxonil following GAP treatment ( $\pm 25\%$ ) were (n = 4): 1.4, 1.9, 2.1 and 2.8 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg (based on the mean + 4 SD) and a STMR of 2.0 mg/kg for fludioxonil in pineapple.

### *Bulb onion*

Bulb onion was previously evaluated by the 2004 JMPR where a maximum residue level of 0.5 mg/kg and a STMR of 0.04 mg/kg were estimated for fludioxonil based on a GAP of the USA comprising four foliar applications at 245 g ai/ha and a 7-day PHI. The ranked order of residues were (n = 13): < 0.02(5), 0.04(3), 0.05, 0.06(2), 0.07 and 0.34 mg/kg.

For the current Meeting additional trials on onion conducted in the USA based on the same GAP (bulb vegetables) were provided. Residues of fludioxonil matching the GAP were (n = 3): < 0.01, 0.02 and 0.10 mg/kg.

The Meeting decided that its previous recommendations for a maximum residue level of 0.5 mg/kg and a STMR of 0.04 mg/kg also accommodated the residues found in the newly submitted data on bulb onion. However, the Meeting decided to withdraw its previous recommendation for a maximum residue level for bulb onion of 0.5 mg/kg and estimated a maximum residue level of 0.5 mg/kg for the Subgroup of Bulb onions.

### *Green onion*

Green onion was previously evaluated by the 2004 JMPR where a maximum residue level of 5 mg/kg and a STMR of 0.59 mg/kg was estimated for fludioxonil based on a GAP from the USA comprising four foliar applications at 245 g ai/ha and a 7-days PHI. The ranked order of residues was (n = 3): 0.14, 0.59 and 3.0 mg/kg.

The current Meeting considered the critical GAP on green onion in the USA that allows four foliar applications at a rate of 245 g ai/ha with a 7 day re-treatment interval and a 7 days PHI. However, no trials

were provided matching this GAP. An alternative GAP from Italy was available that allows three foliar applications at a rate of 250 g ai/ha with a 10 day re-treatment interval and a 7-day PHI.

In field trials with green onion from Europe matching the Italian GAP, residues of fludioxonil were (n = 8): 0.05, 0.10, 0.11(2), 0.17, 0.20, 0.35 and 0.47 mg/kg.

The Meeting estimated a maximum residue level of 0.8 mg/kg and a STMR of 0.14 mg/kg for fludioxonil in the subgroup of green onions.

#### *Head cabbage*

Head cabbage was previously evaluated by the 2004 JMPR where a maximum residue level of 2 mg/kg and a STMR of 0.24 mg/kg were estimated for fludioxonil based on a GAP from the USA using four foliar applications at 250 g ai/ha and a 7 days PHI. The ranked order of residues matching the GAP was (n = 6): 0.17(2), 0.21, 0.27, 0.50 and 1.2 mg/kg.

The 2018 Meeting considered the critical on brassica leafy vegetables from the USA that allows four foliar applications at 250 g ai/ha and a 7-day PHI. Additional trials on cabbage from the USA were provided. Residues of fludioxonil matching the GAP were (n = 5): 0.08, 0.09, 0.21, 0.35 and 0.99 mg/kg.

The Meeting decided that its previous recommendations of a maximum residue level of 2 mg/kg and a STMR of 0.24 mg/kg also accommodate for residues found in the newly submitted data on cabbage.

#### *Mustard greens*

Mustard greens were previously evaluated by the 2004 JMPR where a maximum residue level of 10 mg/kg and a STMR of 1.2 mg/kg were estimated for fludioxonil based on a GAP from the USA comprising of four foliar applications at 240 g ai/ha with a 7 days PHI. The ranked order of residues (combined with watercress) matching the GAP was (n = 9): 0.06, 0.49, 0.54, 0.76, 1.2, 4.2, 4.5, 6.6 and 7.1 mg/kg.

The current Meeting received GAP information for use in brassica leafy vegetables from the USA, which allows four foliar applications at 250 g ai/ha and a 7 days PHI. One additional trial for mustard greens from the USA was provided. Residues of fludioxonil matching the GAP were (n = 1): 1.0 mg/kg.

The Meeting decided that residue levels found in the newly submitted data on mustard greens would be accommodated by its previous recommendations of a maximum residue level of 10 mg/kg and a STMR of 1.2 mg/kg. However, the Meeting decided to withdraw its previous recommendation of a maximum residue level for mustard greens of 10 mg/kg and estimated a maximum residue level of 15 mg/kg for the subgroup of Brassica leafy vegetables.

#### *Lentils and chick-peas*

The current Meeting received GAP information on the use in lentils and chick-peas from Canada, which allows for three foliar applications at a rate of 244 g ai/ha with a 7-day re-treatment interval and a PHI of 7 days.

In dry peas, residues of fludioxonil following GAP treatment ( $\pm 25\%$ ) were (n = 7): 0.018, 0.046(2), 0.11(2), 0.13 and 0.17 mg/kg.

The Meeting estimated a maximum residue level and STMR of 0.3 mg/kg and 0.11 mg/kg respectively for lentils and chick-peas, based on the data from dry peas.

#### *Soya beans (dry)*

Fludioxonil is registered in Brazil for use on soya beans with a GAP comprising two foliar applications at a

rate of 250 g ai/ha with a 7-day re-treatment interval and a PHI of 30 days.

In soya beans, residues of fludioxonil following Brazilian GAP treatment ( $\pm 25\%$ ) were ( $n = 8$ ): < 0.01(4), 0.01, 0.02, 0.03 and 0.13 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and a STMR of 0.01 mg/kg for fludioxonil in soya beans (dry).

### *Carrot*

Carrot was previously evaluated by the 2004 JMPR where a maximum residue level of 0.7 mg/kg and a STMR of 0.2 mg/kg were estimated for fludioxonil based on a GAP from the USA, comprising of four foliar applications at 250 g ai/ha with a 7 days PHI. The ranked order of residues, matching GAP were ( $n = 7$ ): 0.04, 0.16, 0.18, 0.20, 0.20, 0.25, 0.42 mg/kg.

The current Meeting received new GAP information for fludioxonil from the USA which comprised two post-harvest dip/drench applications at a rate of 29 g ai/hL.

In trials conducted in the USA on carrots, residues of fludioxonil matching GAP ( $\pm 25\%$ ) were ( $n = 2$ ): 2.4 and 2.6 mg/kg.

The Meeting noted that the data submitted for post-harvest treatment was insufficient for a recommendation.

An alternative GAP for the use of fludioxonil on carrots was available from Germany with three foliar applications at a rate of 250 g ai/ha, a 7-day re-treatment interval and a PHI of 7 days.

Residues in carrots from European trials with fludioxonil following GAP ( $\pm 25\%$ ) were ( $n = 15$ ): 0.04, 0.05, 0.06(2), 0.07, 0.09, 0.18, 0.19, 0.29, 0.30, 0.40, 0.41, 0.44, 0.52 and 0.54 mg/kg. The Meeting noted that the RTI in the trials was 14 days, i.e. twice as long as the GAP. However, as decline studies showed that no significant degradation occurred, the Meeting decided that the trials approximated the German GAP.

The Meeting estimated a STMR of 0.19 mg/kg and a maximum residue level of 1 mg/kg for fludioxonil in carrot. The latter replaces the previous recommendation for carrots (0.7 mg/kg).

### *Celery*

Fludioxonil is registered in the USA for use on celery with four applications at a rate of 245 g ai/ha with a 7-day re-treatment interval and a 0-day PHI.

In celery trials from the USA, residues of fludioxonil matching following GAP ( $\pm 25\%$ ) were ( $n = 8$ ): 1.8, 2.3, 3.2, 4.0, 5.1, 5.8, 5.9 and 7.8 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg and a STMR of 4.55 mg/kg for fludioxonil in celery.

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

The Meeting received new information on the fate of fludioxonil residues following the processing of carrots.

Estimated processing factors for the commodities considered at this Meeting are summarised below.

Raw commodity	Processed commodity	Individual processing factors	Mean or best estimate processing factor	STMR-P = STMR <sub>RAC</sub> × PF (mg/kg)
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Carrot	Carrots (canned)	0.10, 0.13, 0.13, 0.19	0.14	0.027
	Juice (pasteurised)	0.16, 0.16, 0.14, 0.27	0.18	0.034
	Carrots (cooked)	0.09, 0.12, 0.12, 0.15	0.12	0.023

### *Residues in animal commodities*

#### *Farm animal feeding studies*

The Meeting received one new feeding study involving the dosing of lactating cows with fludioxonil. The study was conducted at treatment rates of 20 and 100 ppm for 28 days. Residues were determined as the total residue of fludioxonil.

In milk, residues in the 20 ppm group were up to 0.067 mg/kg (mean 0.030 mg/kg) and in the 100 ppm group up to 0.26 mg/kg (mean 0.15 mg/kg).

In muscle residue were < 0.01 mg/kg at the 20 ppm level and up to 0.012 mg/kg (mean: 0.011 mg/kg) at the 100 ppm level.

In liver at the 20 and 100 ppm feeding levels, residues were up to 0.079 mg/kg (mean 0.055 mg/kg) and 0.35 mg/kg (mean: 0.29 mg/kg), respectively.

In kidney at the 20 and 100 ppm feeding levels, residues were up to 0.082 mg/kg (mean 0.062 mg/kg) and 0.29 mg/kg (mean: 0.27 mg/kg), respectively.

In fat at the 20 and 100 ppm feeding levels, residues were up to 0.011 mg/kg (mean 0.01 mg/kg) and 0.033 mg/kg (mean: 0.032 mg/kg), respectively.

#### *Estimated maximum and mean dietary burdens of farm animals*

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 OECD diets listed in Appendix IX of the 2016 edition of the FAO manual, are presented in Annex 6 and summarised below.

Previous evaluations included the following potential feed items: rape greens, potato culls, cereal grain, dry beans, apple pomace, rape seed meal, sweet corn cannery waste, cotton meal and tomato pomace. Feed items from this evaluation were additionally cabbage, kale, carrot, dry pea and soya bean.

	Livestock dietary burden, Fludioxonil, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max.	Mean	max.	mean	max.	Mean	max.	Mean
Beef cattle	5.2	3.1	15	5.3	6.3	5.6	0.023	0.023
Dairy cattle	2.3	1.6	15	4.6	23 <sup>a</sup>	6.4 <sup>b</sup>	0.023	0.023
Poultry – broiler	0.029	0.029	1.5	0.78	0.042	0.042	0.023	0.023
Poultry – layer	0.029	0.029	1.9 <sup>c</sup>	0.86 <sup>d</sup>	0.042	0.042	0.023	0.023

<sup>a</sup> Highest maximum beef or dairy cattle burden suitable for maximum residue level estimates for mammalian tissues and milk

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

<sup>c</sup> Highest maximum broiler or laying hen burden suitable for maximum residue level estimates for poultry products and eggs

<sup>d</sup> Highest mean broiler or laying hen burden suitable for STMR estimates for poultry products and eggs

For beef and dairy cattle, a maximum and mean dietary burden of 23 ppm and 6.4 ppm were estimated, respectively.

For maximum residue level estimation, residues were calculated by interpolating between the 20 and 100 ppm dosing levels in the lactating cow feeding study using the maximum dietary burden of 23 ppm.

Maximum residue level beef or dairy cattle	Feed level (ppm) for milk residues	Total residue in milk (mg/kg)	Feed level (ppm) for tissue residues	Total residue of fludioxonil (mg/kg)			
				Liver	Kidney	Muscle	Fat
Feeding study	20	0.030	20	0.079	0.082	< 0.01	0.011
	100	0.15	100	0.35	0.29	0.012	0.033
Dietary burden and highest residue	23	0.035	23	0.089	0.090	0.010	0.012

For the estimation of STMRs the mean dietary burden of 6.4 ppm was used. Although in the previously evaluated feeding study, performed at 5.5 ppm (JMPR 2004) residues were consistently <LOQ (< 0.05 mg/kg), the Meeting decided to extrapolate from the 20 ppm feeding level of the new study, since residues were found.

STMR beef or dairy cattle	Feed level (ppm) for milk residues	Total residue in milk (mg/kg)	Feed level (ppm) for tissue residues	Total residue of fludioxonil (mg/kg)			
				Liver	Kidney	Muscle	Fat
Feeding study	20	0.026	20	0.055	0.062	< 0.01	0.01
Dietary burden and mean residue	6.4	0.008	6.4	0.018	0.020	< 0.01	0.003

### ***Animal commodity maximum residue levels***

The Meeting recommended a maximum residue level for milks at 0.04 mg/kg, edible offal (mammalian) at 0.1 mg/kg, mammalian muscle (fat) at 0.02 mg/kg and mammalian fats at 0.02 mg/kg, withdrawing the previous recommendations of 0.05(\*) mg/kg for edible offal (mammalian), 0.01 mg/kg for milks and 0.01 mg/kg for meat.

The Meeting estimated STMR values of 0.008 mg/kg in milks, 0.01 mg/kg in muscle, 0.003 mg/kg in fat and 0.020 mg/kg in edible offal (mammalian).

For poultry a maximum and mean dietary burden of 1.9 ppm and 0.86 ppm were estimated, respectively. A feeding study performed with poultry at dosing levels of 1.54, 4.64 and 15.4 ppm was evaluated by the 2013 JMPR. In the relevant dosing group of 1.54 ppm liver samples showed residues of fludioxonil at up to 0.08 mg/kg (mean: 0.05 mg/kg). Other tissues from animals in the 1.54 ppm dose group were not analysed since samples were <LOQ at the higher feeding levels.

For maximum residue level estimation, residues were calculated by interpolating between the 1.54 and 4.64 ppm dosing levels using the maximum dietary burden of 1.9 ppm.

Maximum residue level broiler or layer poultry	Feed level (ppm) for egg residues	Total residue in egg (mg/kg)	Feed level (ppm) for tissue residues	Total residue of fludioxonil (mg/kg)		
				Liver	Muscle	Fat
Feeding study	1.54	< 0.01	1.54	0.080	< 0.01	< 0.01
	4.64	0.013	4.64	0.21	< 0.01	< 0.01
Dietary burden and highest residue	1.9	0.011	1.9	0.095	< 0.01	< 0.01

For the estimation of STMR values for eggs and poultry tissues, the mean dietary burden of 0.86 mg/kg was used and residues estimated by extrapolating from the 1.54 ppm feeding level of the previously submitted poultry feeding study (JMPR, 2013).

STMR broiler or layer poultry	Feed level (ppm) for egg residues	Total residue in egg (mg/kg)	Feed level (ppm) for tissue residues	Total residue of fludioxonil (mg/kg)		
				Liver	Muscle	Fat
Feeding study	1.54	< 0.01	1.54	0.050	< 0.01	< 0.01
Dietary burden and mean residue	0.86	< 0.01	0.86	0.028	< 0.01	< 0.01

The Meeting recommended a maximum residue level of 0.02 mg/kg for eggs and 0.1 mg/kg for poultry edible offal, withdrawing the previous recommendation of 0.01(\*) mg/kg for eggs and 0.05 mg/kg for poultry edible offal. The Meeting also recommended a maximum residue level of 0.01(\*) mg/kg for poultry fat and confirmed its previous recommendations of 0.01(\*) mg/kg for poultry meat.

The Meeting estimated a STMR value of 0.028 mg/kg in poultry edible offal and 0.01 mg/kg for eggs and confirmed the previously estimated STMR values of 0 mg/kg for poultry meat and fat.

### 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 for dietary risk assessment for plant commodities: *fludioxonil*.

Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: *sum of fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid and expressed as fludioxonil*.

The residue is fat-soluble.

### DIETARY RISK ASSESSMENT

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

The ADI for fludioxonil is 0–0.4 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for fludioxonil 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 2018 JMPR Report. The IEDIs ranged from 1–6% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of fludioxonil from uses considered by the JMPR is unlikely to present a public health concern.

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

The 2004 JMPR decided that an ARfD for fludioxonil was unnecessary. The current Meeting therefore concluded that the acute dietary exposure to residues of fludioxonil from the uses considered is unlikely to present a public health concern.



## 5.12 FLUXAPYROXAD (256)

### TOXICOLOGY

Fluxapyroxad was evaluated in 2012 by JMPR, which concluded that high doses of fluxapyroxad caused hepatocellular adenomas and carcinomas and thyroid follicular cell adenomas and carcinomas in rats.

Following a request for additional maximum residue levels by CCPR, fluxapyroxad was placed on the agenda of the present Meeting, which assessed additional toxicological information on fluxapyroxad available since the last review.

Five in vitro studies were provided that investigated the potential of fluxapyroxad to activate nuclear hormone receptors and to stimulate cell proliferation using rat or human hepatocytes or rat liver microsomes to support the mode of action proposed for rodent liver tumours and its lack of relevance to humans.

#### *Toxicological data*

In vitro studies in constitutive androstane receptor (CAR) wild-type and knock-out rat hepatocytes show that fluxapyroxad can activate the nuclear receptors CAR and pregnane X receptor (PXR), leading to the induction of the P450 (CYP) enzymes CYP2B and CYP3A and hepatocellular proliferation. Qualitatively, these effects of fluxapyroxad are similar to those of phenobarbital.

An in vitro study using human hepatocytes showed that, similar to phenobarbital, fluxapyroxad can activate human CAR and PXR but does not stimulate proliferation of these cells.

#### **Toxicological evaluation**

The new in vitro studies support the conclusion of the 2012 Meeting that high doses of fluxapyroxad cause hepatocellular adenomas and carcinomas in rats through a mitogenic mode of action associated with induction of CYP2B-type P450, and that this mode of action does not occur in humans.

The Meeting concluded that the new studies support the existing ADI of 0–0.02 mg/kg bw and have no impact on the ARfD of 0.3 mg/kg bw established in 2012.

A toxicological addendum to the monograph was prepared.

### RESIDUE AND ANALYTICAL ASPECTS

Fluxapyroxad is a fungicide from the carboxamide class of active ingredients. It inhibits succinate dehydrogenase in Complex II of the mitochondrial respiratory chain, resulting in inhibition of spore germination, germ tubes, and mycelial growth. Fluxapyroxad was first evaluated by the JMPR in 2012, at which time the Meeting established an ADI of up to 0.02 mg/kg bw and an ARfD of 0.3 mg/kg bw. The 2012 Meeting established residue definitions of *fluxapyroxad* for MRL compliance for both plant and animal commodities.

The residue definition for estimating dietary risk from plant commodities is 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 residue definition for estimating dietary risk from animal

commodities is the 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. Additional new uses were considered by the 2015 Meeting.

Fluxapyroxad was listed by the Forty-ninth Session of the CCPR for the evaluation of additional uses. The 2018 Meeting received information on the registered uses and residue data reflecting use on citrus fruits, mango, papaya, potato, cotton, coffee, and alfalfa, as well as processing studies on citrus and peanut.

### **Methods of analysis**

Residue analysis for all sample results submitted to the 2018 Meeting was done using BASF Method L0137/01. This LC-MS/MS method was found acceptable by the 2012 JMPR.

For all matrices, validation data generated concurrently with each residue study demonstrated adequate method performance for the residues of interest (fluxapyroxad, M700F008, M700F048; recoveries 70–100%, maximum < 20% RSD). The limit of quantitation, defined as the lowest limit of method validation, was 0.01 mg/kg for all analytes and matrices.

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

No new storage stability studies were submitted to the 2018 Meeting. Through evaluation of storage stability and metabolism study data, the 2012 Meeting concluded that fluxapyroxad and M700F048 were stable for up to 27 months in a variety of matrices, and M700F008 was stable for at least 37 to 39 months in wheat forage, grain, and straw, and soya bean seed. The 2018 Meeting concluded that the findings of the 2012 Meeting, coupled with the stability of fluxapyroxad in the hydrolysis study, connote stability of residues for at least 2 years in all of the matrices considered by the 2018 Meeting.

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

The Meeting received supervised trial data for applications of fluxapyroxad to citrus fruits, mango, papaya, potato, cotton, coffee, and alfalfa. Residues from the trials were analysed by suitable analytical methods. Across all studies, samples were stored frozen for a maximum of 1.3 years; therefore, residues of fluxapyroxad are considered to be stable in all samples.

Labels for end-use products containing fluxapyroxad were available from Argentina, Belarus, Brazil, Canada, China, Dominican Republic, El Salvador, France, Guatemala, Honduras, Italy, Mexico, Nicaragua, Slovenia, South Africa, Switzerland, Taiwan Province of China, Trinidad and Tobago, Turkey, Ukraine, the United Kingdom, the USA, and Uruguay describing the registered uses of fluxapyroxad.

When calculating total fluxapyroxad residues (defined as the sum of fluxapyroxad, M700F008, and M700F048, expressed as fluxapyroxad), values below the LOQ were assumed to be at the LOQ and for the metabolites M700F008 and M700F048 values below the LOD (< 0.002 mg/kg or < 0.001 mg/kg) were assumed to be zero; total residues are denoted as being <LOQ only when all residues of interest from a sample were <LOQ. Examples are shown below

Fluxapyroxad, mg/kg		M700F008, mg eq/kg		M700F048, mg eq/kg		Total, mg eq/kg
Reported	Assumed	Reported	Assumed	Reported	Assumed	
ND	0.01	ND	0	ND	0	< 0.01
< 0.01	0.01	< 0.01	0.01	< 0.01	0.01	< 0.03
		ND	0	ND	0	< 0.01
0.321	0.321	ND	0	ND	0	0.321

Fluxapyroxad, mg/kg		M700F008, mg eq/kg		M700F048, mg eq/kg		Total, mg eq/kg
Reported	Assumed	Reported	Assumed	Reported	Assumed	
		< 0.01	0.01			0.331
		0.054	0.054	< 0.01	0.01	0.385

### *Citrus fruits, Group of*

The cGAP is the registration in the USA for use on the citrus crop group. The cGap consists of four applications on a 10-day interval, each at 138 g ai/ha, and a 0-day PHI. Twenty-six trials matching the cGAP were conducted in the USA resulting in 23 independent residue results (lemon (7), grapefruit (5), mandarin (1) and orange (10)).

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;

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

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

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.

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;

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

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

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.

Noting that the median residues of fluxapyroxad, *per se*, for each fruit type are within a 5-fold range, that there is no evidence of a difference in the residue populations across the citrus types by the Kruskal-Wallis test ( $p = 0.025$ ; mandarin was not tested), and that the result for mandarin is encompassed by the results for lemon and orange, the Meeting decided to make a recommendation for the Group of Citrus Fruit based on the combined data.

The combined data, in rank order, for **fluxapyroxad, *per se***, are (n = 23): 0.10, 0.15 (3), 0.16 (2), 0.18, 0.24, 0.27, 0.32, 0.33 (2), 0.37 (2), 0.38 (2), 0.40 (2), 0.44, 0.45, 0.50, 0.52 and 0.58 mg/kg.

The combined data, in rank order, for **total fluxapyroxad** are (n = 23): 0.10, 0.15 (3), 0.16 (2), 0.18, 0.24, 0.27, 0.32, 0.33 (2), 0.37, 0.38, 0.39, 0.40 (2), 0.41, 0.44, 0.46, 0.50, 0.52, and 0.59 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg for the Group of Citrus Fruits, with a corresponding STMR of 0.33 mg/kg and HR of 0.59 mg/kg. Furthermore, the Meeting withdrew its previous maximum residue recommendation of 0.3 mg/kg for Oranges, Sweet, Sour (including Orange-like hybrids)

### *Mango*

The cGAP is for the registration in Brazil and consists of up to four applications on a 7-day interval, each at 66.8 g ai/ha, and a 7-day PHI. Six trials were conducted in Brazil matching the cGAP.

Residues of M700F008 and M700F048 did not contribute significantly to the total residue; therefore, residues of **fluxapyroxad, *per se***, and **total fluxapyroxad** were (n = 6): 0.06, 0.10 0.13, 0.16, 0.20, and 0.37 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg for residues of fluxapyroxad in mango. For dietary assessment of mango, the Meeting estimated a STMR of 0.145 mg/kg and a HR of 0.37 mg/kg.

#### *Papaya*

The cGAP is for the registration in Brazil and consists of up to four applications on a 7-day interval, each at 66.8 g ai/ha, and a 7-day PHI. Six trials were conducted in Brazil matching the cGAP.

Residues of **fluxapyroxad, per se**, were (n = 6): < 0.01 (2), 0.02, 0.07, 0.42, and 0.46 mg/kg.

Residues of **total fluxapyroxad** were (n = 6): < 0.01 (2), 0.02, 0.091, 0.46, and 0.51 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg for residues of fluxapyroxad in papaya. For dietary assessment of papaya, the Meeting estimated a STMR of 0.054 mg/kg and a HR of 0.51 mg/kg.

#### *Potato*

Fluxapyroxad is registered for use on potato with multiple GAPs. The residue data show that the cGAP is for the registration in various European countries, represented by the registration in Italy, and consists of a single, at-planting application at 240 g ai/ha; a PHI not specified. Sixteen trials were conducted across EU countries matching the cGAP for potato.

Residues of **fluxapyroxad, per se**, were (n = 16): < 0.01 (4), 0.01 (4), 0.02 (4), 0.03, and 0.04 (3) mg/kg.

Residues of **total fluxapyroxad** were (n = 16): < 0.03 (4), 0.03 (4), 0.04 (4), 0.05, and 0.06 (3) mg/kg.

The Meeting estimated a maximum residue level of 0.07 mg/kg for residues of fluxapyroxad in potato to replace its previous recommendation of 0.03 mg/kg. For dietary assessment of potato, the Meeting estimated a STMR of 0.035 mg/kg and a HR of 0.06 mg/kg.

In addition to the cGAP for potato, there is a cGAP for the registration of fluxapyroxad in the USA for use on the tuberous and corm vegetable subgroup. The subgroup cGAP is for up to 3 foliar applications on a 7-day interval, each at 0.099 kg ai/ha, and a 7-day PHI. Nineteen independent trials on potato were conducted in the USA matching the subgroup cGAP.

Residues of **fluxapyroxad, per se**, were (n = 19): < 0.01 (17) and 0.02(2) mg/kg.

Residues of **total fluxapyroxad** were (n = 19): < 0.01 (14), < 0.02 (2), 0.02 (2), and < 0.03 mg/kg.

The Meeting estimated a maximum residue level of 0.03 mg/kg for residues of fluxapyroxad in the subgroup of tuberous and corm vegetables except potato. For dietary assessment of that subgroup, the Meeting estimated and STMR of 0.01 mg/kg and a HR of 0.03 mg/kg.

#### *Cotton seed*

The cGAP is for the registration in Brazil and consists of up to four applications on a 12-day interval, each at 58.5 g ai/ha, and a 14-day PHI. Four trials were conducted in Brazil matching the cGAP.

Residues of M700F008 and M700F048 did not contribute significantly to the total residue; therefore, residues of **fluxapyroxad, per se**, and **total fluxapyroxad** were (n = 4): 0.03, 0.06, 0.10, and 0.21 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg for residues of fluxapyroxad in cotton seed to replace its previous recommendation of 0.3 mg/kg. For dietary assessment of cotton commodities, the Meeting estimated a STMR of 0.08 mg/kg.

### *Coffee*

The cGAP is from the registration in Brazil and consists of up to three applications on a 45-day interval, each at 100 g ai/ha, and a 45-day PHI. Eight trials were conducted in Brazil matching the cGAP.

Residues of **fluxapyroxad, per se**, were (n = 9): < 0.01, 0.020, 0.021, 0.022 (2), 0.033, 0.039, 0.041, and 0.076 mg/kg.

Residues of **total fluxapyroxad** were (n = 9): < 0.01, 0.02, 0.022, 0.041, 0.042, 0.053, 0.059, 0.061, and 0.096 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg for residues of fluxapyroxad in coffee beans. For dietary assessment of coffee, the Meeting estimated a STMR of 0.042 mg/kg.

### ***Animal feeds***

#### *Alfalfa*

The cGAP is for the registration in the USA and consists of up to two applications per cutting on a 14-day interval, each at 0.1 kg ai/ha, and a 14-day PHI; not to exceed three applications per year. Ten trials were conducted in Canada and the USA matching the cGAP.

#### *Forage (green)*

Residues of **total fluxapyroxad** in fodder were (n = 10): 0.11, 0.14, 0.18, 0.23, 0.47, 0.58, 1.5, 1.8, 2.1, and 2.8 mg/kg.

For livestock dietary burden considerations, the Meeting estimated a median residue of 0.52 mg/kg and a highest residue of 2.8 mg/kg.

#### *Hay*

Residues of **fluxapyroxad, per se**, in hay were (n = 10): < 0.01 (5), 0.05, 0.33, 0.36, 8.1, and 8.6 mg/kg. On a dry-weight basis, these residues correspond to < 0.011 (5), 0.056, 0.37, 0.4, 9.1, and, 9.6 mg/kg.

Residues of **total fluxapyroxad** in hay (as received) were (n = 10): < 0.01 (4), < 0.02, 0.06, 0.35, 0.89, 8.2 and 9.9 mg/kg.

The Meeting estimated a maximum residue level of 20 mg/kg for residues of fluxapyroxad in alfalfa hay (dry). For livestock dietary burden considerations, the Meeting estimated a median residue of 0.04 mg/kg (as received) and a highest residue of 9.9 mg/kg (as received).

#### *Cotton gin trash*

Cotton gin trash was not assayed in the trials reported to the current meeting. The 2015 Meeting evaluated studies that included residue data from two field trials for cotton gin trash, concluding that the data were insufficient for the estimation of median and highest residues. The current Meeting confirms that conclusion.

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

#### *Residues in processed commodities*

The Meeting received data from processing studies conducted in orange and peanut. Residues of the metabolites M700F008 and M700F048 were below the LOQ in all samples from the processing studies, except for one sample of orange oil. Residues reported as <LOQ were assumed to be at the LOQ

(0.01 mg/kg) for calculating processing factors. In estimating the processing factor for total fluxapyroxad residues, only residues contributing at least 10% to the total were included.

Processing factors calculated for fluxapyroxad, *per se*, and total fluxapyroxad, and estimates of STMR-P and HR-P for studies evaluated by the current Meeting

Crop	Commodity	Fluxapyroxad		Total fluxapyroxad		
		Processing factors [best estimate]	MRL, mg/kg	Processing factors [best estimate]	STMR-P, mg/kg	HR-P, mg/kg
Orange	Whole fruit	--	1	--	0.33	0.59 <sup>a</sup>
	Wet pomace	1.2, 1.15 [1.2]	--	1.2, 1.15 [1.2]	0.46	
	Dried pulp	6.2, 3.48 [4.8]	--	6.2, 3.48 [4.8]	1.8	
	Peel	2.5, 1.23 [1.9]	--	2.5, 1.23 [1.9]	0.72	1.1
	Juice	0.12, 0.018 [0.12]	--	0.032, 0.048 [0.040]	0.015	
	Marmalade	0.045, 0.039 [0.042]	--	0.065, 0.069 [0.067]	0.025	
	Oil	65, 53 [59]	60	65, 53 [59]	22	

<sup>a</sup> From orange

The Meeting estimated a maximum residue level of 60 mg/kg for residues of fluxapyroxad in orange oil. For dietary assessment of orange oil, the Meeting estimated a STMR of 22 mg/kg.

Summary of processing factors for fluxapyroxad residues in potato, derived by 2012 JMPR, and cotton, derived by 2015 JMPR, with updated residue estimates

Crop	Commodity	Fluxapyroxad		Total fluxapyroxad <sup>a</sup>	
		Processing factor	MRL, mg/kg	STMR-P, mg/kg	HR-P, mg/kg
Potato (2012)	Tuber	--	0.07	0.035	0.06
	Granules/flakes	0.5	--	0.018	--
	Chips	0.5	--	0.018	--
	Peel (wet)	5	--	0.18	0.3
	Peeled tuber	0.5	--	0.018	0.03
	Boiled tuber (with peel)	0.5	--	0.018	0.03
	Baked tuber (with peel)	0.5	--	0.018	0.03
	Fried tuber (with peel)	0.5	--	0.018	0.03
	Process waste	0.5	--	0.018	--
	Dried pulp	7.0	--	0.24	--
Cotton (2015)	Undelinted seed	--	0.3	0.08	--
	Meal	0.055	--	0.0044	--
	Hulls	0.185	--	0.015	--
	Refined oil	0.045	--	0.0036	--

<sup>a</sup> The processing factor for fluxapyroxad only and total fluxapyroxad is the same due to levels of metabolites being <LOQ or <LOD.

### Residues in animal commodities

The current Meeting calculated dietary burdens based on residue estimates from previous meetings with updates to reflect feed commodities addressed by the current Meeting. Potential feed items include feedstuffs from pea, soya bean, potato, grains, cotton, almonds, citrus, and alfalfa crops. 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.

Summary of livestock dietary burdens, as ppm of dry matter, for fluxapyroxad

Livestock	Canada and US		European Union		Australia		Japan	
	Max.	Mean	Max.	Mean	Max.	Mean	Max.	Mean
Beef cattle	6.5	2.8	24	7	<b>45</b>	<b>13</b>	28	3.3
Dairy cattle	20	4.9	26	8	<b>42</b>	<b>12</b>	17	2.6
Broiler chickens	1	1.0	1.3	0.9	1.4	1.4	0.39	0.39
Layer hens	1	1	<b>5.1</b>	<b>2.7</b>	1.4	1.4	0.95	0.95

Despite the additional feed items, the Meeting noted that the dietary burdens changed by less than 2.5% from those used by the 2012 and 2015 Meetings to derive residue estimates for animal commodities, and the current Meeting did not consider further the residues in animal commodities.

### RECOMMENDATIONS

On the basis of the available data, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IESTI and IEDI assessments

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

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

The residue is fat-soluble.

### DIETARY RISK ASSESSMENT

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

The ADI for fluxapyroxad is 0–0.02 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for fluxapyroxad 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 2018 JMPR Report. The IEDIs ranged from 6–20% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of fluxapyroxad from uses considered by the JMPR is unlikely to present a public health concern.

#### **Acute dietary exposure**

The ARfD for fluxapyroxad is 0.3 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for fluxapyroxad 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 2018 JMPR Report. The IESTIs varied from 0–10% of the ARfD for children and 0–6% for the general population.

The Meeting concluded that acute dietary exposure to residues of fluxapyroxad from uses considered by the present Meeting is unlikely to present a public health concern.





## 5.13 IMAZALIL (110)

### TOXICOLOGY

Imazalil (synonym: enilconazole, a pharmaceutical) is the ISO-approved common name for 1-[2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl]-1*H*-imidazole (IUPAC), for which the CAS number is 33586-44-0.

Imazalil belongs to the group of imidazole fungicides used to control a wide range of fungi on fruits, vegetables and ornamentals. Its fungicidal mode of action is by inhibition of sterol biosynthesis.

Imazalil was previously evaluated by JMPR in 1977, 1980, 1985, 1986, 1991, 2000, 2001 and 2005. In 1991, JMPR established an ADI of 0–0.03 mg/kg bw, based on a NOAEL for clinical signs, decreased body weight gain and feed consumption, decreased serum concentrations of calcium, increased alkaline phosphatase (ALP) activity and increased liver weight in a 12-month toxicity study in dogs. In 2000, JMPR reaffirmed the ADI and concluded that an ARfD was unnecessary.

In 2005, the Meeting established an ARfD of 0.05 mg/kg bw, using a NOAEL of 5 mg/kg bw per day for maternal and fetal toxicity in a study of developmental toxicity in rabbits and a safety factor of 100.

Imazalil was reviewed by the present Meeting under the periodic review programme of CCPR. New studies included a single-dose toxicity study in rats, an acute neurotoxicity study in rats, a 28-day toxicity study in rats, a 90-day toxicity study in mice, mechanistic studies to evaluate the human relevance of liver and thyroid tumours, published studies on evaluation of endocrine effects and neurodevelopmental effects, and toxicity studies on metabolites.

The evaluation of the biochemical and toxicological aspects of imazalil was based on previous JMPR evaluations, updated as necessary with additional information. All critical studies contained statements of compliance with GLP and were conducted in accordance with relevant national or international test guidelines, unless otherwise specified. A search of the open literature did not reveal any relevant publications that would have an impact on the evaluation.

#### **Biochemical aspects**

After administration of [<sup>14</sup>C]imazalil to rats by gavage at a single dose of 1.25 or 20 mg/kg bw or a repeated dose of 1.25 mg/kg bw for 14 days, [<sup>14</sup>C]imazalil was rapidly and nearly completely absorbed. Most of the label was excreted (approximately 90%) within 24 hours. More imazalil appeared in the urine (49–60% of the administered dose) than in the faeces (36–48% of the administered dose) with all dosing regimens. At 96 hours after oral administration of [<sup>14</sup>C]imazalil, tissue concentrations (including carcass) of radioactivity were about 1% of the administered dose. Nearly 50% of the radiolabel retained in the body was found in the liver.

Very little imazalil was excreted unchanged, and the compound was metabolized to at least 25 metabolites. The metabolic profiles in the urine and faeces were largely comparable. Moreover, identical metabolites were recovered in the excreta regardless of sex, dose or dosing regimen. The main routes of metabolism were epoxidation, epoxide hydration, oxidative *O*-dealkylation, imidazole oxidation and scission, and oxidative *N*-dealkylation. The metabolic pattern was similar for both sexes after both oral and intravenous administration.

#### **Toxicological data**

In rats, the lowest acute oral LD<sub>50</sub> for imazalil was 227 mg/kg bw, the acute dermal LD<sub>50</sub> was > 2000 mg/kg bw and the acute inhalation LC<sub>50</sub> was 1.84 mg/L. Imazalil was mildly irritating to the skin of rabbits and moderately irritating to their eyes. It was not sensitizing to the skin of guinea-pigs, as determined by the

Magnusson and Kligman test and the Buehler test.

In a single-dose oral toxicity study, rats were administered imazalil via gavage at a single dose of 0, 25, 100 or 400 mg/kg bw. The NOAEL was 100 mg/kg bw, based on an increased incidence of "slight" hepatocellular vacuolation in both sexes and increased liver weights in females at 400 mg/kg bw.

Short- and long-term studies in mice, rats and dogs showed that the main target organ of toxicity was the liver.

In a 3-month toxicity study in mice, imazalil was administered in the diet at a concentration of 0, 200, 400 or 800 ppm (equivalent to 0, 30, 60 and 120 mg/kg bw per day, respectively). A NOAEL could not be identified in this study, as hepatocytic vacuolation was seen at all doses in males.

In a 4-week range-finding toxicity study in rats, imazalil was administered at a dietary concentration of 0, 100, 1000, 2000 or 3000 ppm (equal to 0, 11.5, 116.7, 232.1 and 351.3 mg/kg bw per day for males and 0, 11.7, 124.0, 229.0 and 351.6 mg/kg bw per day for females, respectively). The NOAEL was 100 ppm (equal to 11.5 mg/kg bw per day), based on decreased body weights, feed consumption and heart, spleen, kidney and testis weights in males and increased liver weights in females at 1000 ppm (equivalent to 116.7 mg/kg bw per day).

In a 13-week study in rats, imazalil was administered at a dietary concentration of 0, 40, 200 or 1000 ppm (equal to 0, 4.02, 18.78 and 94.58 mg/kg bw per day for males and 0, 4.05, 20.28 and 99.34 mg/kg bw per day for females, respectively). The NOAEL was 40 ppm (equal to 4.02 mg/kg bw per day), on the basis of increased liver weights, histopathology and associated clinical chemistry changes at 200 ppm (equal to 18.78 mg/kg bw per day).

Imazalil was administered to rats for 6 months at a dietary concentration of 0, 25, 100 or 400 ppm (equivalent to 0, 1.25, 5.0 and 20 mg/kg bw per day, respectively). The NOAEL was 100 ppm (equivalent to 5.0 mg/kg bw per day), on the basis of changes in liver, kidney, lung and thymus weights in females and increased relative kidney weights in males at 400 ppm (equivalent to 20 mg/kg bw per day).

In a 1-year study, dogs received imazalil at a dose of 0, 1.25, 2.5 or 20 mg/kg bw per day orally in gelatine capsules. The NOAEL was 2.5 mg/kg bw per day, on the basis of clinical signs, decreased body weight gain and feed consumption, decreased serum calcium concentration, increased ALP activity and increased liver weight at 20 mg/kg bw per day.

In a 2-year study, dogs received imazalil at a dose of 0, 1.25, 5 or 20 mg/kg bw per day by capsule. The NOAEL was 1.25 mg/kg bw per day, based on decreased body weight gain and slight ground glass aspect of the cytoplasm in centrilobular hepatocytes at 5 mg/kg bw per day.

The overall NOAEL for imazalil in dogs was 2.5 mg/kg bw per day, on the basis of decreased body weight, decreased body weight gain and liver toxicity seen at 5 mg/kg bw per day.

In a study of carcinogenicity, mice received imazalil-sulfate via the drinking-water at a concentration of 0, 6.25, 25 or 100 ppm (equivalent to 0, 2.5, 10 and 40 mg/kg bw per day, respectively) for 18 months. This study was not considered acceptable for the evaluation because of several shortcomings in its design and conduct.

In a 23-month study of carcinogenicity, mice received imazalil at a dietary concentration of 0, 50, 200 or 600 ppm (equal to 0, 8.1, 33.4 and 105 mg/kg bw per day for males and 0, 9.9, 41.6 and 131 mg/kg bw per day for females, respectively). The NOAEL for toxicity was 50 ppm (equal to 8.1 mg/kg bw per day), on the basis of morphological changes (foci and nodules) in the livers of males at 200 ppm (equal to 33.4 mg/kg bw per day). Liver adenomas were observed in males at 200 and 600 ppm and in females at 600

ppm. The NOAEL for carcinogenicity was 50 ppm (equal to 8.1 mg/kg bw per day), based on an increased incidence of adenomas seen in males at 200 ppm (equal to 33.4 mg/kg bw per day).

In an 18-month study of toxicity in rats, imazalil was administered at a dietary concentration of 0, 25, 100 or 400 ppm (equivalent to 0, 1.2, 5 and 20 mg/kg bw per day, respectively). The NOAEL was 100 ppm (equivalent to 5 mg/kg bw per day), on the basis of decreased body weight gain in females, decreased plasma albumin concentration in males and pathological changes in the livers of males at 400 ppm (equivalent to 20 mg/kg bw per day). Although there was no evidence that imazalil was carcinogenic, the duration of the study and the number of animals used were insufficient to exclude that possibility.

In a 24-month study of toxicity and carcinogenicity, rats received diets containing imazalil at a concentration of 0, 50, 200, 1200 or 2400 ppm (equal to 0, 2.4, 9.7, 58 and 120 mg/kg bw per day for males and 0, 3.4, 13.5, 79 and 157 mg/kg bw per day for females, respectively). The NOAEL for toxicity was 50 ppm (equal to 2.4 mg/kg bw per day), on the basis of minor haematological changes in both sexes and increased blood glucose concentrations and hepatic changes (increased relative liver weight and an increased frequency of pigment-laden hepatocytes) in females at 200 ppm (equal to 9.7 mg/kg bw per day). The NOAEL for carcinogenicity was 200 ppm (equal to 9.7 mg/kg bw per day), based on an increased incidence of follicular cell neoplasia (adenoma and carcinoma combined) of the thyroid in males at 1200 ppm (equal to 58 mg/kg bw per day).

In a 30-month study of carcinogenicity, imazalil was administered to rats at a dietary concentration of 0, 25, 100 or 400 ppm (equal to 0, 1.0, 3.6 and 15 mg/kg bw per day for males and 0, 1.2, 4.7 and 19.7 mg/kg bw per day for females, respectively). The NOAEL for systemic toxicity was 100 ppm (equal to 3.6 mg/kg bw per day), on the basis of decreased body weight gain in males at 400 ppm (equal to 15 mg/kg bw per day). No treatment-related histopathological effects were observed in the liver, and there was no treatment-related increase in the incidence of tumours. The Meeting noted that the highest dose tested was lower than the LOAEL for carcinogenicity in the 24-month study.

The Meeting concluded that imazalil is carcinogenic in mice and rats.

Imazalil 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 imazalil is unlikely to be genotoxic.

The results of several mechanistic studies of the liver effects of imazalil in mice and rats and thyroid effects in rats indicate that imazalil has a phenobarbital-like mode of action in the induction of liver and thyroid tumours in rodents. The modes of action for these tumours were assessed using the International Programme on Chemical Safety (IPCS) human relevance framework. It was concluded that these carcinogenic responses are not relevant to humans.

In view of the lack of genotoxicity and the lack of human relevance of the tumours observed in mice and rats, the Meeting concluded that imazalil is unlikely to pose a carcinogenic risk to humans.

A two-generation study of reproductive toxicity was conducted in rats, in which imazalil was administered in the diet at a nominal dose of 0, 5, 20 or 80 mg/kg bw per day. The NOAEL for parental toxicity was 20 mg/kg bw per day, on the basis of reduced maternal weight gain and hepatotoxicity (vacuoles) in males at 80 mg/kg bw per day. The NOAEL for offspring toxicity was 20 mg/kg bw per day, on the basis of decreased numbers of live pups, decreased survival rate of pups and increased numbers of stillbirths at 80 mg/kg bw per day. The NOAEL for reproductive toxicity was 20 mg/kg bw per day, on the basis of increased duration of gestation for the F<sub>0</sub> and F<sub>1</sub> females and decreased gestation rate in F<sub>1</sub> females at 80 mg/kg bw per day.

In a developmental toxicity study in mice, imazalil was administered by gavage during gestation days 6 through 16 at a dose of 0, 40, 80 or 120 mg/kg bw per day. The NOAEL for maternal toxicity was 40 mg/kg bw per day, on the basis of reduced body weight gain and feed consumption at 80 mg/kg bw per day. No NOAEL was identified for embryo and fetal toxicity, as litter size and the number of live pups were decreased in all dose groups.

In a second study in mice, imazalil was administered by gavage at gestation days 6 through 16 at a dose of 0, 10, 40, 80 or 120 mg/kg bw per day. The NOAEL for maternal toxicity was 10 mg/kg bw per day, on the basis of decreased body weight gain and reduced feed consumption at 40 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 80 mg/kg bw per day, on the basis of reduced number of live fetuses, increased number of resorptions, and decreased pup body weights at 120 mg/kg bw per day. There was no evidence of teratogenicity.

In a study of developmental toxicity in rats, imazalil was administered by gavage at gestation days 6 through 16 at a dose of 0, 40, 80 or 120 mg/kg bw per day. No teratogenic effects were seen. The NOAEL for embryo and fetal toxicity was 40 mg/kg bw per day, on the basis of reduced pup weight at 80 mg/kg bw per day. A NOAEL for maternal toxicity could not be identified because of lower maternal body weight in all the groups when compared with controls.

The developmental toxicity of imazalil in rabbits was studied at gavage doses of 0, 1.25, 2.5 and 5 mg/kg bw per day administered on gestation days 6–18. The NOAEL for both maternal and embryo/fetal toxicity was 5 mg/kg bw per day, the highest dose tested.

In another study of developmental toxicity in rabbits, at gavage doses of 0, 5, 10 and 20 mg/kg bw per day administered on gestation days 6–18, the NOAEL for maternal toxicity was 5 mg/kg bw per day, on the basis of reduced feed consumption at 10 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 5 mg/kg bw per day, on the basis of an increased incidence of resorptions and a decrease in the number of live pups at 10 mg/kg bw per day.

The Meeting concluded that imazalil is not teratogenic.

In an acute neurotoxicity study, rats were given a single oral dose of imazalil of 0, 60, 180 or 600 mg/kg bw and observed for 14 days. The NOAEL for systemic toxicity was 180 mg/kg bw, on the basis of decreased body weight and body weight gains in males, deaths in females, and functional observational battery (FOB) and motor activity alterations at the time of peak effect on day 0 in females at 600 mg/kg bw. The NOAEL for neurotoxicity was 600 mg/kg bw, the highest dose tested. The Meeting noted that the highest dose used was above the LD<sub>50</sub>, and therefore the FOB results are due to general toxicity.

In a published study of reproductive toxicity in which neurobehavioural end-points were measured, mice were fed imazalil in the diet at a concentration of 0, 120, 240 or 480 ppm (equal to 0, 19, 39 and 79 mg/kg bw per day for F<sub>0</sub> males and 0, 26, 45 and 102 mg/kg bw per day for F<sub>0</sub> females before conception). The NOAEL for developmental neurotoxicity was 120 ppm (equal to 19 mg/kg bw per day), based on effects on surface righting in males at 240 ppm (equal to 39 mg/kg bw per day). The Meeting noted that parameters other than body weight were not measured in the other reproductive toxicity studies and that the lowest concentration used was higher than the NOAEL in other studies.

In a second published study of reproductive toxicity in which neurobehavioural end-points were measured, mice were fed imazalil in the diet at a concentration of 0, 6, 18 or 54 ppm (equal to 0, 0.85, 2.49 and 7.87 mg/kg bw per day, respectively, during gestation). Some neurobehavioural parameters were inconsistently affected at all doses.

The Meeting concluded that imazalil is not neurotoxic.

***Toxicological data on metabolites and/or degradates******R061000 (rat and ruminant metabolite)***

For metabolite R061000 (also known as rat metabolite 8;  $(\pm)$ -3-[2-(2,4-dichlorophenyl)-2-(2,3-dihydroxypropoxy)ethyl]-2,4-imidazolidinedione), the acute oral LD<sub>50</sub> in rats was greater than 2000 mg/kg bw. R061000 was negative for mutagenicity in a bacterial reverse mutation assay, an in vitro chromosomal aberration test and an in vitro mammalian cell gene mutation test.

The Meeting concluded that, based on the structure of R061000 and its low acute toxicity, this metabolite would be covered by the health-based guidance values for the parent compound.

***R043449 (ruminant metabolite)***

For metabolite R043449 (3-[2-(2,4-dichlorophenyl)-2-hydroxymethyl]-2,4-imidazolidinedione), the acute oral LD<sub>50</sub> in rats was greater than 2000 mg/kg bw. R043449 was negative for mutagenicity in a bacterial reverse mutation assay, an in vitro chromosomal aberration test and an in vitro mammalian cell gene mutation test.

For R043449, the Meeting noted that the TTC approach (Cramer class III) could be applied for chronic toxicity.

***R014821 (plant and rat metabolite)***

A single-dose study was conducted for the metabolite R014821 (also known as rat metabolite 11; *(RS)*-1-(2,4-dichlorophenyl)-2-imidazol-1-yl-ethanol). Rats were gavaged with a single R014821 dose of 0, 125, 500 or 2000 mg/kg bw. The NOAEL was 125 mg/kg bw, based on reduced feed consumption and body weight gain at 500 mg/kg bw. R014821 was negative for mutagenicity in an in vitro chromosomal aberration test and an in vitro mammalian cell gene mutation test.

The Meeting concluded that, based on the structure of R014821 and its acute toxicity profile, this metabolite would be covered by the health-based guidance values for the parent compound.

***Human data***

A published case-study involving one woman indicated that imazalil used to treat a fungal infection was well tolerated after oral ingestion at doses of 50 mg per day progressing to 1200 mg per day over 6 months. The only adverse effect noted was nausea.

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

**Toxicological evaluation**

The Meeting reaffirmed the ADI of 0–0.03 mg/kg bw established by the 2001 Meeting. The present Meeting used the overall NOAEL of 2.5 mg/kg bw per day from 1-year and 2-year studies in dogs as the basis for this ADI and a safety factor of 100. The ADI is supported by a NOAEL of 2.4 mg/kg bw per day identified in a combined long-term toxicity and carcinogenicity study in rats. The Meeting noted that the LOAEL in the 2-year rat study was higher than the overall LOAEL in the two dog studies, and therefore the overall NOAEL from the dog studies was used as the basis of the ADI.

The Meeting reaffirmed the ARfD of 0.05 mg/kg bw established by the 2005 Meeting on the basis of a NOAEL of 5 mg/kg bw per day for both maternal (decreased feed consumption) and embryo/fetal toxicity (resorption and decrease in number of live pups) in a developmental toxicity study in rabbits and a

safety factor of 100. The Meeting was not able to determine whether the effects could occur following a single dose.

The ADI and ARfD for imazalil would also apply to the metabolites R061000 and R014821.

A toxicological monograph was prepared.

***Levels relevant to risk assessment of imazalil***

Species	Study	Effect	NOAEL	LOAEL
Mouse	Twenty-three-month study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	50 ppm, equal to 8.1 mg/kg bw per day	200 ppm, equal to 33.4 mg/kg bw per day
		Carcinogenicity	50 ppm, equal to 8.1 mg/kg bw per day	200 ppm, equal to 33.4 mg/kg bw per day
	Developmental toxicity study <sup>b</sup>	Maternal toxicity	40 mg/kg bw per day	80 mg/kg bw per day
		Embryo and fetal toxicity	–	40 mg/kg bw per day <sup>c</sup>
	Developmental toxicity study <sup>b</sup>	Maternal toxicity	10 mg/kg bw per day	40 mg/kg bw per day
		Embryo and fetal toxicity	80 mg/kg bw per day	120 mg/kg bw per day
Rat	Two-year study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	50 ppm, equal to 2.4 mg/kg bw per day	200 ppm, equal to 9.7 mg/kg bw per day
		Carcinogenicity	200 ppm, equal to 9.7 mg/kg bw per day	1 200 ppm, equal to 58 mg/kg bw per day
	Two-generation study of reproductive toxicity <sup>a</sup>	Reproductive toxicity	20 mg/kg bw per day	80 mg/kg bw per day
		Parental toxicity	20 mg/kg bw per day	80 mg/kg bw per day
		Offspring toxicity	20 mg/kg bw per day	80 mg/kg bw per day
	Developmental toxicity study <sup>b</sup>	Maternal toxicity	–	40 mg/kg bw per day <sup>c</sup>
		Embryo and fetal toxicity	40 mg/kg bw per day	80 mg/kg bw per day
	Developmental toxicity study <sup>b</sup>	Maternal toxicity	5 mg/kg bw per day	10 mg/kg bw per day
		Embryo and fetal toxicity	5 mg/kg bw per day	10 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
Dog	One- and 2-year studies of toxicity <sup>d,e</sup>	Toxicity	2.5 mg/kg bw per day	5 mg/kg bw per day
<sup>a</sup> Dietary administration. <sup>b</sup> Gavage administration. <sup>c</sup> Lowest dose tested. <sup>d</sup> Two or more studies combined. <sup>e</sup> Capsule administration.				

*Acceptable daily intake (ADI) (applies to imazalil and metabolites R061000 and R014821, expressed as imazalil)*

0–0.03 mg/kg bw

*Acute reference dose (ARfD) (applies to imazalil and metabolites R061000 and R014821, expressed as imazalil)*

0.05 mg/kg bw

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

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

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

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

Rate and extent of oral absorption	Rapid and nearly complete
Dermal absorption	No data
Distribution	Extensive; highest concentrations in liver followed by kidney
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapid: >90% (about 50% in urine and about 40% in faeces) within 24 hours
Metabolism in animals	Extensive metabolism by epoxidation, epoxide hydration, oxidative O-dealkylation, imidazole oxidation and scission, oxidative N-dealkylation
Toxicologically significant compounds in animals and plants	Imazalil, metabolite R043449

#### *Acute toxicity*

Rat, LD <sub>50</sub> , oral	227 mg/kg bw
Rat, LD <sub>50</sub> , dermal	>2 000 mg/kg bw
Rat, LC <sub>50</sub> , inhalation	>1.84 mg/L
Rabbit, dermal irritation	Slightly irritating
Rabbit, ocular irritation	Moderately irritating

Guinea-pig, dermal sensitization	Not sensitizing (Magnusson and Kligman; Buehler)
<i>Short-term studies of toxicity</i>	
Target/critical effect	Decreased body weight, liver and kidney weights
Lowest relevant oral NOAEL	2.5 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	40 mg/kg bw per day (rabbit)
Lowest relevant inhalation NOAEC	No data
<i>Long-term studies of toxicity and carcinogenicity</i>	
Target/critical effect	Decreased weight gain, liver toxicity and thyroid
Lowest relevant NOAEL	2.4 mg/kg bw per day (rat)
Carcinogenicity	Carcinogenic in rats and mice; liver and thyroid tumours not relevant for humans based on mechanistic data <sup>a</sup>
<i>Genotoxicity</i>	
	No evidence of genotoxicity <sup>a</sup>
<i>Reproductive toxicity</i>	
Target/critical effect	Reduced pup viability
Lowest relevant parental NOAEL	20 mg/kg bw per day
Lowest relevant offspring NOAEL	20 mg/kg bw per day
Lowest relevant reproductive NOAEL	20 mg/kg bw per day
<i>Developmental toxicity</i>	
Target/critical effect	Increased number of resorptions, reduced number of live pups
Lowest relevant maternal NOAEL	5 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	5 mg/kg bw per day (rabbit)
<i>Neurotoxicity</i>	
Acute neurotoxicity NOAEL	600 mg/kg bw, highest dose tested (rat)
Subchronic neurotoxicity NOAEL	No data
Developmental neurotoxicity NOAEL	19 mg/kg bw per day (mouse)
<i>Other toxicological studies</i>	
Immunotoxicity	No data
<i>Studies on toxicologically relevant metabolites</i>	
R061000	Acute oral LD <sub>50</sub> > 2 000 mg/kg bw No evidence of genotoxicity in vitro
R014821	Single-dose study NOAEL: 125 mg/kg bw No evidence of genotoxicity in vitro
R043449	Acute oral LD <sub>50</sub> > 2 000 mg/kg bw No evidence of genotoxicity in vitro
<i>Human data</i>	



High doses (up to 1 200 mg per day over 6 months) were well tolerated

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

### Summary

	Value	Study	Safety factor
ADI	0–0.03 mg/kg bw <sup>a</sup>	One- and 2-year studies of toxicity in dogs	100
ARfD	0.05 mg/kg bw <sup>a</sup>	Developmental toxicity study in rabbits	100

<sup>a</sup> Applies to imazalil and metabolites R061000 and R014821, expressed as imazalil.

## RESIDUE AND ANALYTICAL ASPECTS

Imazalil is an imidazole fungicide with a protective, curative and anti-sporulation mode of action.

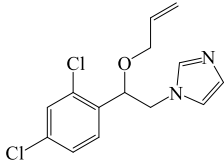
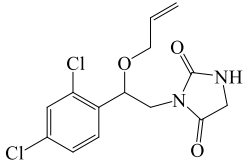
Imazalil was first evaluated by the JMPR in 1977. The current ADI, established in 1991, is 0–0.03 mg/kg bw. In 2005, the JMPR set an ARfD of 0.05 mg/kg bw.

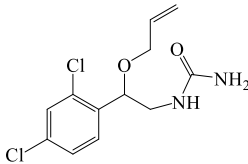
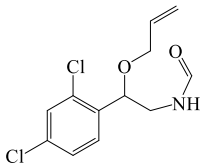
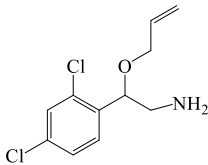
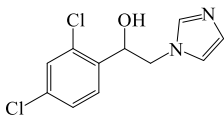
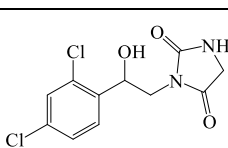
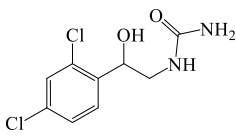
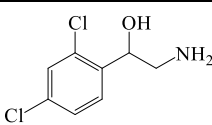
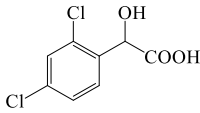
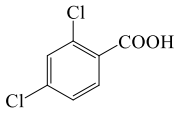
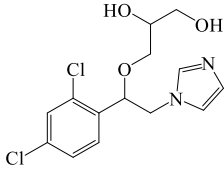
Imazalil was scheduled at the Forty-ninth Session of the CCPR for Periodic Review for residues and toxicology by the 2018 JMPR.

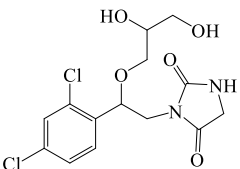
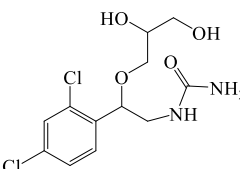
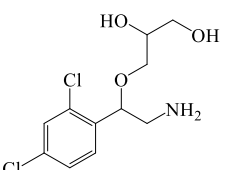
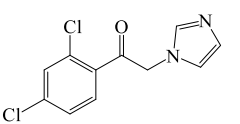
The Meeting received information from the manufacturer on physical and chemical properties, metabolism studies on plants and animals, environmental fate in soil, analytical methods and stability in stored analytical samples, use patterns and supervised residue trials, processing studies, and livestock feeding studies.

Imazalil is a racemate, consisting of equal amounts of two enantiomers.

Metabolites referred to in the appraisal are addressed by their company code numbers:

List of metabolites and degradates of imazalil			
Code Name/ Number	Chemical Name	Chemical Structure	Occurrence in
Imazalil	( <i>RS</i> )-1-[2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl]-1 <i>H</i> -imidazole		Ruminant, Poultry, Potato, Tomato, Wheat, Banana, Apple, Orange
R044179	( <i>RS</i> )-1-[2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl]-imidazolidine-2,5-dione		Ruminant, Tomato, Cucumber

List of metabolites and degradates of imazalil			
Code Name/ Number	Chemical Name	Chemical Structure	Occurrence in
R092977	( <i>RS</i> )-1-[2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl]-urea		Tomato
R055609	<i>N</i> -(2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl)formamide		Ruminant, Tomato
R044177	2-(2,4-dichlorophenyl)-2-(2-propenyloxy)-ethan-1-amine		Ruminant, Potato
R014821	( <i>RS</i> )-1-(2,4-dichlorophenyl)-2- imidazol-1-yl-ethanol		Rat, Ruminant, Potato, Tomato, Banana, Apple, Orange, Wheat
R043449	( <i>RS</i> )-3-[2-(2,4-dichlorophenyl)-2-hydroxyethyl]imidazolidine-2,4-dione		Ruminant Poultry, Tomato
R044085	( <i>RS</i> )- <i>N</i> -[2-(2,4-dichlorophenyl)-2-hydroxyethyl]urea (±)- <i>N</i> -[2-(2,4-dichlorophenyl)-2-hydroxyethyl]urea		Rat, Ruminant, Poultry
R110740	2-amino-1-(2,4-dichlorophenyl)ethan-1-ol		Poultry
R023366	2-(2,4-dichlorophenyl)-2-hydroxyacetic acid		Ruminant
R066996	2,4-dichlorobenzoic acid		Ruminant
R042639	( <i>RS</i> )-1-[[2-(2,4-dichlorophenyl)-2-(2,3-dihydroxypropyl)oxy]ethyl]-1 <i>H</i> -imidazole (±)-1-[[2-(2,4-dichlorophenyl)-2-[(2,3-dihydroxypropyl)oxy]ethyl]-1 <i>H</i> -imidazole		Rat, Ruminant, Poultry, Tomato, Wheat

List of metabolites and degradates of imazalil			
Code Name/ Number	Chemical Name	Chemical Structure	Occurrence in
R061000	( <i>RS</i> )-3-[2-(2,4-dichlorophenyl)-2-(2,3-dihydroxypropoxy)ethyl]imidazolidine-2,4-dione ( $\pm$ )-1-[2-(2,4-dichlorophenyl)-2-[(2,3-dihydroxypropyl)oxy]ethyl]-2,5-imidazolidinedione		Rat, Ruminant, Poultry
R062775	1-(2-(2,4-dichlorophenyl)-2-(2,3-dihydroxypropoxy)ethyl)urea		Ruminant, Poultry
R060998	3-(2-amino-1-(2,4-dichlorophenyl)ethoxy)propane-1,2-diol		Ruminant, Poultry
R045529	1-(2,4-dichlorophenyl)-2-(1 <i>H</i> -imidazol-1-yl)ethan-1-one		Tomato

Based on the physical chemical properties, imazalil is only slightly volatile and is soluble in water and polar solvents. Imazalil is stable to aqueous hydrolysis yet undergoes continuous photolysis in aquatic environments ( $DT_{50} = 11-12$  days). Based on the Log Kow, imazalil is not likely to sequester to fatty matrices.

### Plant metabolism

The Meeting received plant metabolism studies with imazalil following post-harvest treatment to oranges, apples and potatoes, foliar applications to bananas, greenhouse cucumbers and tomatoes and seed treatment of potatoes and cereal grains.

#### Oranges – Post-harvest treatment

Spanish navel oranges (variety *Valencia*) were dipped in an aqueous solution of [ $^3H$ ]-imazalil sulphate, labelled on the stereogenic carbon, at a rate equivalent to 0.05 kg ai/hL (0.2-fold critical GAP). After treatment, the oranges were stored in a dark room. Samples were taken immediately (2 hours) after dipping, then after 1, 3, 6 and 12 weeks. For all samples, peel and pulp were analysed separately. Results for the whole fruits were calculated using the respective weights of peel and pulp.

The total radioactive residues (TRRs) remained relatively unchanged over the entire storage duration in whole fruit, peel and pulp, ranging from 1.9–2.6 mg eq/kg, 5.8–7.2 mg eq/kg and 0.04–0.1 mg eq/kg, respectively, with the majority of the radioactivity predominantly found in the peel.

Sequential extraction of peel and pulp samples with methanol:concentrated ammonia, methanol:glacial acetic acid and heptane:isoamyl alcohol released 76–93% TRR and 71–88% TRR, respectively. The radioactivity in the post-extraction solids ranged from 3–9% TRR.

Imazalil accounted for the majority of the radioactivity in the peel, decreasing from 78% TRR, 2 hours after treatment, to 57% TRR, 12 weeks thereafter. Radioactivity in pulp followed a similar trend, decreasing from 68% TRR, 2-hours post-treatment, to 45%TRR following a 12-week storage period. The concentrations of the alcohol metabolite, R014821, in peel and pulp reached maximum levels following 12 weeks of storage (4.6% TRR [0.29 mg eq/kg]; 17.7% TRR [0.01 mg eq/kg], respectively). A limitation of the study included the lack of accountability of the applied radioactivity including identification of all potential metabolites.

#### *Apple – Post-harvest treatment*

Apples (*variety* Golden Delicious) were dipped in solutions of unlabelled imazalil-sulfate at a rate of 0.05 kg ai/hL to determine the residue level of the parent compound and its metabolites, equivalent to a magnitude of the residue study. Another set of apples was treated with a blend of [<sup>14</sup>C]-imazalil labelled on the stereogenic carbon and unlabelled imazalil (ratio 1:9) to investigate the degradation of imazalil and to determine the extractability of the radioactivity as a function of storage time. Fruits were subsequently stored in a controlled atmosphere and sampled immediately (4 hours) after dipping and after 1, 2, 4, 6 and 7 months of storage. One [<sup>14</sup>C]-imazalil apple was treated with the same radiolabelled imazalil test substance for the volatilization test. The treated apple was incubated in a flow-through system similar to that of soil metabolism studies and was initiated on the same day as the storage samples and continued until the end of the storage period (7 months).

Residues in apples treated with radiolabelled material ranged from 2.4–3.2 mg eq/kg which were higher than those treated at the same rate with unlabelled imazalil, where residues ranged from 1.5–2.0 mg/kg.

Residues extracted using heptane:isoamyl alcohol (95:5, v:v) accounted for 97% TRR immediately after treatment and decreased to 82% TRR following 7 months of storage. Imazalil and R014821 accounted for most of the extracted radioactivity, where levels of imazalil decreased (95% TRR to 73% TRR) with a corresponding increase in R014821 (2% TRR to 9% TRR), as a function of storage duration. No other transformation product was identified. The radioactivity levels in the trapping solutions did not exceed those in the control (blank) solutions. Therefore, volatilization of imazalil and imazalil-derived metabolites does not appear to be a route of dissipation.

#### *Tomato – Foliar application*

Greenhouse tomatoes were treated with three foliar applications of [<sup>14</sup>C- U-ring]-imazalil formulated as an emulsifiable concentrate at a rate of 300 g ai/ha per application for a total application rate of 900 g ai/ha (low dose; 4.5-fold cGAP)) during the growing period. Additional plants were treated three times at 1500 g ai/ha per application for a seasonal application rate of 4500 g ai/ha (high dose; 22.5-fold cGAP). Treatments were made at 10-day intervals and tomatoes were harvested 1 day after the last application (DALA).

The TRR in the tomatoes represented 0.44 mg eq/kg (low dose) and 2.85 mg eq/kg (high dose).

Highest TRRs were in the acetonitrile surface wash ( $\geq$  50% TRR) followed by pomace (~40% TRR), with < 10% TRR found in the tomato juice.

Extraction of the TRRs in pomace using acetonitrile, methanol and acetonitrile-water was limited, ranging from 13–15% TRR. However, following hydrolysis of the PES using basic harsh conditions, the

unextracted residues remaining in the pomace accounted for 4.0% and 0.5% TRR for the low and high dose rates, respectively.

In whole tomato fruit, the free parent compound represented 54% TRR (0.23–1.5 mg eq/kg) for both dose levels, while the conjugated parent, released following hydrolysis of the PES, accounted for 20–23% TRR (0.09–0.66 mg eq/kg). In addition to the parent compound, up to five known metabolites (R043449, R042639/R045529, R014821, R055609/R092977 and R044179) were detected at both dose levels, none of which exceeded 10% TRR ( $\leq 0.17$  mg eq/kg).

Enantiomeric analysis of the juice, pomace extracts and surface wash revealed that no change in the enantiomer ratio is expected and that stereospecific metabolism of imazalil is highly unlikely.

#### *Potato – Post-harvest treatment*

[ $^{14}\text{C}$ ]-Imazalil uniformly labelled in the phenyl ring and formulated as a solution containing 100 g ai/L, was applied by simulated drench application to ten potato tubers (variety *Laura*) at a target rate of 15 mg ai/kg potato tubers (1-fold cGAP), after which they were stored on a wire grid in storage boxes at approximately 5 °C.

TRRs in potato tuber samples, taken immediately after treatment (day 0) and after 14, 29, 91 and 188 days of storage, decreased slightly from 17.2 mg eq/kg to 15.6 mg eq/kg.

At each sampling interval, potato tubers were washed with acetonitrile:water. The residue in the surface wash decreased from 64% TRR (11 mg eq/kg) on day 0 to 35% TRR (5.4 mg eq/kg) by day 188. Washed potatoes were subsequently peeled. The extracted residue in the peel increased from 33% TRR (5.7 mg eq/kg) on day 0 to 46% TRR on day 188 (7.2 mg eq/kg). The unextracted peel residue increased from 3% TRR (0.5 mg eq/kg) on day 0 to a maximum of 23% TRR (3.6 mg eq/kg) on day 91. Residues released following acidic reflux were significantly lower than those in the surface wash and the pomace extracts. Residues in peeled tubers were approximately 0.2% TRR (0.03 mg eq/kg) except for day 14 where the radioactivity in the tuber accounted for 0.9% TRR (0.15 mg eq/kg). Based on the distribution of the radioactivity in the treated potato tubers, limited penetration was observed from the peel into the pulp.

HPLC-UV analysis of the surface wash and peel extracts confirmed the presence of imazalil as the predominant residue, decreasing from 94% TRR (16.1 mg eq/kg) on day 0 to 70% TRR (10.9 mg eq/kg) on day 188. The metabolites R014821 and R044177 reached a maximum of 9.0% TRR (1.4 mg eq/kg) and 3.4% TRR (0.54 mg eq/kg), respectively, in surface wash and peel extracts by day 188. Imazalil accounted for < 0.02% TRR (< 0.003 mg/kg) in the tuber extract. Unknown metabolites ranged from 3–6% TRR (0.5–1.0 mg eq/kg). Following acidic reflux extraction of the peel solids, the analytes identified included the parent (1.3–4.0 %TRR), metabolites R014821 (0.1–0.2% TRR) and R044177 (0.04–0.1% TRR) as well as other unknown fractions that were likely aglycones of conjugates hydrolysed under acidic reflux conditions.

Enantiomeric analysis of the surface wash and peel extract sampled on day 0, 91 and 188 showed that the ratios of imazalil enantiomers remained unchanged during storage of treated potato and that stereospecific metabolism of imazalil is highly unlikely.

#### *Spring wheat – Seed treatment*

$^{14}\text{C}$ -imazalil, radiolabelled on the stereogenic carbon, was applied to spring wheat seeds (variety *Axona*) at a rate of 49.3 g ai/100 kg seed (5-fold cGAP). Treated seeds were sown in pots left outdoors. Forage was sampled 42 days after sowing while straw and grain were harvested approximately 5 months after sowing.

TRRs in forage, straw and grain were 1.36, 0.15 and 0.003 mg eq/kg, respectively. Due to the very low level of TRRs in grain, no further investigation was carried out.

Greater than 72% TRR (0.99 mg eq/kg) in the forage was extracted using methanol:chloroform:HCl (0.1 N) (2:1:0.8; v:v:v) followed by Soxhlet extraction with methanol:HCl (0.1 N). Successive mild and harsh acid and base hydrolysis of the PES released 12.6% TRR (0.16 mg eq/kg). The radioactivity in the remaining bound residues accounted for 7.7% TRR (0.11 mg eq/kg). Similar extraction of mature straw released significantly less radioactivity compared to forage (44% TRR; 0.06 mg eq/kg). Mild and harsh acid and base hydrolysis released a further 16.4% TRR (< 0.03 mg eq/kg) with 58.5% TRR (0.09 mg eq/kg) remaining in the bound residues.

The parent compound was observed in both matrices, 24% TRR (0.33 mg /kg) in forage and 17% TRR (0.03 mg /kg) in straw. The levels of the metabolites R014821 and R042639 in forage were 8% TRR (0.11 mg eq/kg) and 5%TRR (0.06 mg eq/kg), respectively, while both were <4% TRR (< 0.01 mg eq/kg) in straw. Several unknown compounds with similar retention times were observed in both forage and straw, none of which accounted for > 4.3% TRR.

#### *Banana, Cucumber – Foliar application / Barley, Potato – Seed treatment*

Various experiments were conducted on foliar-treated greenhouse-grown bananas and cucumber seedlings and seed-treated barley and potatoes.

While limited in scope, these studies demonstrated that the majority of the radioactivity present in the banana, cucumber, barley and potato plants was located predominantly on the site of application with limited radioactivity in the untreated plant parts including edible commodities (bananas, cucumbers, barley grain and potato tubers), demonstrating minimal translocation.

In summary, the metabolism of imazalil is adequately understood in fruits and vegetables following post-harvest, foliar-treated greenhouse vegetables and seed treated cereal grains. The majority of the radioactive residues in oranges, apples and potatoes, following post-harvest treatment, were located on the surface of the crops with limited penetration from the peel to the pulp. The predominant analyte was the parent, imazalil with the metabolite R014821 which accounted for significantly lower levels than those of the parent.

Following foliar application of imazalil to greenhouse grown tomatoes, imazalil accounted for the majority of the identified radioactivity, however, six metabolites were also identified at lower levels than those of the parent, demonstrating a more extensive metabolic profile than that following post-harvest treatment.

In the spring wheat seed-treatment metabolism study, the metabolism of imazalil was similar to that following post-harvest treatment, where limited metabolism of imazalil was observed with R014821 and R042639 being the only two metabolites identified,

While limited in scope, the banana and cucumber (foliar application) and barley and potato (seed treatment) studies demonstrated that the majority of the radioactivity present on the plants was located in most part on the site of application with limited radioactivity in the untreated plant parts including edible commodities (bananas, cucumbers, barley grain and potato tubers), demonstrating minimal translocation.

The degradation of <sup>14</sup>C-imazalil proceeds predominantly via O-dealkylation to form metabolite R014821, While less predominant, imazalil also undergoes dihydroxylation followed by cleavage of the imidazole ring and hydroxylation of the alkyl chain. The major plant metabolite, R014821, was identified as a major metabolite in rats.

#### ***Animal metabolism***

The Meeting received animal metabolism studies with imazalil in goats, hens and rats. Evaluation of the rat

metabolism study was carried out by the WHO Core Assessment Group.

### *Lactating goat*

The metabolism of  $^{14}\text{C}$ -imazalil, radiolabelled on the stereogenic carbon, was investigated in a lactating goat, dosed orally by intubation, twice daily at a dose level of 188 ppm for 3 consecutive days. The goat was sacrificed 6 hours after administration of the last dose.

Greater than half of the administered dose (AD) was excreta-related (57% AD). Limited radioactivity was eliminated in the milk (0.1% AD) and the tissue burden was low (1.4% AD). The overall recovered radioactivity accounted for 59% AD.

At sacrifice, TRRs were highest in liver (19.8 mg eq/kg), followed by kidney (9.6 mg eq/kg), muscle (round, loin and flank; 0.36 mg eq/kg) and fat (perirenal, omental, subcutaneous; 0.09 mg eq/kg).

Successive extractions of milk and tissues using various organic solvents released up to 97% of the radioactivity. The unextracted residues ranged from 5–12% TRR.

The distribution of radioactivity in milk (56–72 hours after the last administration, containing the highest amount of radioactivity) indicated that the majority of the radioactive residue (92% TRR) was contained in whey, while those in fat and protein accounted for 7% and 4% TRR, respectively. These fractions were not further analysed. Imazalil was not observed in milk whey, however, a total of 10 minor metabolites were identified, ranging from 1.0–7.2% TRR (0.01–0.07 mg eq/kg).

In liver, imazalil accounted for a total of 6% TRR (1.3 mg/kg). Nine additional minor metabolites were identified, none of which accounted for greater than 5% TRR (0.99 mg eq/kg).

Imazalil accounted for a total of 4% TRR (0.4 mg /kg) in kidney and 3% TRR (0.009 mg/kg) in muscle. The metabolite R061000 was a predominant metabolite in kidney representing 15% TRR (1.45 mg eq/kg). In muscle, R043449 and R061000, were both major metabolites accounting for 15% TRR (0.05 mg eq/kg) and 21% TRR (0.07 mg eq/kg), respectively. Four additional minor metabolites were observed in kidney, representing 0.5–3% TRR (0.05–0.3 mg eq/kg). In contrast, only 2 additional minor metabolites were observed in muscle, accounting for 7–8% TRR (0.02–0.03 mg eq/kg).

Imazalil was a minor residue (6% TRR; 0.006 mg /kg) in fat, as was the metabolite R043449, accounting for 9% TRR (0.02 mg eq/kg). R044179 was the only predominant metabolite observed, accounting for 25% TRR (0.03 mg eq/kg).

Up to 15 unknown metabolites were detected in milk whey and tissues, ranging from 0.2–34% TRR (0.01–2.2 mg/kg). In some cases, radio-HPLC analysis of metabolite fractions revealed that they comprised of several individual metabolites, none of which accounted for greater than 10% TRR. There was no evidence of conjugates in any of the ruminant matrices.

### *Laying hen*

Ten laying hens were dosed orally for 10 consecutive days with  $[\text{U-}^{14}\text{C}]$ -imazalil at 66 ppm in the feed (dry matter). The hens were sacrificed 20 hours after the final dose.

Almost all the administered radioactivity was recovered in excreta (95% AD), cage wash and cage debris (4% AD). Limited radioactivity was eliminated in the eggs (0.3% AD) and the tissue burden was low (2% AD). The overall recovered radioactivity accounted for 101%.

TRRs were highest in liver (10 mg eq/kg) followed by skin (0.44 mg eq/kg), muscle (0.13–0.16 mg eq/kg) and fat (0.12–0.13 mg eq/kg).

Extraction of the eggs and tissues using methanol:ammonia followed by Soxhlet extraction of the PES released 54–85% of the TRRs.

Imazalil was not observed in liver as it underwent rapid and extensive metabolism to a large number of metabolites. Six metabolites were identified, including R016000, however, none accounted for greater than 10% TRR ( $\leq 0.95$  mg eq/kg).

Imazalil was also not detected in muscle. However, in contrast with liver, only 2 major metabolites were identified, R042639 (15% TRR) and R110740/R044085, together accounting for 16% TRR (0.02 mg eq/kg). Following Soxhlet extraction of the PES, 33% TRR (0.05 mg eq/kg) remained unextracted. While, 30% TRR was further released following mild acid or base hydrolysis, no attempt to characterise the released radioactivity was undertaken.

In fat, only parent (11% TRR; 0.01 mg eq/kg) and the metabolite R043449 were identified (10% TRR, 0.01 mg eq/kg).

Imazalil was detected in eggs (8% TRR; 0.06 mg/kg) as were several metabolites accounting for a total of  $\leq 11\%$  TRR ( $\leq 0.09$  mg eq/kg).

The Meeting concluded that, in all species investigated (goats, hens and rats), the total administered radioactivity was predominantly eliminated in excreta. The metabolic profiles differed quantitatively between the species, yet qualitatively there are no major differences with the exception that the metabolism in goats was more extensive than hens and rats. The routes and products of metabolism were similar across all animals, resulting from 1) dihydroxylation followed by cleavage of the imidazole ring; 2) hydroxylation of the alkyl chain followed by oxidation and cleavage of the imidazole ring; 3) dihydroxylation of the alkyl chain followed by oxidation and cleavage of the imidazole ring.

### ***Environmental fate***

While the Meeting received information on soil aerobic degradation, hydrolysis and photolysis properties of imazalil; studies on the behaviour of [ $^{14}\text{C}$ ]-imazalil in confined rotational crops were not received.

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

The degradation of  $^{14}\text{C}$ -imazalil radiolabelled at the stereogenic carbon was investigated in various soil types (including loam, sandy loam, silt loam and sandy clay loam) under aerobic laboratory conditions (10–25 °C for 120–366 days).

Following first order kinetics, the resulting  $\text{DT}_{50}$  values for imazalil ranged from 28–113 days.

The only radioactive degradation product exceeding 5% of the applied radioactivity (AR) was identified as R014821, accounting for up to 10% of AR. No other metabolites were identified.

The degradation rate of the soil metabolite, R014821, was also investigated in three soils (silt loam, sandy loam and silt loam) under aerobic laboratory conditions at 20 °C.

Following first order kinetics, the resulting  $\text{DT}_{50}$  values for R014821 ranged from 7–23 days.

#### ***Photolysis - Aqueous***

Sterile buffer solutions maintained at pH 7 were treated with imazalil [ $^{14}\text{C}$ -phenyl-ring] at a mean initial concentration of about 0.15 mg/L and irradiated for a continuous period of 19 days.

$^{14}\text{C}$ -Imazalil underwent continuous photolysis. By the end of the study, it had declined to 5% AR. In the dark control samples, virtually no hydrolysis of the test item was observed. Four photodegradates,



accounting for greater than 10% of the applied radioactivity were formed: R044177, R044179, R055609 and R018238.

Overall, the Meeting concluded that the degradation of imazalil in soil proceeds via hydroxylation of the alkyl chain to form the alcohol metabolite R014821. Imazalil is moderately persistent in soil under field conditions ( $DT_{50}$  values ranging from 28–113 days), stable to hydrolysis yet undergoes photolysis in the aquatic environment ( $DT_{50}$  values ranging from 11–12 days).

### ***Methods of analysis***

QuEChERS based multi-residue methods have been reported in the scientific literature for the analysis of imazalil in orange juice and grapes. Adequate recoveries were obtained at LOQ's of 8.5 µg/L and 0.05 mg/kg, respectively.

The Meeting received the description and validation data for several analytical methods capable of quantifying imazalil and the alcohol metabolite, R014821, in plant commodities. Extraction of the residues was accomplished using various solvents such as heptane:isoamyl alcohol, hexane:acetone, ethyl acetate:hexane, acetonitrile:water and acetonitrile. Liquid partitioning was typically used for the clean-up step. The residue analytical methods relied on GC-ECD, GC-MS or LC-MS/MS detectors. The typical LOQ achieved for the plant commodities using the LC-MS/MS methods is 0.01 mg/kg. Methods were successfully validated by independent laboratories, demonstrating good reproducibility. The Meeting did not receive any information on radiovalidation.

The Meeting received descriptions and validation data for several analytical methods for residues of imazalil and its metabolites R043449 and R061000 in ruminant matrices and imazalil, R042639, R044085 and R110740 in poultry matrices. Extraction solvents used for each of the matrices were made up of different combinations of methanol and/or acetonitrile and/or acetone. Clean-up of the extracts was performed using liquid partitioning or an RP8 column eluted with various solvents. The residue analytical methods relied predominantly on GC-ECD and LC-MS/MS detectors. The LOQs achieved for all animal commodities were 0.02, 0.04 or 0.05 mg/kg (GC-ECD) and 0.01 mg/kg (LC-MS/MS). The LC-MS/MS methods were successfully validated by independent laboratories, demonstrating good reproducibility. The Meeting did not receive any information on radiovalidation.

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

The Meeting received storage stability studies on imazalil and imazalil alcohol (R014821) in orange and its processed commodities, apple and its processed commodities, bananas, melons, tomatoes, potatoes and cereal grain and straw. Samples were fortified with each analyte at various concentrations and stored frozen. Samples were taken for analysis at intervals up to 12 months.

No dissipation of residues of imazalil and R014821 was observed in any of the raw agricultural commodities or the processed commodities.

Studies on storage stability of imazalil in animal tissues were not provided to the Meeting as all animal samples in the livestock feeding studies were extracted and analysed within 30 days from sampling.

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

The nature of the imazalil residues was investigated in oranges, apples and potatoes following post-harvest treatment, bananas, greenhouse cucumbers and tomatoes following foliar treatment, and potatoes, spring wheat and barley following seed treatment.

The majority of the radioactive residues in oranges, apples and potatoes, following post-harvest treatment were located on the surface of the crops with limited penetration from the peel to the pulp. The predominant analyte identified immediately after treatment (0-DAT) was the parent, imazalil (78–95% TRR). In all three studies, residues of imazalil decreased steadily as a function of storage duration with a corresponding increase in the residues of the metabolites R014821, and to a lesser extent R044177 (potato).

Following foliar application to greenhouse grown tomatoes at exaggerated rates (4.5–22.5-fold critical GAP), free imazalil accounted for the majority of the identified radioactivity (54% TRR). While five minor metabolites were also identified, none exceeded 10% TRR (0.002–0.17 mg eq/kg).

In the spring wheat seed-treatment metabolism study conducted at exaggerated rates (10-fold cGAP), imazalil accounted for the majority of the extracted radioactivity (17–24% TRR) in forage and straw. The only metabolites identified in these feed commodities were R014821 and R042639, each representing < 10% TRR ( $\leq 0.11$  mg eq/kg).

Imazalil was the only analyte present as a major compound in all tested plant matrices. Suitable analytical methods are available to analyse the parent compound. The Meeting considered that imazalil was a suitable marker for enforcement of MRLs for fruits, vegetables and cereal crops.

In deciding which compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence and the toxicological properties of the metabolite R014821. The Meeting concluded that the toxicity of R014821, observed in plants, would be covered by the parent compound, given its toxicity profile as well as its detection in rats at significant levels.

Following foliar spray applications to greenhouse-grown cucumbers, residues of R014821 were consistently low  $\leq 0.01$  mg/kg. While residues of R014821 were not analysed in the greenhouse tomato supervised residue trials, it did not account for more than 0.3% of the parent residues in the tomato metabolism study. However, the tomato metabolism study showed that the conjugated form of the parent compound accounted for up to 50% of the levels measured of the parent. Therefore, conjugated imazalil is likely to contribute to the dietary exposure of foliar-treated crops, yet it would not be relevant to post-harvest and seed treatment uses.

In the spring wheat seed treatment trials, all residues of imazalil were < 0.01 mg/kg in wheat grain. Although residues of R014821 were not measured in these trials, TRRs in grain from the metabolism study were 0.003 mg eq/kg. Therefore, it is reasonable to expect that levels of this metabolite will be significantly below < 0.01 mg/kg.

In the post-harvest treatment metabolism studies and the post-harvest treatment trials, the alcohol metabolite R014821 in citrus (whole fruit) and potatoes was not detected at the critical GAP PHI of 0-days. As residues of imazalil decreased with an increase in storage duration, residues of the metabolite were consistently below 10% those of the parent compound and/or < 0.01 mg eq/kg. Therefore, R014821 is not likely to contribute to the total exposure of imazalil in the diet.

Noting the above, the Meeting decided the residue definition for dietary risk assessment for plant commodities should be free and conjugated imazalil.

The nature of the imazalil residues was investigated in lactating goat and laying hen following oral administration of the test substance. In the lactating goat metabolism study (180 ppm feed), imazalil was extensively metabolised. No imazalil was observed in milk whey and none of the identified metabolites accounted for greater than 10% TRR. In tissues, the parent represented less than 6% TRR. Several metabolites were observed in liver, however, none accounted for greater than 5% TRR. Two major metabolites, R061000 (kidney and muscle) and R043449 (muscle) were detected at higher concentrations

(15–21% TRR and 15%TRR, respectively) than that of the parent (4% TRR). In fat, R061000 was not observed yet R043449 and R044179 accounted for 9% TRR (0.01 mg eq/kg) and 25%TRR (0.03 mg eq/kg), respectively.

In the dairy cattle feeding study at the lowest feeding level (equivalent to 1.4-fold the maximum estimated dietary burden), residues of imazalil were less than 0.02 mg/kg in milk, muscle and fat, while residues of imazalil were < 0.02–0.36 mg/kg in liver and kidney.

In the laying hen metabolism study (66 ppm feed), imazalil was also extensively metabolised and only detected in eggs and fat, representing 8% TRR (0.06 mg/kg) and 11% TRR (0.01 mg/kg), respectively. The metabolite R061000 was only observed in liver and eggs, accounting for 6–9% TRR (0.05–0.95 mg eq/kg) and the metabolite R043449 was only observed in fat and eggs at levels of 2–10% TRR (0.01 mg eq/kg).

In the poultry feeding study, residues of imazalil were below 0.02 mg/kg (LOQ) in tissues and below 0.01 mg/kg (LOQ) in eggs at all dose levels tested.

At the maximum estimated dietary burden, imazalil residues are only expected in ruminant matrices (liver and kidney). Therefore, the Meeting decided that the parent was a suitable marker for all animal matrices.

Suitable methods are available for imazalil in animal commodities.

The Meeting concluded that for enforcement of MRLs, imazalil is a suitable marker for animal matrices.

In deciding which compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence and the toxicological properties of the metabolites R061000, R043449 and R044179.

In the lactating goat metabolism study, R061000 and R043449 may contribute to the consumer exposure as they collectively account for a significant proportion of the TRRs in milk whey (12% TRR; 0.15 mg eq/kg), liver (6.2% TRR; 1.33 mg eq/kg), kidney (15% TRR, 1.45 mg eq/kg), muscle (36.4%TRR, 0.12 mg eq/kg) and fat (9% TRR, 0.01 mg eq/kg). Moreover, the levels of these metabolites in liver were similar to that of the parent. In kidney and muscle, the levels of metabolites were 5–13-fold higher than those of imazalil while in fat, the metabolite R043449 was approximately 2-fold higher than parent. The major metabolite R044179 detected in fat (25% TRR, 0.03 mg eq/kg) is also expected to contribute to the consumer exposure considering it represents up to 5-fold the levels of the parent (6% TRR; 0.006 mg eq/kg).

In the dairy cattle feeding study, residues of imazalil, R061000 and R043449 were not quantifiable (< 0.02 mg/kg) in milk, muscle and fat at the lowest dose level tested (1.4-fold the maximum estimated dietary burden) while the residues of these metabolites were collectively similar to that of the parent in liver and 5-fold greater than that of the parent in kidney. Although residues of R044179 were not measured in the feeding study, considering the rate of exaggeration of the metabolism study, these are not anticipated to be present at measureable levels in fat, when cattle are fed a diet equivalent to the maximum estimated dietary burden.

In the poultry metabolism study, imazalil and R043449, present only in fat and eggs (0.01–0.06 mg eq/kg), are not expected to contribute significantly to the consumer exposure. Conversely, R061000 was the only major metabolite present at 9% TRR (0.95 mg eq/kg) in liver, which may contribute to the overall consumer exposure.

The Meeting concluded that the toxicity of R061000, observed in ruminants and poultry, would be covered by the parent compound, given its toxicity profile as well as its detection in rats at significant levels.

For the metabolite R043449, as no specific data were available on the toxicity of the metabolite the TTC approach was applied<sup>23</sup>. The exposure of R043449 is below the TTC for a Cramer Class III compound (1.5 µg/kg bw) and is therefore unlikely to present a public health concern based on the uses considered by the Meeting.

Noting the above, the Meeting decided the residue definition for dietary risk assessment for animal commodities should be the sum of imazalil and R061000, expressed as imazalil equivalents

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

Definition of the residue for dietary risk assessment for plant commodities: *free and conjugated imazalil*.

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

Definition of the residue for dietary risk assessment for animal commodities: *sum of imazalil and the metabolite R061000 ((RS)-3-[2-(2,4-dichlorophenyl)-2-(2,3-dihydroxypropoxy)ethyl]imidazolidine-2,4-dione (±)-1-[2-(2,4-dichlorophenyl)-2-[(2,3-dihydroxypropyl)oxy]ethyl]-2,5-imidazolidinedione), expressed as imazalil equivalents.*

The Log K<sub>ow</sub> of imazalil is 2.15, indicating a potential to sequester into fatty matrices. In lactating goats, the ratio of residues (sum of imazalil and R061000) in fat to muscle was 1-fold. The Meeting considered the residue not fat-soluble.

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

The Meeting noted that supervised residue trials were not provided for melons (except watermelons), Japanese persimmons, raspberries (red, black) and strawberries and that the use on pome fruits is no longer supported by the manufacturer. Therefore, the Meeting withdraws its previous recommendations of 2 mg/kg for melons (except watermelons), 2 mg/kg for Japanese persimmons, 5 mg/kg for pome fruits and 2 mg/kg each for raspberries (red, black) and strawberries.

#### *Citrus fruits*

The critical GAP for citrus fruits is in the USA, a combination of 2 post-harvest applications, dip or drench at 0.075 kg ai/hL followed by a wax application of 0.2 kg ai/hL, for a total application rate of 0.275 kg ai/hL. The minimum post-treatment interval is 0 days.

#### *Lemons*

A total of nine independent supervised residue trials were conducted in Greece, Italy and Spain approximating critical GAP in the USA, where residues of imazalil in whole lemons were, in ranked order (n = 9): 3.0, 3.1, 3.3, 4.1, 5.0, 5.7, 6.4, 7.8 and 9.7 mg/kg.

#### *Mandarins*

Only two trials were conducted on mandarins in accordance to the USA critical GAP, therefore, there were an insufficient number of trials to allow the Meeting to estimate a maximum residue level.

#### *Oranges*

A total of 12 independent supervised residue trials were conducted in Greece, Italy and Spain, approximating the critical GAP in the USA, where residues of imazalil found in whole oranges were, in

<sup>23</sup> See Toxicology section for further details

ranked order: 1.8, 2.0, 2.2, 2.5, 2.6, 2.7, 3.0, 3.4, 3.6, 4.2, 4.4 and 4.8 mg/kg.

#### *Grapefruits*

No trials conducted on grapefruit reflected the USA critical GAP; therefore, the Meeting could not estimate a maximum residue level.

#### *Summary – Citrus fruits*

While the USA label is approved for use on the entire citrus fruit crop group, the Meeting only received adequate trials for oranges and lemons. Therefore, the Meeting recommended maximum residue levels 15 mg/kg for the subgroup of Lemons and limes and 8 mg/kg for the Subgroup of Oranges, Sweet, Sour, both of which were based on the mean + 4SD. The Meeting withdraws its previous recommendation of 5 mg/kg for citrus fruits.

For dietary risk assessment, the residues of imazalil in lemon pulp were, in ranked order: 0.05 (2), 0.11, 0.12, 0.18, 0.20, 0.23, 0.27 and 0.36 mg/kg. The Meeting estimated a HR and STMR of 0.36 mg/kg and 0.18 mg/kg, respectively.

For dietary risk assessment, the residues of imazalil in orange pulp, analysed in 16 of the 18 trials, were in ranked order: 0.05 (2), 0.06 (2), 0.07 (2), 0.11 (2), 0.12, 0.13, 0.18, 0.20, 0.21, 0.23, 0.26 and 0.27 mg/kg. The Meeting estimated a HR and STMR of 0.27 mg/kg and 0.12 mg/kg, respectively.

#### *Bananas*

The critical GAP for post-harvest treatment of bananas is in Honduras, with a dip application at 0.11 kg ai/hL and 0-day post-treatment interval. However, the Meeting could not recommend a maximum residue level as none of the trials reflected this critical GAP.

In Columbia, the critical GAP for post-harvest treatment of bananas is a dip application at 0.06 kg ai/hL and a 0-day post-treatment interval. A total of 2 independent trials were conducted in Spain in accordance with the critical GAP, where residues of imazalil in whole fruit were, in ranked order: 2.94 and 3.34 mg/kg.

As there were an insufficient number of trials to estimate a maximum residue level on bananas, the Meeting considered the residue decline trials conducted in European countries, where little dissipation of imazalil residues, as a function of time post-harvest, was observed. Therefore, the Meeting decided to combine the residue data from the thirteen independent trials conducted in Honduras and Panama with those conducted in Spain, at rates approximating the critical GAP of Columbia, and at longer post-treatment intervals. In ranked order, the combined residues of imazalil in whole banana fruit were: 0.74, 0.92, 0.95, 1.22, 1.35, 1.44, 1.79, 2.03, 2.14, 2.32, 2.34, 2.68, 2.91, 2.94 and 3.34 mg/kg.

The Meeting estimated a maximum residue level of 6 mg/kg (based on mean + 4SD).

For dietary risk assessment, the residues of imazalil in banana pulp were, in ranked order: < 0.05, 0.07 (3), 0.08, 0.09, 0.11, 0.16 (2), 0.20, 0.24, 0.57 and 0.72 mg/kg. The Meeting estimated a HR and STMR of 0.72 mg/kg and 0.11 mg/kg, respectively.

The IESTI represented greater than 100% of the ARfD of 0.05 mg/kg bw in the case of bananas (120% children).

An alternative GAP exists in France for the dip treatment of bananas at 0.0375 kg ai/hL and a 0-day post-treatment interval. Thirteen post-harvest dip treatment trials were conducted at 0.03 kg ai/hL in Honduras and Panama. Considering the limited decline in imazalil residues as a function of storage

duration, residues from the 14 and 22-day post-treatment intervals were used in calculating the maximum residue level.

The residues in whole fruit, in ranked order, were: 0.22, 0.31, 0.39, 0.58, 0.61, 0.71, 1.01, 1.12, 1.30, 1.34, 1.54, 1.68 and 1.69 mg/kg. The Meeting estimated a maximum residue level of 3 mg/kg (based on  $CF \times 3$  mean). The Meeting replaces its previous recommendation of 2 mg/kg for bananas.

For dietary risk assessment, the residues of imazalil in banana pulp ( $n = 11$  as two trials did not analyse residues in pulp) were, in ranked order: < 0.05 (8), 0.06, 0.07 and 0.10 mg/kg. The Meeting estimated a HR and STMR of 0.10 mg/kg and 0.05 mg/kg, respectively.

### *Cucumber*

In Belgium, the critical GAP for imazalil on greenhouse cucumbers is three foliar spray applications at 0.005 kg ai/hL, 7 day re-treatment interval, and a PHI of 1 day.

Two independent trials were conducted in European countries, where three foliar applications were made at 0.0075 kg ai/hL/application (higher than the critical GAP).

The Meeting agreed to utilise the proportionality approach to estimate residues matching critical GAP. Unscaled imazalil residues in cucumbers were 0.01 and 0.02 mg/kg. Using a scaling factor of 1.5, scaled residues were 0.007 and 0.013 mg/kg.

The Meeting concluded there were insufficient trials to estimate a maximum residue level. The meeting recommends withdrawing its previous recommendations of 0.5 mg/kg for cucumbers and gherkins.

### *Tomato*

In Belgium, the critical GAP for imazalil on greenhouse tomatoes is three foliar spray applications at 0.02 kg ai/hL, a 7 day re-treatment interval, and a PHI of 1 day.

Six independent supervised residue trials were conducted in accordance with the critical GAP where imazalil residues, in ranked order, were 0.04 (2), 0.08, 0.09, 0.15 and 0.16 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg. For dietary risk assessment, the total residues of free and conjugated imazalil (using an adjustment factor of 1.5 to account for conjugated imazalil) were, in ranked order: 0.06 (2), 0.12, 0.14, 0.22 and 0.24 mg/kg. The Meeting estimated a HR of 0.24 mg/kg and a STMR of 0.13 mg/kg.

### *Potato- Post-harvest treatment*

In Europe, the critical GAP for imazalil as a post-harvest treatment is 0.015 kg ai/tonne with a minimum post-treatment interval of 0-day.

Eight independent supervised residue trials were conducted in Germany and the UK on stored potatoes receiving a single post-harvest application, in accordance with the critical GAP. The residues of imazalil in potatoes, in ranked order, were 0.46, 0.88, 1.4, 1.8, 2.6, 4.1, 4.5 and 4.6 mg/kg. The Meeting estimated a maximum residue level of 9 mg/kg (using  $CF \times 3$  mean), a HR of 4.6 mg/kg and a STMR of 2.2 mg/kg. The Meeting replaces its previous recommendation of 5 mg/kg.

### *Cereal grains*

The critical GAP for the seed treatment of wheat and barley is in the USA at 0.1 kg ai/tonne.

No trials were provided matching the critical GAP for wheat.

Five independent supervised seed treatment trials on barley were carried out in various European countries in 2005–2006 in accordance with the critical GAP. All residues of imazalil in barley grain samples were < 0.01 mg/kg.

The supervised seed treatment trials on wheat, carried out in Germany and Poland in 2005-2006, were not conducted in accordance with the critical GAP. However, the Meeting noted that, in the spring wheat metabolism study conducted at 5-fold the critical GAP, residues of imazalil in grain were < 0.01 mg/kg.

Considering the residue profile in barley and wheat are the same following seed treatment use, the datasets can be combined for mutual support.

The Meeting estimated a maximum residue level of 0.01 (\*) mg/kg and a STMR of 0 mg/kg for barley, and triticale and maintains its previous recommendation of 0.01 (\*) mg/kg for wheat.

### ***Animal feed items***

The critical GAP for the seed treatment of wheat is in the USA at 0.1 kg ai/tonne.

### ***Straw, Fodder and Forage of Cereal Grains***

No trials matching the critical GAP for wheat were provided to the Meeting.

When comparing the barley trials with the spring wheat metabolism study, the Meeting considered the residue profile in barley and wheat forage and straw to be the same following seed treatment use.

Five independent supervised seed treatment trials on barley were carried out in various European countries in 2005–2006 in accordance with the USA critical GAP. The residues of imazalil, in all barley forage/whole plant and straw samples were < 0.01 mg/kg.

Noting the above, the Meeting estimated a highest residue of 0.01 mg/kg and median residue of 0.01 mg/kg for each barley forage (whole plant) and wheat forage (whole plant).

For barley straw and fodder (dry) and triticale straw and fodder (dry), the Meeting estimated maximum residue levels of 0.01 mg/kg, highest residues of 0.01 mg/kg and median residues of 0.01 mg/kg for each commodity. The Meeting recommends a maximum residue level, highest residue and median residue of 0.01, 0.01 and 0.01 mg/kg, respectively, for wheat straw and fodder (dry), to replace its previous recommendation of 0.1 mg/kg.

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

#### ***High temperature hydrolysis***

Imazalil was shown to be hydrolytically stable for all hydrolytic conditions tested in this study: at pH 4 and 90 °C simulating pasteurisation, at pH 5 and 100 °C simulating baking/brewing/boiling and at pH 6 and 120 °C simulating the process of sterilisation. There was no evidence of any hydrolysis or reaction products formed during incubation.

#### ***Processing***

The Meeting received information on the fate of imazalil residues during the processing of citrus fruits and potatoes. Processing factors calculated for imazalil for the processed commodities of the citrus fruits and potatoes are shown in the tables below. Processing factors, best estimates, HR-Ps and STMR-Ps were calculated.

*Citrus*

As the residue concentrations of imazalil in all orange and lemon processed commodities are not higher than the estimated maximum residue level for the oranges subgroup, separate maximum residue levels will not be estimated for any of the orange processed commodities.

The Meeting could not recommend maximum residue levels for grapefruit in the absence of sufficient trials, therefore, HR-Ps and STMR-Ps for grapefruit processed commodities could not be determined.

Commodity	Calculated Processing Factors	Best Estimate	RAC STMR, mg/kg	STMR-P, mg/kg	RAC HR, mg/kg	HR-P, mg/kg
Oranges						
Juice	0.01, < 0.02, 0.03, 0.05, 0.10, 0.11, 0.14, 0.33, 0.35	0.10 (median)	0.09	0.01	0.26	0.03
Chopped fresh peel	0.29, 0.48	0.39 (mean)		0.04		0.10
Cold pressed oil	23.8, 33.4	28.6 (mean)		2.6		7.4
Marmalade	0.15, 0.25, 0.25, 0.27, 0.28, 0.56, 0.68	0.27 (median)		0.02		0.07
Jam	0.03, 0.04	0.04 (mean)		0.004		0.01
Jelly	0.02, 0.03	0.03 (mean)		0.003		0.008
Canned orange	< 0.02, 0.04	0.03 (mean)		0.003		0.008
Dry pomace (dried pulp)	4.0, 4.0, 4.4, 4.5, 4.9, 6.7, 9.6	4.5 (median)		0.40		1.2
Lemons						
Juice	0.05,0.04	0.05 (mean)	0.18	0.01	0.36	0.02
Chopped fresh peel	0.38, 0.34	0.36 (mean)		0.06		0.13
Cold pressed oil	4.3, 2.6	3.5 (mean)		0.6		1.3
Dried peel	1.0, 1.0	1.0 (mean)		0.2		0.36

*Potato*

As the residue concentrations of imazalil in all potato processed commodities are not higher than the estimated maximum residue level for potato, separate maximum residue levels will not be estimated for any of the potato processed commodities.

Commodity	Calculated Processing Factors	Best Estimate	RAC STMR, mg/kg	STMR-P, mg/kg	RAC HR, mg/kg	HR-P, mg/kg
Baked, with peel (without foil)	0.40, 0.80	0.60 (mean)	2.2	1.3	4.6	2.8
Baked, with peel (with aluminium foil)	0.37, 0.60	0.49 (mean)		1.1		2.3
Boiled, washed with peel	0.28, 0.50	0.39 (mean)		0.86		1.8
Microwaved, with peel	1.1, 1.6	1.4 (mean)		3.1		6.5
Peel	2.7, 3.2	3.0 (mean)		6.6		13.8
Peeled	0.003, 0.01	0.01 (mean)		0.02		0.05



Commodity	Calculated Processing Factors	Best Estimate	RAC STMR, mg/kg	STMR-P, mg/kg	RAC HR, mg/kg	HR-P, mg/kg
Steamed, washed and peeled	0.01, 0.05	0.03 (mean)		0.07		0.14
Fries	0.01, 0.02	0.02 (mean)		0.04		0.09
Crisps	0.02, 0.02	0.02 (mean)		0.04		0.09
Canned (after sterilization)	0.002, 0.01	0.01 (mean)		0.02		0.05
Flakes	< 0.002, < 0.002	< 0.002 (mean)		0.004		0.009

### ***Residues in animal commodities***

#### ***Farm animal feeding studies***

The Meeting received information on the residue levels arising in tissues and milk when three groups of dairy cows were fed with a diet containing 46.4, 148.6 and 440.5 ppm feed/day for 28 consecutive days. As the estimated dietary burdens for beef and dairy cattle are lower than the lowest feeding level tested, residues of imazalil and its metabolites will only be reported for the low dose feeding level.

Residues of imazalil, R06100 and R043449 in milk were each <LOQ (0.02 mg/kg).

In muscle, residues of imazalil, R06100 and R043449 were each <LOQ (0.02 mg/kg).

In fat, residues of imazalil, R06100 and R043449 were each <LOQ (0.02 mg/kg).

In liver, quantifiable residues of imazalil, R06100 and R043449 were observed at the low dose feeding level, where mean (maximum) residues were 0.326 (0.362), 0.153 (0.224) and 0.153 (0.213) mg/kg, respectively.

Similarly, in kidney, lower yet quantifiable residues of imazalil, R06100 and R043449 were observed at the low dose feeding level, where mean (maximum) residues were 0.020 (0.033), 0.069 (0.078) and 0.022 (0.026) mg/kg, respectively.

The Meeting also received information on the residue levels arising in tissues and eggs when groups of laying hens were fed with a diet containing imazalil at rates of 0.225, 0.728 and 2.56 ppm feed/day for 28 consecutive days. Residues of imazalil, R042639 and R044085 were each <LOQ (0.02 mg/kg/analyte) in tissue samples collected at all dose levels. Similarly, residues of imazalil, R042639, R044085 and R110470 in eggs were each <LOQ (0.01 mg/kg/analyte) at all dosing levels.

#### ***Estimated dietary burdens of farm animals***

Maximum and mean dietary burden calculations for imazalil are based on the feed items evaluated for cattle and poultry as presented in Annex 6. The calculations were made according to the livestock diets from Australia, the EU, Japan and USA-Canada in the OECD feeding tables listed in Appendix IX of the 2016 edition of the FAO Manual.

The post-treatment application of imazalil to oranges and potatoes and seed treatment use on wheat and barley resulted in residues in the following feed items: dried pulp, potato culls, potato peel (waste), wheat and barley straw and grain. Based on the named feed items, the calculated maximum animal dietary burden for dairy or beef cattle was in EU, followed by US/Canada and Australia. For poultry broiler or layer, the calculated maximum dietary burden was in the EU.

	Livestock dietary burden, imazalil							
	US/Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	23.4	19.8	28.9 <sup>a</sup>	25.3 <sup>b</sup>	5.08	3.88	-	23.4
Dairy Cattle	7.81	6.61	23.4 <sup>c</sup>	19.8 <sup>d</sup>	2.46	1.26	-	7.81
Poultry, broiler	-	-	2.3	1.1	-	-	-	-
Poultry, layer	-	-	2.3 <sup>e</sup>	1.1 <sup>f</sup>	-	-	-	-

<sup>a</sup> Suitable for maximum residue level estimate for meat, fat and edible offal of mammals

<sup>b</sup> Suitable for STMR estimate for meat, fat and edible offal of mammals

<sup>c</sup> Suitable for maximum residue level estimate for milk

<sup>d</sup> Suitable for STMR estimate for milk

<sup>e</sup> Suitable for maximum residue level estimate for eggs, meat, fat and edible offal

<sup>f</sup> Suitable for STMR estimate for eggs, meat, fat and edible offal

### Animal commodities residue level estimation

Anticipated residues for maximum residue level recommendation resulting from the dietary burdens and based on the feeding studies are summarised below:

	Feed level for milk residues (ppm)	Imazalil Residues in milk (mg/kg)	Feed level for tissue residues (ppm)	Imazalil Residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
maximum residue level Estimation - Beef or Dairy Cattle							
Feeding level	46.4	< 0.02	46.4	< 0.02	0.36	0.03	< 0.02
Dietary burden and anticipated residues	23.4	< 0.02	28.9	< 0.02	0.22	0.02	< 0.02

Anticipated residues for dietary exposure assessment resulting from the dietary burdens and based on the feeding studies are summarised below:

	Feed level for milk residues (ppm)	Total imazalil residues <sup>a</sup> in milk (mg/kg)	Feed level for tissue residues (ppm)	Total imazalil residues <sup>1</sup> (mg/kg)			
				Muscle	Liver	Kidney	Fat
HR Estimation – Beef Cattle							
Feeding level	-	-	46.4	< 0.04	0.80	0.14	< 0.04
Dietary burden and anticipated residues	-	-	28.9	< 0.04	0.50	0.09	< 0.04
STMR Estimation – Beef or Dairy Cattle							
Feeding level	46.4	< 0.04	46.4	< 0.04	0.63	0.11	< 0.04
Dietary burden and anticipated residues	19.8	< 0.04	25.3	< 0.04	0.34	0.06	< 0.04

<sup>a</sup> Total residues of imazalil and R061000, expressed as parent equivalents.

The Meeting estimated a maximum residue level and STMR of 0.02(\*) mg/kg and 0 mg/kg, respectively for milks. For meat (from mammals other than marine mammals), the Meeting estimated a maximum residue level, HR and STMR of 0.02(\*) mg/kg, 0.04 mg/kg and 0.04 mg/kg and for mammalian

fat (except milk fats), the Meeting estimated a maximum residue level, HR and STMR of 0.02 mg/kg, 0.04 mg/kg and 0.04 mg/kg. For edible offal (mammalian), a maximum residue level, HR and STMR of 0.3 mg/kg, 0.50 mg/kg and 0.34 mg/kg, respectively, based on liver residue are recommended. For kidney, the HR and STMR are 0.09 and 0.06 mg/kg, respectively.

In the poultry feeding study, residues of imazalil from all feeding levels were < 0.01 mg/kg in eggs and < 0.02 mg/kg in fat, muscle and liver. Therefore, the meeting estimated a maximum residue level of 0.01(\*) mg/kg for eggs and 0.02(\*) mg/kg for each poultry meats, fats and edible offal of poultry. Based on an estimated dietary burden for poultry of 1.3 ppm, the Meeting estimated HRs and STMRs of 0.02 and 0.02 mg/kg for eggs and 0.04 mg/kg and 0.04 mg/kg for poultry meats, fats and edible offal of poultry.

## 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 IESTI and IEDI assessments.

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

Definition of the residue for dietary risk assessment for plant commodities: *free and conjugated imazalil*.

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

Definition of the residue for dietary risk assessment for animal commodities: *sum of imazalil and the metabolite R061000 ((RS)-3-[2-(2,4-dichlorophenyl)-2-(2,3-dihydroxypropoxy)ethyl]imidazolidine-2,4-dione (±)-1-[2-(2,4-dichlorophenyl)-2-[(2,3-dihydroxypropyl)oxy]ethyl]-2,5-imidazolidinedione), expressed as imazalil equivalents.*

The residue is not fat-soluble.

## DIETARY RISK ASSESSMENT

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

The ADI for imazalil is 0–0.03 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for imazalil 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 2018 JMPR Report. The IEDIs ranged from 2–40% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of imazalil from uses considered by the JMPR is unlikely to present a public health concern.

### **Acute dietary exposure**

The ARfD for imazalil is 0.05 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for imazalil 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 2018 JMPR Report. The IESTIs varied from 0–40% of the ARfD for children and 0–90% for the general population.

The Meeting concluded that acute dietary exposure to residues of imazalil from uses considered by the present Meeting is unlikely to present a public health concern.



## 5.14 ISOSETAMID (290)

### RESIDUE AND ANALYTICAL ASPECTS

Isofetamid is a succinate dehydrogenase inhibitor (SDHI) fungicide with a single site of action that inhibits cellular respiration. Isofetamid was first evaluated for toxicology and residues by the JMPR in 2016. The 2016 JMPR set an ADI of 0–0.05 mg/kg bw and an ARfD of 3 mg/kg bw for isofetamid. The 2016 Meeting also concluded that the residue definition for plant commodities for compliance with the MRL and for dietary risk assessment was parent isofetamid. The residue definition for compliance with the MRL and dietary risk assessment for animal commodities was, the sum of isofetamid and 2-[3-methyl-4-[2-methyl-2-(3-methylthiophene-2-carboxamido) propanoyl] phenoxy] propanoic acid (PPA), expressed as isofetamid. The residue is fat-soluble.

Isofetamid was scheduled at the Forty-ninth Session of the CCPR for the evaluation of additional uses by the 2018 JMPR. The Meeting received information on use patterns, supervised residue trials and processing studies. A dairy cow feeding study was also provided to the Meeting along with an analytical method for isofetamid and PPA residues in milk and liver matrices.

#### ***Methods of analysis***

The 2016 JMPR Meeting reviewed analytical methods for isofetamid in plant commodities, and for isofetamid and PPA in animal commodities. All methods were sufficiently validated and acceptable for the consideration of the residue data and enforcement. The methods for determining isofetamid residues in plant commodities including pome fruit, stone fruit, blueberry, raspberry, kiwi fruit, snap bean, lima bean, green bean, dry bean and dry pea were supported with concurrent recovery data from supervised trials submitted to the current Meeting. Analytical methods for determining isofetamid and PPA in cattle milk and liver matrices were independently validated and the methods were considered to be equivalent with the methods for animal commodities reviewed by 2016 JMPR. The methods were considered suitable for the plant and animal commodities evaluated.

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

The 2016 JMPR indicated that isofetamid residues are stable at -20 °C for at least 12 months in almonds, rape seeds, grapes, lettuce, potatoes and dry beans.

The current Meeting received residue storage stability data for isofetamid in almonds, rape seed, grapes, lettuce, potatoes and dry beans. Residues of isofetamid in these commodities are stable for at least 24 months when stored frozen at approximately -20 °C.

The Meeting also received a residue study on the stability of isofetamid and PPA in milk, liver, kidney, muscle and fat. Isofetamid and PPA were found to be stable for at least 68 days in milk, muscle, fat, kidney and liver.

The Meeting agreed that the demonstrated storage stability in various representative plant and animal commodities covered the residue sample storage intervals used in the field trials considered by the current Meeting.

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

The Meeting received information on supervised field trials involving foliar treatments of isofetamid to pome fruits (including apple and pear), stone fruits (including peach, plum and cherry), berries, kiwi fruit, grape, legume vegetables and pulses.

### *Pome fruits*

Results of supervised trials on apple and pear conducted in Canada and the USA were provided to the Meeting.

#### *Apple and Pear*

The critical GAP for isofetamid on pome fruits in the USA is for 6 foliar applications of 0.365 kg ai/ha with a re-treatment interval of 7 days and a PHI of 20 days.

In 16 trials on apples conducted in North America matching the GAP in the USA, the residues of isofetamid in apples (whole fruit) were (n = 16): 0.030, 0.042, 0.049, 0.066, 0.075, 0.083, 0.11, 0.14, 0.17(2), 0.18(2), 0.27(2), 0.32 and 0.38 mg/kg.

In eight trials on pears conducted in North America matching the GAP in the USA, the residues of isofetamid in pears (whole fruit) were (n = 8): 0.041, 0.043, 0.13(3), 0.14, 0.15 and 0.29 mg/kg.

The Meeting noted that residues from apples and pears were similar (Mann-Whitney test) and could be combined. The combined residue data set were (n = 24): 0.030, 0.041, 0.042, 0.043, 0.049, 0.066, 0.075, 0.083, 0.11, 0.13(3), 0.14(2), 0.15, 0.17(2), 0.18(2), 0.27(2), 0.29, 0.32 and 0.38 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg, a STMR of 0.135 mg/kg and a HR of 0.42 mg/kg (highest individual value) for isofetamid on the group of pome fruits.

### *Stone fruits*

Results from supervised trials on peach, plum and cherry conducted in Canada and the USA were provided to the Meeting.

The critical GAP for isofetamid on stone fruits in Canada and the USA is for up to 3 foliar applications of 0.365 kg ai/ha with a re-treatment interval of 7 days and a PHI of 1 day.

#### *Peaches*

In 11 trials on peach conducted in North America and matching the GAP of the USA, residues of isofetamid were (n = 11): 0.24, 0.32, 0.45, 0.54, 0.68, 0.76, 0.78, 0.83, 0.88, 1.3 and 1.7 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, a STMR of 0.76 mg/kg and a HR of 1.7 mg/kg for isofetamid on the subgroup of peaches.

#### *Plums*

In eight trials on plums conducted in North America and matching the GAP of the USA, the residues of isofetamid were (n = 8): 0.03, 0.05(2), 0.14, 0.21, 0.33, 0.35 and 0.36 mg/kg.

The Meeting estimated a maximum residue level of 0.8 mg/kg, a STMR of 0.175 mg/kg and a HR of 0.39 mg/kg (highest individual) for isofetamid on the subgroup of plums.

#### *Cherries*

In 13 trials on cherry conducted in North America and matching the GAP of the USA, the residues of isofetamid were (n = 13): 0.31, 0.40, 0.66, 0.76, 0.86, 1.0, 1.1, 1.2, 1.3, 1.4, 1.7, 2.2 and 2.5 mg/kg.

The Meeting estimated a maximum residue level of 4 mg/kg, a STMR of 1.1 mg/kg and a HR of 3.4 mg/kg (highest individual) for isofetamid on the subgroup of cherries.

*Berries and other small fruits**Bush berries*

The critical GAP for isofetamid in “Berry and Small Fruit Crop Group” from Canada is for 3 foliar applications at 0.496 kg ai/ha with a re-treatment interval (RTI) of 7 days and a PHI of 7 days.

In several trials in similar locations the varietal and management differences were considered likely to result in sufficiently different residue scenarios and thus were considered to be independent.

In 10 independent trials on blueberry conducted in North America and similar to the Canadian GAP but at higher application rates of 0.650 kg ai/ha the residues of isofetamid in blueberry were (n = 10): 0.18, 0.25, 0.27, 0.30, 0.34, 0.46, 0.77, 0.89, 0.99 and 3.6 mg/kg.

Using the proportionality approach, residue were scaled with factors ranging from 0.761 to 0.839.

Scaled isofetamid residues were (n = 10): 0.14, 0.19, 0.20, 0.23, 0.27, 0.35, 0.59, 0.68, 0.77 (factor 0.781) and 3.0 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a STMR of 0.31 mg/kg and a HR of 3.0 mg/kg for isofetamid on the subgroup of bush berries.

*Cane berries*

The critical GAP for isofetamid on cane berries included in “Berry and Small Fruit Crop Group 13-07” in Canada is for 3 foliar applications at 0.496 kg ai/ha with a re-treatment intervals of 7 days and a PHI of 7 days.

In five independent trials on raspberries conducted in North America, and similar to the Canadian GAP but at higher application rates of 0.650 kg ai/ha, the residues of isofetamid in raspberries were (n = 5): 0.20, 0.53, 0.88, 1.4 and 1.6 mg/kg.

Using the proportionality approach, residues were scaled with factors ranging from 0.762 to 0.781.

Scaled isofetamid residues were (n = 5): 0.16, 0.41, 0.68, 1.1 and 1.2 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, a STMR of 0.68 mg/kg and a HR of 1.2 mg/kg for isofetamid on subgroup of cane berries.

*Assorted tropical and subtropical fruits – inedible peel**Kiwi fruit*

The critical GAP for isofetamid on “Fruit, Small Vine Climbing Fruit except Grapes Subgroup 13-07E” in the USA is for 4 foliar applications at 0.448 kg ai/ha (seasonal maximum of 1.794 kg ai/ha) with re-treatment intervals of 14 days and a PHI of 7 days.

In three trials conducted in the USA, 3 foliar applications of 0.65 kg ai/ha with a PHI of 7 days resulted in isofetamid residues in kiwi fruits of (n = 3): < 0.01, 0.89 and 3.8 mg/kg.

The Meeting agreed that there were insufficient data with which to estimate a maximum residue level for kiwi fruit.

*Legume vegetables*

The critical GAP for isofetamid in legume vegetables in Canada and the USA is for the following foliar applications:

- beans and peas with pods: 2 × 0.5 kg ai/ha, 7-14 days RTI and a PHI of 7 days;
- Succulent beans and peas without pods: 2 × 0.5 kg ai/ha, 7–14 days RTI and a PHI of 14 days.

#### *Beans with pods*

In seven trials on snap beans conducted in Canada and the USA, matching the critical GAP the residues of isofetamid were (n = 7): 0.031, 0.057, 0.077, 0.096, 0.16, 0.16 and 0.32 mg/kg.

#### *Peas with pods*

None of the submitted trials matched the cGAP. The Meeting noted that as beans with pods is a representative crop for both the subgroup of beans with pods and the subgroup of peas with pods, the maximum residue level recommendation for beans with pods could also be applied to peas with pods.

Based on the data for snap beans the Meeting estimated a maximum residue level of 0.6 mg/kg, a STMR of 0.096 mg/kg and a HR of 0.36 mg/kg (highest individual) for isofetamid on subgroup of beans with pods and for subgroup of peas with pods.

#### *Succulent beans without pods*

The critical GAP for isofetamid in “Legume Vegetables, Edible podded” in Canada is for 2 foliar applications at 0.5 kg ai/ha with a re-treatment interval of 7 days and a PHI 14 days.

In two trials on lima beans conducted in the USA and matching the critical GAP the residues of isofetamid were (n = 2): < 0.01 (2) mg/kg.

The Meeting agreed that there was insufficient data to estimate a maximum residue level for succulent beans without pods.

#### *Succulent peas without pods*

In three trials on peas conducted in Canada and the USA, and matching the cGAP the residues of isofetamid were (n = 3): < 0.01 (2) and 0.023 mg/kg.

The Meeting agreed that there was insufficient data to estimate a maximum residue level for succulent peas without pods.

### *Pulses*

The critical GAP for isofetamid on pulses including dry beans and dry peas in the USA and Canada is for 2 foliar applications of 0.5 kg ai/ha with a 7 day re-treatment interval and a PHI of 30 days.

#### *Dry beans*

In eight trials on dry beans conducted in North America and matching the critical GAP the residues of isofetamid were (n = 8): < 0.01 (7), 0.036 mg/kg.

#### *Dry peas*

In 11 trials on dry peas conducted in North America and matching the critical GAP the residues of isofetamid were (n = 11): < 0.01 (9), 0.02, 0.08 mg/kg.

The Meeting noted that residues from dry beans and dry peas were similar (Mann-Whitney test) and could be combined. The combined residue data were (n = 19): < 0.01 (16), 0.02, 0.036 and 0.08 mg/kg



The Meeting estimated a maximum residue level of 0.05 mg/kg, and a STMR of 0.01 mg/kg for isofetamid on subgroup of dry beans except soya bean, and subgroup of dry peas.

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

The Meeting received studies on the effect of processing on isofetamid residues in apple and plum.

Summary of isofetamid processing factors and STMR-P values in apple and plum processed commodities

Matrix	Isofetamid		RAC STMR (mg/kg)	STMR-P (mg/kg)
	Calculated processing factors	PF		
Apple juice	0.31	0.31	0.13	0.04
Apple wet pomace	4.1	4.1		0.53
Dried prune	4.1, 3.8	4.0 (mean)	0.14	0.56

The Meeting estimated a maximum residue level of  $4 \times 0.8 = 3$  mg/kg for dried prune, along with a STMR-P of  $4 \times 0.14 = 0.56$  mg/kg and a HR of  $4 \times 0.38 = 1.5$  mg/kg.

### ***Residues in animal commodities***

#### ***Farm animal feeding studies***

An isofetamid feeding study in dairy cow was provided to the Meeting. Isofetamid was administered orally once daily in the diet to dairy cows for 28 days at levels of 0.5 (low), 1.5 (mid) and 5.01 (high) ppm diet (dry wt/day). The metabolite PPA was not detected in milk, muscle, fat, kidney or liver. Isofetamid residues were below the LOQ (0.01 mg/kg) in all animal matrices.

#### ***Estimation of livestock dietary burdens***

The current Meeting noted that residues in apple (pomace), dry beans and dry peas may contribute to the livestock dietary burden. The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO manual. The dietary burden for dairy cattle and beef cattle remained unchanged. The slight increase in estimated maximum and mean dietary burdens for poultry layers (0.008 ppm) were not expected to add significantly to residues in poultry. The meeting confirmed the 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 and dietary risk assessment for plant commodities: *Isofetamid*.

Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: *the sum of isofetamid and 2-[3-methyl-4-[2-methyl-2-(3-methylthiophene-2-carboxamido)propanoyl]phenoxy]propanoic acid (PPA), expressed as isofetamid*.

The residue is fat-soluble.

## DIETARY RISK ASSESSMENT

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

The ADI for isofetamid is 0–0.05 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for isofetamid 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 2018 JMPR Report. The IEDIs ranged from 0–6% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of isofetamid from uses considered by the JMPR is unlikely to present a public health concern.

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

The ARfD for isofetamid is 3 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for isofetamid were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the current JMPR and for which consumption data were available. The results are shown in Annex 4 of the 2018 JMPR Report. The IESTIs varied from 0–3% of the ARfD for children and 0% for the general population.

The Meeting concluded that acute dietary exposure to residues of isofetamid from uses considered by the the current JMPR is unlikely to present a public health concern.

## 5.15 KRESOXIM-METHYL (199)

### TOXICOLOGY

Kresoxim-methyl is the ISO-approved common name for methyl-(*E*)-2-methoxyimino-2-[2-(2-methylphenoxy)methyl]phenyl] acetate (IUPAC), with the CAS number 143390-89-0.

Kresoxim-methyl is a broad-spectrum fungicide and a member of the strobilurin family, a class of biologically active compounds structurally related to strobilurin A, a natural product of the wood-decaying fungus *Strobilurus tenacellus*. It is intended for use as an agricultural spray in the control and treatment of fungal infections on crops and fruits. Strobilurins are known to bind bcl complex (complex III), one of the oxidoreductase enzymes in the electron transport chain in mitochondria.

Kresoxim-methyl was previously evaluated by JMPR in 1998, when an ADI of 0–0.4 mg/kg bw was established on the basis of a NOAEL of 36 mg/kg bw per day in a 24-month study of toxicity and carcinogenicity in rats, with application of a 100-fold safety factor. It was considered to be unnecessary to establish an ARfD.

Kresoxim-methyl was reviewed by the present Meeting as part of the periodic review programme of CCPR.

Studies on acute toxicity, carcinogenicity in a different strain of rat, genotoxicity and neurotoxicity that were not evaluated at the 1998 Meeting were made available to the present Meeting.

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 rats, orally administered radiolabelled kresoxim-methyl was rapidly, but incompletely, absorbed from the gastrointestinal tract. The extent of oral absorption was about 63% at the low dose (50 mg/kg bw) in both sexes, based on recovery of the radiolabel in bile and urine, and 23–27% at the high dose (500 mg/kg bw). Kresoxim-methyl was excreted mainly in the faeces (70% of the low dose and 80% of the high dose), with about 40% excreted via the bile at the low dose and 15% at the high dose within 48 hours. Lesser amounts were excreted in urine (about 20% of the low dose and 10% of the high dose). Peak levels of the radiolabel in plasma were reached 0.5–1 hour after the low dose and 8 hours after the high dose. The plasma half-life of radiolabel was 17–19 hours at the low dose and 22–31 hours at the high dose.

Radioactive material was distributed in all tissues and organs throughout the body, and the total radioactivity in the organs was less than 2% of the administered dose 96 hours after dosing. The highest radioactivity was associated with the gastrointestinal tract, liver and kidney. There was no evidence of accumulation of radioactive material after dosing with <sup>14</sup>C-labelled kresoxim-methyl.

After oral administration in the rat, absorbed kresoxim-methyl was rapidly and completely metabolized. The metabolic pathways of kresoxim-methyl consisted of hydrolytic cleavages of the ester, the oxime ether and the benzyl ether bonds; hydroxylation at the *para* position of the phenoxy ring; oxidation of the aryl-methyl group to benzyl alcohol and its subsequent oxidation to the corresponding carboxylic acid; and conjugation of the resulting hydroxy groups with glucuronate and sulfate. The major metabolites identified in urine and faeces were M1, a hydrolytic product of the acetyl ester; M2, an oxidative metabolite of the aryl-methyl moiety of M1; and M9, a hydroxylated metabolite of the phenoxy ring of M1. M1 and M9 were the major metabolites identified in tissues.

***Toxicological data***

The acute toxicity of kresoxim-methyl in rats was studied by the oral route ( $LD_{50} > 2000$  mg/kg bw), the dermal route ( $LD_{50} > 2000$  mg/kg bw) and inhalation ( $LC_{50} > 5.6$  mg/L air). Kresoxim-methyl is not irritating to the skin of rabbits or irritating to the eyes of rabbits. Kresoxim-methyl 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 mice, rats and dogs, the predominant target organ was the liver.

In a 28-day range-finding study in mice administered kresoxim-methyl in the diet at a concentration of 0, 500, 2000 or 8000 ppm (equal to 0, 113, 485 and 2141 mg/kg bw per day for males and 0, 182, 798 and 3755 mg/kg bw per day for females, respectively), the NOAEL was 8000 ppm (equal to 2141 mg/kg bw per day), the highest dose tested.

In a 3-month study in mice administered kresoxim-methyl in the diet at a concentration of 0, 250, 1000, 4000 or 8000 ppm (equal to 0, 57, 230, 909 and 1937 mg/kg bw per day for males and 0, 80, 326, 1326 and 2583 mg/kg bw per day for females, respectively), the NOAEL was 4000 ppm (equal to 909 mg/kg bw per day), based on decreases in body weight gain ( $>10\%$ ) in males at 8000 ppm (equal to 1937 mg/kg bw per day).

In a 28-day range-finding study in rats administered kresoxim-methyl in the diet at a concentration of 0, 1000, 4000 or 16 000 ppm (equal to 0, 91, 365 and 1428 mg/kg bw per day for males and 0, 95, 375 and 1481 mg/kg bw per day for females, respectively), the NOAEL was 4000 ppm (equal to 365 mg/kg bw per day), based on the increased serum gamma-glutamyl transferase (GGT) activity in males, increased albumin concentration in males and increased relative liver weight in females at 16 000 ppm (equal to 1428 mg/kg bw per day).

In a 90-day study in rats administered kresoxim-methyl in the diet at a concentration of 0, 500, 2000, 8000 or 16 000 ppm (equal to 0, 36, 146, 577 and 1170 mg/kg bw per day for males and 0, 43, 172, 672 and 1374 mg/kg bw per day for females, respectively), the NOAEL was 2000 ppm (equal to 146 mg/kg bw per day), based on decreased body weight and body weight gain and increased GGT activity in males at 8000 ppm (equal to 577 mg/kg bw per day).

In a 90-day study in dogs administered kresoxim-methyl in the diet at a concentration of 0, 1000, 5000 or 25 000 ppm (equal to 0, 30, 150 and 776 mg/kg bw per day for males and 0, 34, 168 and 846 mg/kg bw per day for females, respectively), the NOAEL was 5000 ppm (equal to 150 mg/kg bw per day), on the basis of vomiting and diarrhoea in both sexes and reduced body weight gain in females at 25 000 ppm (equal to 776 mg/kg bw per day).

In a 12-month study in dogs administered kresoxim-methyl in the diet at a concentration of 0, 1000, 5000 or 25 000 ppm (equal to 0, 27, 140 and 710 mg/kg bw per day for males and 0, 30, 150 and 760 mg/kg bw per day for females, respectively), the NOAEL was 5000 ppm (equal to 140 mg/kg bw per day), based on infrequent diarrhoea and vomiting occurring in both sexes and significantly reduced body weights of males at study termination at 25 000 ppm (equal to 710 mg/kg bw per day).

The overall NOAEL for dogs was 5000 ppm (equal to 150 mg/kg bw per day), and the overall LOAEL was 25 000 ppm (equal to 710 mg/kg bw per day).

In an 18-month assay for carcinogenicity in mice, kresoxim-methyl was administered at a dietary concentration of 0, 400, 2000 or 8000 ppm (equal to 0, 60, 304 and 1305 mg/kg bw per day for males and 0, 81, 400 and 1662 mg/kg bw per day for females, respectively). The NOAEL for systemic toxicity was 2000 ppm (equal to 304 mg/kg bw per day), on the basis of reductions in body weight and body weight gain in

both sexes and histopathological changes in the liver and increased liver weights in females at 8000 ppm (equal to 1305 mg/kg bw per day). Kresoxim-methyl was not carcinogenic in mice up to 8000 ppm (equal to 1305 mg/kg bw per day), the highest dose tested.

In a 24-month toxicity study in Wistar rats (Chbb.THOM(SPF) administered kresoxim-methyl in the diet at a concentration of 0, 200, 800, 8000 or 16 000 ppm (equal to 0, 9, 36, 370 and 746 mg/kg bw per day for males and 0, 12, 48, 503 and 985 mg/kg bw per day for females, respectively), the NOAEL for toxicity was 800 ppm (equal to 36 mg/kg bw per day), on the basis of increased activity of serum GGT, increased relative liver weight, and increased incidence and degree of severity of eosinophilic foci in males at 8000 ppm (equal to 370 mg/kg bw per day). An increased incidence of hepatocellular tumours was observed in both sexes from 8000 ppm (equal to 370 mg/kg bw per day). This study was not powered to characterise the carcinogenic potential of kresoxim-methyl.

In a 24-month study of carcinogenicity in Wistar rats (Chbb.THOM(SPF)) administered kresoxim-methyl at a dietary concentration of 0, 200, 800, 8000 or 16 000 ppm (equal to 0, 9, 36, 375 and 770 mg/kg bw per day for males and 0, 12, 47, 497 and 1046 mg/kg bw per day for females, respectively), the NOAEL for systemic toxicity was 800 ppm (equal to 36 mg/kg bw per day), on the basis of reduced body weight and body weight gain and hepatic alterations at 8000 ppm (equal to 375 mg/kg bw per day). It should be noted that this study was not designed to assess chronic toxicity, and the evaluation of non-neoplastic effects was less thorough than would be required for this purpose. A robust NOAEL for carcinogenicity could not be clearly identified, as the increase in the incidence of hepatocellular tumours in female rats at 800 ppm (equal to 36 mg/kg bw per day) was equivocal, with the incidences varying in the different pathology evaluations performed; clear increases in liver tumours were evident in both sexes at 8000 and 16 000 ppm.

The Meeting concluded that the analysis of the liver tumours produced by kresoxim-methyl in rats was best performed by a benchmark dose (BMD) analysis using the combined tumour incidences in the chronic toxicity study with 20 rats per group and the carcinogenicity study with 50 rats per group. The two studies were performed concurrently in the same laboratory, with the same batch of animals, with no differences in study design that would likely have an impact on the evaluation of liver carcinogenicity. Of the three pathology evaluations performed on these liver tumours, the Meeting concluded that the analysis by the pathology working group was the most robust and should be utilized for the BMD analysis. The lowest lower confidence limit on the benchmark dose for a 10% response (BMDL<sub>10</sub>) for liver tumours in female rats identified using "PROASTweb" software was 29.1 mg/kg bw per day, and this was selected as the point of departure (POD) for consideration in the risk assessment.

In a limited 24-month carcinogenicity study, kresoxim-methyl was administered to the CrlGlxBrlHan:WI strain of Wistar rats by feed at a concentration of 0 or 16 000 ppm (equal to 0 and 752.1 mg/kg bw per day for males and 0 and 1021.6 mg/kg bw per day for females, respectively). At 16 000 ppm, an increase in liver tumours (hepatocellular adenoma and carcinoma) was observed in both sexes.

The Meeting concluded that kresoxim-methyl is carcinogenic in rats, but not in mice.

Kresoxim-methyl was tested for genotoxicity in an adequate range of in vitro and in vivo assays. No evidence of genotoxicity was found. In the Syrian hamster embryo assay (morphology transformation assay), exposure after 24 hours increased cell transformation only at cytotoxic concentrations.

The Meeting concluded that kresoxim-methyl was unlikely to be genotoxic.

A series of mechanistic studies was conducted with kresoxim-methyl, including tests for tumour initiating and promoting potential. In a study on tumour initiating activity, kresoxim-methyl did not increase the number of placental-type glutathione *S*-transferase-positive hepatocellular foci in rats at a single dose of 2388 mg/kg bw. In a study on the promoting potential of kresoxim-methyl, rats received an initiating

dose of *N*-nitrosodiethylamine and then a diet containing 0, 200, 800, 8000 or 16 000 ppm (equal to 0, 10.78, 42.47, 430.6 and 886 mg/kg bw per day, respectively) of kresoxim-methyl for 6 weeks. The NOAEL for the promoting effect was 800 ppm (equal to 42.47 mg/kg bw per day), based on dose-dependent increases in placental-type glutathione *S*-transferase-positive hepatocellular foci, indicating a promoting effect of kresoxim-methyl on hepatocarcinogenesis at 8000 ppm (equal to 430.6 mg/kg bw per day).

Four *in vivo* studies were conducted to investigate the effect of kresoxim-methyl on hepatic cell proliferation in rat liver by measuring bromodeoxyuridine incorporation into hepatocyte DNA during S-phase DNA synthesis. The NOAEL for cell proliferation was 800 ppm (equal to 61 mg/kg bw per day).

Overall, the above mechanistic data support a threshold-based mode of action for carcinogenesis.

Several additional studies were conducted to investigate unscheduled DNA synthesis and S-phase response in rat hepatocytes, the morphology of hepatic proliferation in rats, effects on hepatocyte mitochondria, the induction of hepatic metabolic enzyme activities and the mechanism of decreased serum enzyme activities in rats. The Meeting concluded that these studies did not contribute to the risk assessment of kresoxim-methyl.

In view of the lack of genotoxicity, the absence of carcinogenicity in mice and the fact that only hepatocellular tumours were observed and that these were increased in both sexes of rats by a threshold-dependent mode of action, the Meeting concluded that kresoxim-methyl is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation study of reproductive toxicity, rats fed with diets containing kresoxim-methyl at a concentration of 0, 50, 1000, 4000 or 16 000 ppm (equal to 0, 5.1, 102.6, 411.0 and 1623.1 mg/kg bw per day for males and 0, 4.3, 84.3, 348.9 and 1389.3 mg/kg bw per day for females, respectively), the NOAEL for parental toxicity was 1000 ppm (equal to 84.3 mg/kg bw per day), based on reduced body weight and body weight gain, increased serum GGT activity and increased relative kidney weights at 4000 ppm (equal to 348.9 mg/kg bw per day). The NOAEL for reproductive toxicity was 16 000 ppm (equal to 1389.3 mg/kg bw per day), the highest dose tested, as no reproductive effects were observed at any dose. The NOAEL for offspring toxicity was 1000 ppm (equal to 84.3 mg/kg bw per day), based on retarded growth at 4000 ppm (equal to 348.9 mg/kg bw per day), leading to a lower rate of F<sub>1b</sub> pups per litter with pinna unfolding.

In a developmental toxicity study in rats using gavage dosing at 0, 100, 400 or 1000 mg/kg bw per day on days 6–15 of gestation, the NOAEL for maternal toxicity was 1000 mg/kg bw per day, the highest dose tested. The NOAEL for embryo/fetal toxicity was 400 mg/kg bw per day, on the basis of a slight increase in incidence of reduced ossification in fetuses at 1000 mg/kg bw per day.

In a developmental toxicity study in rabbits using gavage dosing at 0, 100, 400 or 1000 mg/kg bw per day on days 7–19 of gestation, the NOAEL for maternal and embryo/fetal toxicity was 1000 mg/kg bw per day, the highest dose tested.

The Meeting concluded that kresoxim-methyl is not teratogenic in rats or rabbits.

In an acute neurotoxicity study in rats administered a single oral kresoxim-methyl dose of 0, 500, 1000 or 2000 mg/kg bw by gavage, the NOAEL for systemic toxicity and neurotoxicity was 2000 mg/kg bw, the highest dose tested.

In a 90-day study of neurotoxicity in rats given diets containing kresoxim-methyl at a concentration of 0, 1000, 4000 or 16 000 ppm (equal to 0, 72, 292 and 1180 mg/kg bw per day for males and 0, 84, 341 and 1354 mg/kg bw per day for females, respectively), the NOAEL for neurotoxicity was 16 000 ppm (equal to 1180 mg/kg bw per day), the highest dose tested.

The Meeting concluded that kresoxim-methyl is not neurotoxic.

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

The acute oral toxicity of the rat and plant metabolites 490M1, 490M2 and 490M9 was investigated ( $LD_{50} > 2000$  mg/kg bw). 490M1, 490M2, 490M9 and 490M15 are not genotoxic.

490M9 is found in urine at over 10% of the dose and is derived from 490M1, and therefore their toxicity could be considered to be covered by the toxicity of the parent compound.

490M2 is present at less than 6% in faeces and urine of rats. For chronic toxicity, the TTC approach (Cramer class III) could be applied for 490M2 and its conjugate, expressed as 490M2.

***Human data***

No adverse health effects suspected to be related to kresoxim-methyl exposure have been observed in persons handling crop protection products.

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

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

No epidemiological studies are available.

The Meeting concluded that the existing database on kresoxim-methyl was adequate to characterise the potential hazards to the general population, including fetuses, infants and children.

***Toxicological evaluation***

The Meeting established an ADI of 0–0.3 mg/kg bw, derived from a  $BMDL_{10}$  of 29.1 mg/kg bw per day from the 2-year chronic toxicity and carcinogenicity studies in rats, on the basis of liver tumours produced by a threshold-based mode of action. A safety factor of 100 was applied.

The Meeting concluded that it was not necessary to establish an ARfD for kresoxim-methyl in view of its low acute oral toxicity and the absence of any other toxicological effects, including developmental toxicity, that would be likely to be elicited by a single dose.

The Meeting concluded that the ADI could be applied to the metabolites 490M1 and 490M9 and their conjugates.

A toxicological monograph was prepared.

***Levels relevant to risk assessment of kresoxim-methyl***

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	2 000 ppm, equal to 304 mg/kg bw per day	8 000 ppm, equal to 1 305 mg/kg bw per day
		Carcinogenicity	8 000 ppm, equal to 1 305 mg/kg bw per day <sup>b</sup>	–
Rat	Two-year study of toxicity <sup>a</sup>	Toxicity	800 ppm, equal to 36 mg/kg bw per day	8 000 ppm, equal to 370 mg/kg bw per day
	Two-year study of carcinogenicity <sup>a</sup>	Toxicity	800 ppm, equal to 36 mg/kg bw per day	8 000 ppm, equal to 375 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
		Carcinogenicity	29.1 mg/kg bw per day (BMDL <sub>10</sub> )	–
		Reproductive toxicity	16 000 ppm, equal to 1389.3 mg/kg bw per day <sup>b</sup>	–
		Parental toxicity	1 000 ppm, equal to 84.3 mg/kg bw per day	4 000 ppm, equal to 348.9 mg/kg bw per day
		Offspring toxicity	1 000 ppm, equal to 84.3 mg/kg bw per day	4 000 ppm, equal to 348.9 mg/kg bw per day
	Developmental toxicity study <sup>c</sup>	Maternal toxicity	1 000 mg/kg bw per day <sup>b</sup>	–
		Embryo and fetal toxicity	400 mg/kg bw per day	1 000 mg/kg bw per day
	Acute neurotoxicity study <sup>c</sup>	Neurotoxicity	2 000 mg/kg bw <sup>b</sup>	–
	Ninety-day neurotoxicity studies <sup>a</sup>	Neurotoxicity	1 180 mg/kg bw per day <sup>b</sup>	–
Rabbit	Developmental toxicity study <sup>c</sup>	Maternal toxicity	1 000 mg/kg bw per day <sup>b</sup>	–
		Embryo and fetal toxicity	1 000 mg/kg bw per day <sup>b</sup>	–
Dog	Ninety-day and 1-year studies of toxicity <sup>a,d</sup>	Toxicity	5 000 ppm, equal to 150 mg/kg bw per day	25 000 ppm, equal to 710 mg/kg bw per day

<sup>a</sup> Dietary administration.

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

<sup>c</sup> Gavage administration.

<sup>d</sup> Two or more studies combined.

*Acceptable daily intake (ADI) (applies to kresoxim-methyl, 490M1 and 490M9 and their conjugates, expressed as kresoxim-methyl)*

0–0.3 mg/kg bw

*Acute reference dose (ARfD)*

Unnecessary

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

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



***Critical end-points for setting guidance values for exposure to kresoxim-methyl***

<i>Absorption, distribution, excretion and metabolism in mammals</i>	
Rate and extent of oral absorption	Rapidly, but incompletely, absorbed (~60%)
Dermal absorption	No data
Distribution	Widely distributed
Potential for accumulation	None
Rate and extent of excretion	In faeces (70% of the low dose and 80% of the high dose); in urine (about 20% of the low dose and 10% of the high dose)
Metabolism in animals	Extensive
Toxicologically significant compounds in animals and plants	Kresoxim-methyl
<i>Acute toxicity</i>	
Rat, LD <sub>50</sub> , oral	>2 000 mg/kg bw
Rat, LD <sub>50</sub> , dermal	>2 000 mg/kg bw
Rat, LC <sub>50</sub> , inhalation	>5.6 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Guinea-pig, dermal sensitization	Not sensitizing (Buehler & maximization)
<i>Short-term studies of toxicity</i>	
Target/critical effect	Diarrhoea, vomiting, reduced body weight gain
Lowest relevant oral NOAEL	150 mg/kg bw (dog)
Lowest relevant dermal NOAEL	1 000 mg/kg bw per day, highest dose tested (rat)
Lowest relevant inhalation NOAEC	No data
<i>Long-term studies of toxicity and carcinogenicity</i>	
Target/critical effect	Liver; hepatotoxicity and tumours (rat)
Lowest relevant BMDL <sub>10</sub>	29.1 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic in mice, carcinogenic in rats <sup>a</sup>
<i>Genotoxicity</i>	
	No evidence of genotoxicity in vitro or in vivo <sup>a</sup>
<i>Reproductive toxicity</i>	
Target/critical effect	No reproductive effects
Lowest relevant parental NOAEL	84.3 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	84.3 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	1 389.3 mg/kg bw per day, highest dose tested (rat)
<i>Developmental toxicity</i>	
Target/critical effect	Reduced ossification (rat)

Lowest relevant maternal NOAEL	1 000 mg/kg bw per day (rat and rabbit)
Lowest relevant embryo/fetal NOAEL	400 mg/kg bw per day (rat)
<i>Neurotoxicity</i>	
Acute neurotoxicity NOAEL	2 000 mg/kg bw, highest dose tested (rat)
Subchronic neurotoxicity NOAEL	1 180 mg/kg bw per day, highest dose tested (rat)
Developmental neurotoxicity NOAEL	No data

<sup>a</sup> Unlikely to pose a carcinogenic risk to humans from the diet.

### Summary

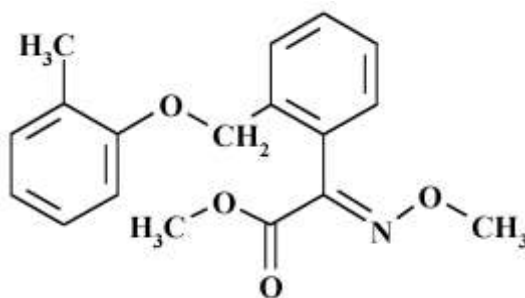
	Value	Study	Safety factor
ADI	0–0.3 mg/kg bw <sup>a</sup>	Two-year chronic toxicity and carcinogenicity studies in rats	100
ARfD	Unnecessary	–	–

<sup>a</sup> Applies to kresoxim-methyl, 490M1 and 490M9 and their conjugates, expressed as kresoxim-methyl.

### RESIDUE AND ANALYTICAL ASPECTS

Kresoxim-methyl is a strobilurin fungicide for the control of scab and other fungal diseases on a wide range of crops. It acts by inhibiting the mitochondrial respiration. It was first evaluated by JMPR in 1998 (T, R), when an acceptable daily intake (ADI) of 0–0.4 mg/kg bw was established. An acute reference dose (ARfD) was not considered necessary. In 2001 the JMPR evaluated the compound for residues and recommended a number of maximum residue levels. Kresoxim-methyl was scheduled by the Forty-ninth Session of the CCPR for the periodic evaluation of residue and toxicology by the 2018 JMPR.

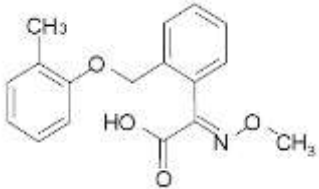
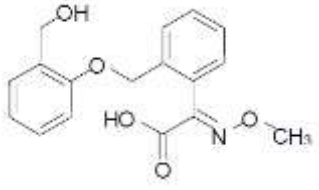
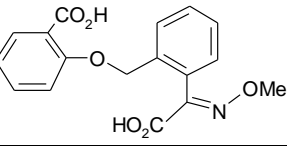
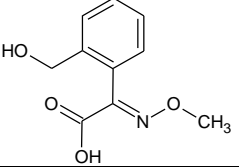
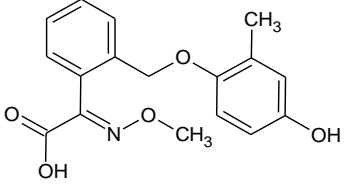
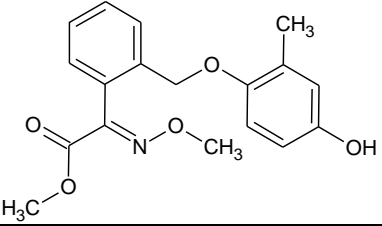
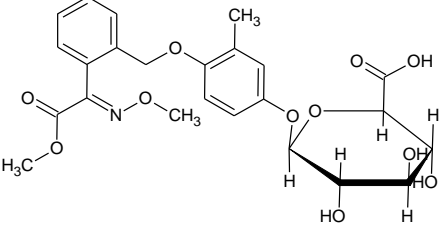
The Meeting received information on identity, physicochemical properties, metabolism (plant, confined rotational crops and animals), environmental fate, methods of residue analysis, freezer storage stability, registered use patterns, supervised residue trials in citrus, apple, peach, black currant, strawberry, grape, mango, leek, onion, garlic, cucumber, squash, gherkin, melon, sweet pepper, tomato, vine leaves, sugar beet, wheat, barley, pecan nuts and olives, fate of residues in processing, and livestock feeding studies.



The IUPAC and CA name of kresoxim-methyl is methyl (2E)-[2-(hydroxymethyl)phenyl] (methoxyimino)acetate.

Metabolism and environmental fate studies were conducted using either [phenoxy-<sup>14</sup>C]- or [phenyl-<sup>14</sup>C]-kresoxim-methyl. Moreover, [<sup>13</sup>C]-kresoxim-methyl was used.

The following abbreviations are used for the metabolites discussed below:

Code Names	Chemical Names (IUPAC)	Structure
490M1 BF 490-1	(2E)-(methoxyimino){2-[(2-methylphenoxy)methyl]phenyl}acetic acid	 <p>Molar mass: 299.33 g/mol</p>
490M2 BF 490-2	(2E)-(2-{[2-(hydroxymethyl)phenoxy]methyl}phenyl)(methoxyimino)acetic acid	 <p>Molar mass: 315.33 g/mol</p>
490M04 BF 490-5	2-({2-[(E)-carboxy(methoxyimino)methyl]phenyl}methoxy)benzoic acid	
490M6	(2E)-[2-(hydroxymethyl)phenyl](methoxyimino)acetic acid	
490M9 BF 490-9	(2E)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid	 <p>Molar mass: 315.33 g/mol</p>
490M15 BF 490-4	methyl (2E)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetate	
490M28 (glucuronid of 490M15)	[2-({2-[(E)-carboxy(methoxyimino)methyl]phenyl}methoxy)phenyl]methyl glucuronide	

Code Names	Chemical Names (IUPAC)	Structure
490M46	methyl (2E)-(2-([4-hydroxy-2-(hydroxymethyl)phenoxy]methyl)phenyl)(methoxyimino) acetate	
490M48 BF 490-03	methyl (2E)-(hydroxyimino){2-[(2-methylphenoxy)methyl]phenyl}acetate	
490M51 (sulfate conjugate of 490M46)	methyl (2E)-(2-([2-(hydroxymethyl)-4-(sulfooxy)phenoxy]methyl)phenyl)(methoxyimino) acetate	
490M54	(2E)-2-[(5-hydroxy-2-methylphenoxy)methyl]phenyl(methoxyimino)acetic acid	
490M58	[(1E)-1-(2-([2-(hydroxymethyl)phenoxy]methyl)phenyl)-2-methoxy-2-oxoethylidene]azinic acid	
490M66 (sulfate conjugate of 490M15)	methyl (2E)-(methoxyimino)(2-([2-methyl-4-(sulfooxy)phenoxy]methyl)phenyl)acetate	
490M68/490M69	2-[carboxy(methoxyimino)methyl]benzoic acid	
490M76/490M77	Not applicable	

### ***Plant metabolism***

The Meeting received plant metabolism studies in sugar beet, apples, grapes, and wheat following application of [phenoxy-<sup>14</sup>C]- and/or [phenyl-<sup>14</sup>C]-kresoxim-methyl.

On sugar beet, [phenoxy-<sup>14</sup>C]-kresoxim-methyl was applied in two foliar applications at a rate equivalent to 0.15 kg ai/ha each. The first application took place at BBCH 39 (leaves cover 90% of ground) and the second 3 weeks later or 28 days before harvest (BBCH stage not given). Samples of leaves and root were taken before and directly after the second treatment and at harvest.

Maximum TRR levels found were highest in leaves immediately after the second treatment (1.8 mg eq/kg) and remained fairly steady with 1.3–1.7 mg eq/kg until 28 days after last treatment (DALT). In roots, maximum TRR levels were up to 0.053 mg eq/kg at 0 DALT, but dropped to 0.008–0.009 mg eq/kg after 28 DALT.

Samples were sequentially extracted with methanol followed by water. Extracted radioactivity ranged between 91–99% TRR in leaves and 63–93% TRR in roots.

Due the low TRR, no attempts were undertaken to characterise the radioactivity in sugar beet roots. In sugar beet leaves, parent kresoxim-methyl accounted for 67–98% TRR (1.1–1.4 mg eq/kg). Major metabolites 490M1 and the sugar conjugate of 490M2 were identified in leaves at 28 DALT up to 9.7% TRR (0.12 mg eq/kg) and 9.2% TRR (0.12 mg eq/kg), respectively.

On apples, three different application schemes of [phenyl-<sup>14</sup>C]-kresoxim-methyl were applied:

1. Foliar application (whole tree): 6×0.4 kg ai/ ha at the beginning of flowering (1), petal fall (2), application every 28–42 days (3–5) and 2 weeks before harvest (6). Samples were harvested 14 DALT.
2. Early application (whole tree): 2×0.4 kg ai/ ha at the beginning of flowering and at petal fall. Samples were harvested 149 DALT.
3. Fruit spray treatment (leaves and branches were covered with foil): 2×0.8 kg ai/ ha at 6 weeks before harvest and 2 weeks before harvest. Samples were harvested 14 DALT.

Based on whole apple, the calculated TRR was highest after fruit treatment at up to 0.84 mg eq/kg. TRR levels were highest for all treatment regimes in apple peel at up to 5.7 mg eq/kg (fruit treatment), followed by apple core at up to 0.044 mg eq/kg (foliar application) and apple flesh at up to 0.036 mg eq/kg (foliar treatment). TRR in leaves ranged from 0.23–1.0 mg eq/kg.

Samples of apple peel and pulp were extracted with methanol. Extracted radioactivity ranged between 86–98% TRR for all matrices.

In all three treatment regimes, parent kresoxim-methyl was the predominant residue accounting for 74–98% TRR (0.038–0.82 mg eq/kg). Additionally, metabolites 490M1, 490M2 and 490M9 were identified, but none occurred in amounts >3% TRR.

On grapes, [phenoxy-<sup>14</sup>C]- and [phenyl-<sup>14</sup>C]-kresoxim-methyl was applied in five foliar applications at a rate equivalent to 0.5 kg ai/ha per application with intervals of 14–21 days and harvested at 14 DALT.

Grapes were rinsed with methanol, followed by determination of the radioactivity in the rinsed grapes. TRR levels for the sum of radioactivity in the rinse and the grapes ranged between 3.6–4.7 mg eq/kg, with 37–38% of the TRR recovered in the rinse.

Rinsed, homogenised fruits were further extracted methanol or acetone/water in parallel. Extracted radioactivity for both solvents was similar, ranging between 46–60% TRR. In total, the initial methanol rinse and the subsequent extraction accounted for 86–92%TRR.

Parent kresoxim-methyl was the predominant residue accounting for 55–57% TRR (2.2–2.7 mg eq/kg). As a major metabolite, 490M2 (sum of free and conjugated) was identified at up to 14% TRR (0.55 mg eq/kg). Additionally, metabolites 490M1, 490M9 and 490M54 were identified, but none occurred in amounts >5.8% TRR.

On wheat, [phenyl-<sup>14</sup>C]-kresoxim-methyl was applied in two foliar application at 0.25 kg ai/ha (1×), or two foliar application at an exaggerated rate of 1.25 kg ai/ha (5×). The first treatment occurred for both application rates at growth stage BBCH 29 (leaf sheaths lengthen); while the second treatment occurred 56 days later at growth stage BBCH 52 (first ears just visible). Forage samples were taken at 4 hours and 55 days after the first treatment and at 4 hours after the second treatment. Straw, husk and grain samples were taken 64 days after the second treatment.

TRR levels in the 1× treatment group were highest in straw at up to 13 mg eq/kg, followed by forage (day 0 after 1<sup>st</sup> application) at up to 11 mg eq/kg. In the 5× treatment group TRR was highest in forage (day 0 after 1<sup>st</sup> application) at up to 76 mg eq/kg, followed by straw at up to 62 mg eq/kg. TRR levels in grain were significantly lower in both treatment group at up to 0.064 mg eq/kg for the 1× treatment and 0.31 mg eq/kg for the 5× treatment.

Samples were sequentially extracted with methanol followed by aqueous ammonia. Kresoxim-methyl conjugates in the extracts were hydrolysed with β-glucosidase and hesperidinase. Extracted radioactivity in all matrices except grain ranged between 90–100% TRR. For grain it was lower with 61–75%TRR.

The predominant residue in all matrices was parent kresoxim-methyl ranging from 17–40%TRR in grain to 64–97% TRR in forage and straw. As a major metabolite, conjugated 490M9 was identified at up to 11% TRR (1.0 mg eq/kg) in straw. Additionally, the Z-isomer of kresoxim-methyl and metabolites 490M1, 490M2 and 490M17 were identified in forage, straw and grain, but none occurred in amounts >3.9% TRR.

In summary, kresoxim-methyl was only moderately metabolised in studies performed with sugar beet, apple, grape and wheat. Parent kresoxim-methyl accounted for most of the residue with 55–98% TRR, which the exception of wheat grain (17–40% TRR). Major identified metabolites were 490M2 (unconjugated and conjugated) in grapes (14% TRR) and 490M9 (conjugated) in straw (11% TRR). All major identified metabolites were also found in the rat.

### ***Animal metabolism***

Information was available on the metabolism of kresoxim-methyl in laboratory animals, lactating goats and laying hens. The evaluation of the metabolism studies in rats was carried out by the WHO group.

In lactating goats, the metabolic fate of kresoxim-methyl was investigated using [phenoxy-<sup>14</sup>C]- and [phenyl-<sup>14</sup>C]-radiolabelled kresoxim-methyl. In the first study, [phenyl-<sup>14</sup>C]-radiolabelled kresoxim-methyl was administered orally to two lactating goats. Goat A received 7.1 ppm (0.26 mg/kg bw) for five consecutive days, while goat B received 454 ppm (21 mg/kg bw) for eight consecutive days. In a second study [phenoxy-<sup>14</sup>C]-radiolabelled kresoxim-methyl was administered for five consecutive days to one lactating goat by gavage at 13.9 ppm feed (1.6 mg/kg bw)

For both labels most of the administered radioactivity was recovered from urine (59–70% AR) and faeces (18–25% AR). In edible tissues residues were low with up to 0.07% AR in the liver. The highest TRRs

were found in kidney (0.052–14 mg eq/kg) and liver (0.041–6.8 mg eq/kg). In milk, the radioactive residues ranged between 0.003–2.7 mg eq/kg for both labels.

Residue levels in milk reached a plateau in goat A (dosed with [phenyl-<sup>14</sup>C]-kresoxim-methyl) and the [phenoxy-<sup>14</sup>C]-radiolabelled kresoxim-methyl dosed goat after approximately 3 days. However, for goat B, which received the exaggerated dose of [phenyl-<sup>14</sup>C]-kresoxim-methyl, no plateau was reached after 8 days.

Milk and tissue samples of the [phenyl-<sup>14</sup>C]-kresoxim-methyl dosed goat B were sequentially extracted with methanol followed by water, while tissues of the [phenoxy-<sup>14</sup>C]-radiolabelled kresoxim-methyl dosed goat were extracted with acetonitrile followed by water. Resulting extraction rates for both methods were 101% TRR in milk, 43–63% TRR in liver, 86–98% TRR in kidney, 72% TRR in muscle and 72% TRR in fat.

Identification and characterisation of the radioactivity was done only for the [phenyl-<sup>14</sup>C]-kresoxim-methyl dosed goat receiving the exaggerated dose and for the [phenoxy-<sup>14</sup>C]-radiolabelled kresoxim-methyl dosed goat (only in liver and kidney). Kresoxim-methyl was not detected in milk and tissues, except for fat at up to 6.6% TRR (0.024 mg eq/kg). However, several metabolites were detected for both labels at significant levels: 490M1 in muscle, fat, liver and kidney ranging between 14–26% TRR (0.059–3.0 mg eq/kg); 490M2 in milk, muscle, fat, liver and kidney ranging between 11–34% TRR (0.032–4.6 mg eq/kg); 490M9 in milk, muscle, liver and kidney ranging between 10–63% TRR (0.023–4.0 mg eq/kg)

In laying hens, the metabolic fate of kresoxim-methyl was investigated using [phenyl-<sup>14</sup>C]-radiolabelled kresoxim-methyl. The compound was administered for 6 consecutive days to 2 groups of laying hens by gavage. Group A was dosed daily at 10 ppm (1 mg/kg bw) and group B at 180 ppm (18 mg/kg bw).

Most of the administered radioactivity was recovered from excreta (72–83% AR). For both dosing groups, liver had the highest TRR (0.082 / 7.0 mg eq/kg), followed by kidney (0.065 / 6.4 mg eq/kg).

TRR levels in eggs did not reach a plateau after 5–6 days.

Egg and tissue samples were sequentially extracted with methanol followed by water. Resulting extraction rates were 76% TRR in egg, 65–82% TRR in liver, 84% TRR in muscle, 92% TRR in fat and 66–87% TRR in skin.

Kresoxim-methyl was only detected in significant amounts in skin at up to 11% TRR (0.082 mg eq/kg) and fat at up to 41% TRR (0.31 mg eq/kg).

However, several metabolites were detected at significant levels: 490M9 in liver at 20% TRR (1.4 mg eq/kg); 490M15 (including its glucuronide conjugate 490M28) in fat at 17% TRR (0.12 mg eq/kg) and in liver at 17% TRR (1.1 mg eq/kg); 490M48 in eggs at 14% TRR (0.92 mg eq/kg) and 490M58 in skin at 10% TRR (0.079 mg eq/kg). Metabolites 490M51 (sulphate of 490M46) and 490M66 (sulphate of 490M15) were not chromatographically resolved and were detected in muscle and eggs from 16–20% TRR (0.019–0.035 mg eq/kg);

In summary, strong metabolic degradation of kresoxim-methyl was observed. In lactating goats, the sum of unconjugated metabolites 490M1, 490M2 and 490M9 represented most of the residue. Although, a more complex situation was seen in laying hens, where the pattern of significant metabolites was quantitatively different, the major metabolic pathways were the same as in the goat.

### ***Environmental fate in soil & water***

The Meeting received new information for anaerobic and aerobic degradation of kresoxim-methyl in soil.

These reports were kinetic evaluations based on laboratory soil degradation studies and field dissipation studies previously submitted in the context of the first JMPR evaluation in 1998.

These studies were not taken into consideration, as uses of kresoxim-methyl only comprise of foliar applications.

The Meeting received two confined rotational crop metabolism studies.

The first study was conducted with [phenyl-<sup>14</sup>C]-kresoxim-methyl applied at a rate equivalent to 0.3 kg ai/ha to a sandy loam soil. After a plant-back interval (PBI) of 30 days, lettuce, green beans, carrots and wheat were planted/sowed. At harvest, the highest total radioactive residues were found in the roots of lettuce, beans and wheat, ranging from 0.23–1.1 mg eq/kg. This was followed by bean forage at 0.21 mg eq/kg and wheat straw at 0.15 mg eq/kg. In edible commodities radioactive residues > 0.01 mg eq/kg were only found in lettuce heads (0.02 mg eq/kg).

Samples were extracted with methanol and kresoxim-methyl conjugates in the extracts were hydrolysed with  $\beta$ -glucosidase and hesperidinase. Extracted radioactivity in lettuce (immature), carrot greens, bean forage and wheat straw ranged between 54–82% TRR, except for wheat forage where extractability was lower at 38%TRR.

Due to the low radioactivity, only lettuce (immature), carrot greens, bean forage, wheat forage and straw were further characterised. Only metabolites 490M2 and 490M9 (including their conjugates) were detected at levels >0.01 mg eq/kg in bean forage (up to 0.038 mg eq/kg) and wheat straw (up to 0.013 mg eq/kg).

The second confined rotational crop study was conducted with lettuce, radish and wheat, planted on a sandy loam soil treated with [phenyl-<sup>14</sup>C]-kresoxim-methyl at a rate equivalent to 1.5 kg ai/ha after plant-back intervals (PBIs) of 30, 120 and 365 days.

TRR levels found in the model crops generally declined with longer PBIs, ranging between 0.011–0.17 mg eq/kg at 365 days PBI, compared to 0.094–2.0 mg eq/kg at 30 days PBI.

Samples were sequentially extracted with methanol followed by water. At least 49% TRR or more was extracted from immature and mature lettuce, radishes, wheat forage and chaff at 30 days PBI and wheat straw at 30 and 120 days PBI. Extractability was lowest for wheat grain for all PBIs, ranging between 16–17% TRR.

Parent kresoxim-methyl was only found in mature lettuce (30 days PBI) at up to 0.003 mg eq/kg (6.1% TRR) and immature radish (30 days PBI) at up to 0.040 mg eq/kg (9.1% TRR). As a major metabolite, 490M78 was found in immature radish (30 days PBI) and mature radish root and leaves (30 days PBI) at up to 0.19 mg eq/kg (44% TRR). At later PBIs, levels of 490M78 were significantly lower.

Other identified metabolites comprised of 490M06, 490M68/490M69 and 490M76/490M77 at levels ranging between 0.14–0.26 mg eq/kg (8.7–16%TRR). However, these metabolites were identified only in wheat straw at 30 days PBI, but not at later PBIs.

Hydrolytic treatments of the post extraction solids indicated the residues of kresoxim-methyl are further degraded to polar components and became integrated into natural constituents (e.g. starch, lignin).

In summary the Meeting concluded that a significant transfer of kresoxim-methyl residues from soil to succeeding crops is not expected.

### ***Methods of analysis***

The Meeting received analytical methods for the determination of kresoxim-methyl and metabolites 490M1,



490M2 and 490M9 in plant matrices.

For matrices of plant origin, the basic principle of most methods employed extraction with methanol or methanol/water, followed by clean-up using liquid-liquid partitioning with isooctane or dichloromethane alone, or in combination with additional clean-up steps, such as SPE on a silica gel, C18 or NH<sub>2</sub> cartridge. Parent kresoxim-methyl was either directly determined by LC-MS/MS, GC-ECD or GC-MS, or hydrolysed (10 M KOH, 1hour) to metabolite 490M1 (kresoxim acid) followed by LC-LC-UV detection. Hence, it should be noted that for the latter method always the sum of kresoxim-methyl and 490M1 is determined. Conjugates of metabolites 490M2 and 490M9 were cleaved by enzymatic hydrolysis (hesperidinase and  $\beta$ -glucosidase) and determined by LC-LC-UV, as well. Although, the limit of quantification for most methods was at 0.01 or 0.05 mg/kg per analyte, one method had higher LOQs of 0.2 and 0.4 mg/kg.

For animal matrices, methods were provided for metabolites 490M1, 490M2 and 490M9, but not for parent kresoxim-methyl.

In animal matrices, metabolite 490M1 was determined in tissues, eggs and milk by extraction with methanol without any additional clean-up and LC-MS/MS detection with a LOQ of 0.01 mg/kg. Alternatively, after extraction with methanol, clean-up by partitioning with dichloromethane, SPE on a NH<sub>2</sub>-cartridge and preparative HPLC on a RP C18 column, followed by LC-LC-UV analysis with a LOQ of 0.001 mg/kg was employed for metabolites 490M1, 490M2 and 490M9 in tissues. In milk, metabolites 490M2 and 490M9 were determined by extraction with acetone followed by clean-up using liquid-liquid partition with isooctane or dichloromethane, SPE on a NH<sub>2</sub>-cartridge and LC-LC-UV analysis with an LOQ of 0.001 mg/kg.

The Meeting concluded that suitable data generation and monitoring methods are available to measure residues of kresoxim-methyl in plants only and/or metabolites 490M1, 490M2 and 490M9 in plant and animal commodities. It was also noted, that a method for the determination of metabolites 490M2 and 490M9 in eggs was missing.

No multi-residue method for the determination of parent kresoxim-methyl or its metabolites was submitted. The Meeting noted that in the European Reference Laboratories (EURL data pool) the QuEChERS method was validated for parent kresoxim-methyl in high water content, high acid content and dry matrices with an LOQ of 0.01 mg/kg.

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

The Meeting received information on the storage stability of kresoxim-methyl and metabolites 490M2 and 490M9 (as glucoside and aglycon) in a variety of plant matrices stored at -10 to -28 °C.

Kresoxim-methyl was stable in high starch and high protein matrices for at least 24 months, while in high water and acid content matrices for least 12 months. In high oil matrices kresoxim-methyl was stable for a maximum of 3 months in soya beans and for at least 6 months in pecan nuts.

Metabolite 490M2 was stable in high starch, high protein and high oil matrices for at least 24 months, while the respective glucoside was stable in high water and acid content matrices for least 12 months and in high oil matrices for at least 6 months.

Metabolite 490M9 was stable in high starch and high protein matrices for at least 24 months, while in high oil matrices (soya bean) 490M9 was not stable (53% after 1 month). The respective glucoside of 490M9 was stable in high water and acid content matrices for least 12 month and in high oil matrices for at least 6 months.

For animal matrices, the Meeting received information on the storage stability of metabolites 490M1, 490M2 and 490M9 in tissues and milk stored at -18 °C.

Metabolites 490M2 and 490M9 in milk and metabolites 490M1, 490M2 and 490M9 in tissues were considered stable for at least 15 months.

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

In the plant metabolism studies conducted on sugar beet, apples, grapes and wheat the predominant residue was parent kresoxim-methyl at 74–98% TRR in apples, 55–57% TRR in grapes and 17–40% TRR in wheat grain. In feed matrices, residues of kresoxim-methyl ranged from 67–98% TRR in sugar beet leaves and 64–97% TRR in wheat forage and straw.

In confined rotational crops parent kresoxim-methyl was only detected in significant amounts in immature radish at up to 9.1% (0.04 mg eq/kg) at 30 days PBI, while levels in mature crops and/or later PBIs were constantly lower or non-detected. At 30 days PBI, metabolite 490M78 was found in radish root, immature radish and mature radish leaves at up to 44% TRR (0.19 mg eq/kg). At later PBIs, levels of 490M78 declined to around 0.01 mg eq/kg or lower. In summary, a significant transfer of kresoxim-methyl residues from soil to succeeding crops is not expected.

The Meeting concluded that parent kresoxim-methyl is the major residue in primary crops and is a suitable marker compound for compliance with MRLs. Analytical methods are capable of measuring kresoxim-methyl in all plant matrices.

For dietary exposure purposes, the metabolites found in primary metabolism studies at potentially significant levels were 490M2 (free and conjugated) in grapes (14% TRR) and 490M9 (conjugated) in wheat straw (11% TRR).

In supervised field trials metabolite 490M2 occurred in grapes and mango at levels similar or higher (up to 2.5 fold) compared to the levels of kresoxim-methyl. Also, metabolite 490M9 occurred in field trials with grapes at levels similar or higher (up to 2.0 fold) compared to the levels of kresoxim-methyl.

In a nature of residue study during processing, it was demonstrated that parent kresoxim-methyl is hydrolysed to kresoxim acid (490M1) under the conditions of sterilisation at up to 71%.

The Meeting concluded that residues of the plant metabolites 490M2 and 490M9, including their conjugates, may add significantly to the overall dietary exposure to kresoxim-methyl residues. Additionally, metabolite 490M1 (kresoxim acid) was considered relevant since it can be formed during processing.

Kresoxim was toxicologically evaluated by the current Meeting. The Meeting concluded that metabolites 490M1 and 490M9 were covered by the toxicological reference values of parent kresoxim-methyl.

The Meeting noted that as no specific data were available on the toxicity of the metabolite 490M2, the TTC approach could be applied<sup>24</sup>. The estimated exposure based on plant and animal commodities, using worst case assumptions to assess exposure that the estimated exposure is below the applicable threshold of toxicological concern for Cramer Class 3 compounds. The Meeting concluded that no dietary risk from this metabolite can be expected from the uses considered by the current Meeting.

The Meeting decided to include 490M1 and 490M9, including their conjugates, into the residue definition for dietary exposure purposes.

In lactating goats, kresoxim-methyl was only detected in fat at 6.6%TRR (0.024 mg eq/kg), following treatment at an exaggerated rate of 454 ppm and a short interval (4 hours) between the last dose and sacrifice. Major metabolites in milk, were 490M2 and 490M9 at 20% (0.039 mg eq/kg) and 63% TRR (0.12 mg eq/kg), respectively. In muscle, fat, liver and kidney, amounts of metabolites accounting for more

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<sup>24</sup> See Toxicology section for further details

than 10% TRR were 490M1 ranging between 11–26% TRR (0.006–3.0 mg eq/kg), 490M2 between 11–34% TRR (0.018–4.6 mg eq/kg) and 490M9 between 10–30% TRR (0.023–4.0 mg eq/kg).

A cow feeding study was conducted at treatment rates of 7, 21 and 70 ppm. In milk no residues >LOQ (0.002 mg/kg) were detected in all dosing groups. In tissues, no residues >LOQ (0.01 mg/kg) were detected in the lowest treatment group, except for 490M1 in kidney at 0.03 mg/kg. In the higher treatment groups, residues >LOQ were found for 490M1 in liver (up to 0.32 mg/kg), kidney (up to 0.20 mg/kg) and in fat (up to 0.089 mg/kg), as well as for 490M9 in liver (up to 0.016 mg/kg) and kidney (0.022 mg/kg).

Since parent kresoxim-methyl was only detected in a highly overdosed goat metabolism study, the Meeting concluded that no residues of above 0.01 mg/kg are expected in animal products under actual conditions. Although metabolite 490M2 was detected in significant relative amounts in both goat metabolism studies, only the exaggerated study resulted in significant absolute amounts. Since additionally metabolite 490M2 was not detected in the cow feeding study, the Meeting concluded that no residues above 0.01 mg/kg are expected in animal products.

In laying hens, kresoxim-methyl was found in significant amounts in skin and fat ranging between 11–41%TRR, following administration of 180 ppm kresoxim-methyl in the diet. Additionally several metabolites were detected at significant levels: 490M9 in liver at 20% TRR (1.4 mg eq/kg); 490M15 (including its glucuronide conjugate 490M28 in fat at 17% TRR (0.12 mg eq/kg) and in liver at 17% TRR (1.1 mg eq/kg); 490M48 in eggs at 14% TRR (0.92 mg eq/kg) and 490M58 in skin at 10% TRR (0.079 mg eq/kg). Metabolites 490M51 (sulphate of 490M46) and 490M66 (sulphate of 490M15) were not chromatographically resolved and were detected in muscle and eggs from 16–20% TRR (0.019–0.035 mg eq/kg). Taking into consideration a poultry dietary burden for kresoxim-methyl of maximal 0.35 ppm, the poultry metabolism study is about 500 times overdosed. Hence, no residues above 0.01 mg/kg for these metabolites are expected in animal products under actual conditions and therefore the contribution of these metabolites to the overall dietary exposure was considered as insignificant by the Meeting.

The Meeting concluded that metabolites 490M1 and 490M9 should be included in the residue definition for compliance with the MRL and dietary risk assessment for animal commodities.

In muscle and fat tissues of all animals investigated, residue concentrations of the sum of metabolites 490M1 and 490M9 were of similar proportions. The log  $P_{ow}$  of metabolite 490M1 is 0.15. The Meeting decided that residues of the sum of metabolite 490M1 and 490M9 are not fat-soluble.

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.*

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

Residues referred to as “total residue” comprises of the sum of kresoxim-methyl and metabolite 490M1, determined as 490M1 plus metabolite 490M9

*Citrus fruits*

The critical GAP for citrus in Japan allows three outdoor foliar applications of kresoxim-methyl at 25 g ai /hL and a PHI of 14 days, RTI not specified.

Outdoor field trials conducted with mandarins, natsudaïdai, kabosu and sudachi in Japan were performed with three foliar applications of kresoxim-methyl at rates of 25 g ai/hL with a 7±1 day interval between applications.

For the subgroup of mandarins, the ranked order of residues following GAP treatment was (n = 2): 2.3, 3.8 mg/kg.

For the subgroup of pummelo and grapefruits (natsudaïdai), the ranked order of residues following GAP treatment was (n = 2): 0.92, 1.8 mg/kg.

For the subgroup of lemons and limes (kabosu and sudachi), the ranked order of residues following GAP treatment was (n = 3): < 0.10, 1.5, 4.6 mg/kg.

Based on the lack of data matching the GAP, the Meeting concluded that no maximum residue level could be estimated for kresoxim-methyl in citrus fruits based on the Japanese GAP.

Alternatively, a GAP for citrus in Turkey was provided allowing a maximum of four foliar applications of kresoxim-methyl at 12.5 g ai/hL with an RTI of 12 days and a PHI of 35 days. One trial matching the number of treatments and/or application rate within ±25% of the GAP was submitted.

Residues of kresoxim-methyl in oranges were (n = 1): 0.15 mg/kg. The trial had received three applications instead of four as required in the GAP, but was considered within 25% of the GAP.

Based on the lack of data matching the GAP, the Meeting concluded that no maximum residue level could be estimated for citrus fruits.

The Meeting agreed to withdraw the previous maximum residue level recommendation for kresoxim-methyl in oranges and grapefruit (0.5 mg/kg).

*Apple*

The GAPs provided for apple were from Japan allowing for three foliar applications of kresoxim-methyl at 33 g ai /hL and a PHI of 1 day, RTI not specified and from Brazil allowing three application at 10 g ai /hL (100 g ai/ha) with an interval of 8–12 days and a PHI of 35 days.

No corresponding supervised field trial data were submitted for either GAP.

The Meeting concluded to withdraw the previous maximum residue level recommendation for kresoxim-methyl in pome fruits (0.2 mg/kg).

*Peach*

The critical GAP for peach in Japan allows three foliar applications of kresoxim-methyl at 25 g ai /hL and a PHI of 1 day, RTI not specified. Field trials with peach conducted in Europe were performed with 4 foliar applications of kresoxim-methyl at rates of 20 or 30 g ai/hL with an 8–14 day interval between applications. The Meeting noted trials had one additional treatment but concluded that the first application did not contribute significantly to the residue level.

For estimating maximum residue levels of kresoxim-methyl in peach, the ranked order of residues following GAP treatment (±25%) was (n = 6): 0.13, 0.14, 0.25, 0.34, 0.41, 0.66 mg/kg.

For dietary risk assessment, the ranked order of the total residue following GAP treatment ( $\pm 25\%$ ) was ( $n = 6$ ): 0.18, 0.20, 0.32, 0.42, 0.51, 0.75 mg/kg

The Meeting estimated a maximum residue level of 1.5 mg/kg and a STMR of 0.37 mg/kg for kresoxim-methyl in peach.

#### *Currants, black, red, white*

The critical GAP for currant in the United Kingdom allows three foliar applications of kresoxim-methyl at 100 g ai /ha with a RTI of 10 days and a PHI of 14 days. Field trials with currant conducted in Europe were performed with 3 foliar applications of kresoxim-methyl at rates of 100 g ai/ha with a 14 day interval between applications.

For estimating maximum residue levels of kresoxim-methyl in currant, the ranked order of residues following GAP treatment were ( $n = 5$ ): 0.13, 0.16, 0.18, 0.22 and 0.50 mg/kg.

For dietary risk assessment, the ranked order of the total residues following GAP treatment were ( $n = 5$ ): 0.18(2), 0.21, 0.23 and 0.57 mg/kg.

The Meeting estimated a maximum residue level of 0.9 mg/kg and a STMR of 0.21 mg/kg for kresoxim-methyl in currants, black, red, white.

#### *Strawberry*

The critical GAP for strawberries in the Netherlands allows three outdoor foliar applications of kresoxim-methyl at 150 g ai /ha with a RTI of 10 days and a PHI of 7 days.

None of the trials provided matched the GAPs (e.g. no indoor use on label). Hence, the Meeting concluded that no maximum residue level could be estimated for kresoxim-methyl in strawberry.

#### *Grapes*

The critical GAP for grapes in the USA allows four foliar application of kresoxim-methyl at 224 g ai /ha with an RTI of 7 days and a PHI of 14 days. Matching field trials conducted in the USA were performed with four foliar applications of kresoxim-methyl at rates of 224 g ai/ha with a  $10 \pm 1$  day interval between applications.

For estimating maximum residue levels of kresoxim-methyl in grapes, the ranked order of residues following GAP treatment was ( $n = 18$ ): < 0.05, 0.063, 0.071, 0.11, 0.12(2), 0.25, 0.27, 0.30, 0.31(2), 0.35, 0.36, 0.42(2), 0.61, 0.69, 0.91 mg/kg.

For dietary risk assessment, the ranked order of the total residue following GAP treatment was ( $n = 18$ ): < 0.10, 0.11, 0.12, 0.17, 0.16, 0.30, 0.32, 0.35, 0.36, 0.37, 0.38, 0.40, 0.41, 0.47(2), 0.66, 0.74, 0.96 mg/kg.

The Meeting estimated a STMR value of 0.365 mg/kg and a maximum residue level of 1.5 mg/kg for kresoxim-methyl in grapes. The latter replaces the previous recommendation (1.0 mg/kg).

#### *Olives*

The critical GAP for olives in France allows three foliar applications of kresoxim-methyl at 100 g ai/ha and a PHI of 30 days. One application is performed when the fruits are present while the remaining two are performed between harvest and flowering.

Field trials with olives conducted in Europe were performed with one foliar application at BBCH 79 (fruit size about 90% of final size) to BBCH 85 (increasing of specific fruit colouring) of kresoxim-methyl at rates of 100 g ai/ha. The Meeting noted that despite a lower number of applications, trials were acceptable

as the application of the two additional treatments included in the GAP occur when no fruits were present. Also, kresoxim-methyl is not systemic and no translocation into olive fruits from treatments before fruit formation are expected.

For estimating maximum residue levels of kresoxim-methyl in olives, the ranked order of residues following GAP treatment ( $\pm 25\%$ ) was ( $n = 5$ ):  $< 0.05(3)$ , 0.11, 0.23 mg/kg.

For dietary risk assessment, the ranked order of the total residue following GAP treatment ( $\pm 25\%$ ) was ( $n = 5$ ):  $< 0.10(3)$ , 0.14 and 0.16 mg/kg

The Meeting estimated a maximum residue level of 0.2 mg/kg and a STMR of 0.10 mg/kg for kresoxim-methyl in olives.

### *Mango*

The critical GAP for mango in Brazil allows two foliar applications of kresoxim-methyl at 120 g ai /ha with a RTI of 15 days and a PHI of 7 days. Matching field trials conducted in Brazil were performed with two foliar applications of kresoxim-methyl at rates of 120 g ai/ha with a 14 day interval between applications.

For estimating maximum residue levels of kresoxim-methyl in mango, the ranked order of residues following GAP treatment was ( $n = 5$ ):  $< 0.010(2)$ , 0.014, 0.041, 0.049 mg/kg.

For dietary risk assessment, the ranked order of the total residue following GAP treatment was ( $n = 5$ ):  $< 0.020(2)$ , 0.024, 0.055, 0.059 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg and a STMR of 0.024 mg/kg in mango.

### *Bulb onion*

Kresoxim-methyl is registered for the use on shallots in Taiwan, Province of China, with two foliar applications of kresoxim-methyl at a rate of 400 g ai/ha with a 7 day interval between applications and 10 day PHI and in the Netherlands for bulb onion with 3 foliar applications at 200 g ai/ha with a 7 day interval between applications and the PHI covered by the growth stage.

None of the trials provided matched the GAPs. The Meeting concluded that no maximum residue level could be estimated for kresoxim-methyl in onion.

### *Garlic*

The critical GAP for garlic in Brazil allows four foliar applications of kresoxim-methyl at 70 g ai/ha with a RTI of 10 days and a 7 day PHI. Available trials matched the critical GAP for garlic in Brazil allowing four application at 70 g ai /ha with a RTI of 7 days and a 7 day PHI .

For estimating maximum residue levels of kresoxim-methyl in garlic, the ranked order of residues following GAP treatment was ( $n = 4$ ):  $< 0.01(4)$  mg/kg.

For dietary risk assessment, the ranked order of the total residue following GAP treatment was ( $n = 4$ ):  $< 0.02(4)$  mg/kg.

The Meeting noted that garlic falls under category 3 of the minor crop classification, requiring a minimum of five supervised field trials to estimate maximum residue levels. However, the Meeting considered four trials were sufficient, as no residues  $> 0.01$  mg/kg were detected. The Meeting estimated a maximum residue level of 0.01 mg/kg and a STMR of 0.02 mg/kg.

*Leek*

The critical GAP for leek in the Netherlands allows three foliar applications of kresoxim-methyl at 375 g ai /ha with a RTI of 10 days and a PHI of 14 days. Field trials with leek conducted in Europe were performed with three foliar applications of kresoxim-methyl at rates of 375 g ai/ha with a 9–14 day interval between applications and a 14 day PHI.

For estimating maximum residue levels of kresoxim-methyl in leek the ranked order of residues following GAP treatment was (n = 8): 2.7, 2.8, 3.1(2), 3.3(2), 3.4, 4.5 mg/kg.

For dietary risk assessment, the ranked order of the total residues following GAP treatment was (n = 8): 2.7, 2.8, 3.1(2), 3.3(2), 3.4, 4.5 mg/kg.

The Meeting estimated a maximum residue level of 10 mg/kg and a STMR of 3.2 mg/kg in leek.

*Fruiting vegetables, Cucurbits – Cucumber and Summer Squashes*

The critical GAP for cucumber and summer squashes in the USA allows four foliar application of kresoxim-methyl at 168 g ai /ha with a RTI of 7 days and a PHI of 0 days. Field trials with cucumber and summer squash conducted in the USA were performed with six foliar applications of kresoxim-methyl at rates of 196 g ai/ha with a 7±1 day interval between applications. Although a higher number of applications in connection with a higher application rate were applied in the supervised field trials from the USA, the Meeting noted that cucumbers and summer squashes have a short period between flowering and harvest. When taking into account the intervals of 7±1 days, the fruits did not receive all six applications until harvest. Since kresoxim-methyl is non-systemic, additional treatments before the formation of the edible part of the crop will not affect the terminal residue, making the USA trials suitable for an assessment.

*Cucumber*

For estimating maximum residue levels of kresoxim-methyl in cucumber, the ranked order of residues was (n = 8): < 0.05(4), 0.06(3), 0.11 mg/kg

For dietary risk assessment of cucumber, the ranked order of the total residue was (n = 8): < 0.10(4), 0.11(3), 0.17 mg/kg

*Summer squash*

For estimating maximum residue levels of kresoxim-methyl in summer squash, the ranked order of residues was (n = 5): < 0.05(4), 0.22 mg/kg.

For dietary risk assessment of summer squash, the ranked order of the total residue was (n = 5): < 0.10(4), 0.27 mg/kg

*Melon*

The critical GAP for melon in the USA allows four foliar applications of kresoxim-methyl at 168 g ai /ha with a RTI of 7 days and a PHI of 0 days. Available field trials with melon from France and Spain matching the USA GAP, received four foliar applications at 150 g ai/ ha with a 10-day interval between applications.

For estimating maximum residue levels of kresoxim-methyl in melon, the ranked order of residues was (n = 5): 0.05, 0.06, 0.13, 0.19, 0.20 mg/kg.

For dietary risk assessment of melon, the ranked order of the total residue was (n = 5): 0.10, 0.11, 0.18, 0.24, 0.25 mg/kg

The Meeting noted that the GAP in the USA is for cucurbits, including cucurbits with edible and inedible peel. Since median residues of cucumbers, summer squash and melons were within a 5-fold range, the Meeting considered estimating a maximum residue level for the group. It was recognised that the residue population from trials on cucumber, summer squash and melon were not significantly different according to the Kruskal-Wallis H-test. Therefore, the Meeting decided to combine the data to estimate a maximum residue level and STMR for the group of fruiting vegetables, cucurbits.

For estimating a maximum residue level, the combined residues of kresoxim-methyl in cucumber, summer squash and melon in ranked order were (n = 18): < 0.05(8), 0.05, 0.06(4), 0.11, 0.13, 0.19, 0.20, 0.22 mg/kg.

For dietary risk assessment, the combined residues of kresoxim-methyl in cucumber, summer squash and melon in ranked order were (n = 18): < 0.10(8), 0.10, 0.11(4), 0.17, 0.18, 0.24, 0.25, 0.27 mg/kg.

The Meeting estimated a STMR of 0.105 mg/kg and a maximum residue level of 0.5 mg/kg for the group of fruiting vegetables, cucurbits. The latter replaces the previous recommendation for cucumber (0.05 mg/kg).

#### *Sweet pepper*

The critical GAP for sweet pepper in Brazil allows four foliar applications of kresoxim-methyl at 100 g ai/ha with a RTI of 10 days and a PHI of 3 days. Matching field trials with pepper conducted in Brazil were performed with 4 foliar applications of kresoxim-methyl at rates of 97 g ai/ha with a  $7 \pm 1$  day interval between applications.

Ranked residues of kresoxim-methyl in sweet pepper from Brazil were (n = 4): < 0.01, 0.02, 0.03, 0.04 mg/kg.

The data on sweet pepper from Brazil are insufficient for an assessment. However, the Meeting noted that additional field trials with sweet pepper performed outdoors in Spain are available, which received four foliar applications at 250 g ai/ha with a 10 day interval between applications.

Ranked residues of kresoxim-methyl in sweet pepper from Europe were (n = 2): 0.16, 0.44 mg/kg.

Since the European trials were overdosed, the Meeting decided that the proportionality principle could be applied in this case, as the application rate is not higher than 4× of the GAP rate. Therefore, a scaling factor of 0.4 was applied to residues >LOQ from Europe, resulting in a total residue population of (n = 6): < 0.01, 0.02, 0.03, 0.04, 0.064<sup>scaled</sup>, 0.18<sup>scaled</sup> mg/kg.

For dietary risk assessment, the corresponding ranked order of the total residue of kresoxim-methyl in pepper was (n = 6): < 0.02, 0.03, 0.04, 0.05, 0.084<sup>scaled</sup>, 0.20<sup>scaled</sup> mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and a STMR of 0.045 mg/kg in sweet pepper.

#### *Tomato*

The critical GAP for tomato in Brazil allows two foliar applications of kresoxim-methyl at 200 g ai/ha with a RTI of 7 days and a PHI of 3 days.

None of the trials provided matched the GAPs. Hence, the Meeting concluded that no maximum residue level could be estimated for kresoxim-methyl in tomato.

#### *Grape leaves*

The critical GAP for grape leaves in Turkey allows three foliar applications of kresoxim-methyl at 30 g ai



/ha with a RTI of 10 days and a PHI of 14 days. Field trials with grape leaves conducted in Europe were performed with three foliar applications of kresoxim-methyl at rates of 150 g ai/ha with an 8–10 day interval between applications.

None of the trials provided matched the GAPs. As a result the Meeting concluded that no maximum residue level could be estimated for kresoxim-methyl in grape leaves.

#### *Sugar beets, beet roots and turnip*

The critical GAP for beet root in Germany allows two foliar applications of kresoxim-methyl at 125 g ai /ha with a RTI of 10 days and a PHI of 28 days. For sugar beet and turnip, the GAP in Germany allows for one application at 125 g ai/ha with a PHI of 28 days. Field trials with sugar beet conducted in France and Germany were performed with two foliar applications of kresoxim-methyl at rates of 125 g ai/ha with a 21 day interval between applications.

For estimating maximum residue levels of kresoxim-methyl in sugar beets, the ranked order of residues following GAP treatment was (n = 10): < 0.05 (10) mg/kg.

For dietary risk assessment, the ranked order of the total residue following GAP treatment was (n = 10): < 0.10 (10)mg/kg.

The Meeting estimated a maximum residue level of 0.05(\*) mg/kg and a STMR of 0 mg/kg in beet root, supported by evidence from a metabolism study performed with sugar beet, and decided to extrapolate its estimations to sugar beets and turnips.

#### *Wheat*

The critical GAP for wheat, rye and triticale in the United Kingdom allows two foliar applications of kresoxim-methyl at 125 g ai /ha (RTI not given) and the PHI is covered by conditions of use (last application up to BBCH 65). Field trials with wheat conducted in Europe were performed with two foliar applications of kresoxim-methyl at rates of 125 g ai/ha with an 11–24 day interval between applications and the last application at BBCH 69.

For estimating maximum residue levels of kresoxim-methyl in wheat grain, the ranked order of residues following GAP treatment was (n = 12): < 0.01(9), 0.01(2), 0.04 mg/kg.

For dietary risk assessment, the ranked order of residues following GAP treatment was (n = 12): < 0.02(9), 0.02(2), 0.05 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg and a STMR of 0.02 mg/kg. The Meeting decided to withdraw its previous recommendation of a maximum residue level for wheat of 0.05 mg/kg, to be replaced by a maximum residue level of 0.05 mg/kg for the subgroup of wheat grain.

#### *Barley*

The critical GAP for barley and oat in the United Kingdom allows two foliar applications of kresoxim-methyl at 125 g ai /ha (RTI not given) and the PHI is covered by conditions of use (last application up to BBCH 59). Field trials with barley conducted in Europe were performed with two foliar applications of kresoxim-methyl at rates of 125 g ai/ha with a 14–25 day interval between applications and the last application at BBCH 69 or 71.

For estimating maximum residue levels of kresoxim-methyl in barley grain, the ranked order of residues following GAP treatment was (n = 10): 0.01, 0.02(4), 0.03(2), 0.04, 0.06, 0.08 mg/kg.

For dietary risk assessment, the ranked order of residues following GAP treatment was (n = 10): 0.02, 0.03(4), 0.04(2), 0.05, 0.07, 0.09 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg and a STMR of 0.035 mg/kg. The Meeting decided to withdraw its previous recommendation of a maximum residue level for barley of 0.1 mg/kg, to be replaced by a maximum residue level of 0.15 mg/kg for the subgroup of barley grain.

#### *Pecan nuts*

The critical GAP for pecan nuts in the USA allows three foliar applications of kresoxim-methyl at 168 g ai /ha with a RTI of 14 days and a PHI of 45 days. Field trials with pecan nuts conducted in the USA were performed with 8 foliar applications of kresoxim-methyl at rates of 224 g ai/ha with a 14–21 day interval between applications.

For estimating maximum residue levels of kresoxim-methyl in pecan nuts, the ranked order of residues following GAP treatment was (n = 6): < 0.05(6) mg/kg.

For dietary risk assessment, the ranked order of residues following GAP treatment was (n = 6): < 0.10(6) mg/kg.

Although all trials were overdosed, the Meeting concluded that recommendations could be given since all residues were <LOQ and estimated a maximum residue level of 0.05(\*) mg/kg and a STMR of 0.10 mg/kg in pecan nuts.

#### **Animal feeds**

##### *Sugar beet tops*

The critical GAP for sugar beet in Germany allows one foliar applications of kresoxim-methyl at 125 g ai /ha and a PHI of 28 days. Field trials with sugar beet conducted in Europe were performed with two applications of kresoxim-methyl at rates of 125 g ai/ha with a 21 day interval between applications.

None of the trials provided matched the GAP for sugar beet.

##### *Cereal forage*

Data was provided for cereal whole plant with the last application performed at BBCH 69–71 and 0 day PHI. The Meeting concluded that the growth stage of the last treatment was not at the forage stage anymore and decided not to consider cereal forage for the livestock dietary burden calculation.

##### *Cereal straw*

The critical GAP for wheat and barley in the United Kingdom allows two foliar applications of kresoxim-methyl at 125 g ai /ha (RTI not given) and the PHI is covered by conditions of use (last application up to BBCH 65 and 59 for wheat and barley, respectively). Field trials with wheat conducted in Europe were performed with two foliar applications of kresoxim-methyl at rates of 125 g ai/ha with an 11–24 day interval between applications.

Residues of total kresoxim-methyl in wheat and barley straw following GAP treatment ( $\pm 25\%$ ) were (n = 22): 0.05, 0.08, 0.15, 0.17(2), 0.22, 0.27, 0.30, 0.33, 0.37, 0.48, 0.52, 0.55, 0.59, 0.62, 0.63, 0.68, 0.76, 0.89, 1.3, 1.6 and 2.3 mg/kg as received.

The Meeting estimated a highest residue of 2.3 mg/kg (as received) for total kresoxim-methyl in cereal straw, a median residue of 0.50 mg/kg (as received) and a maximum residue level of 3 mg/kg (DM,

based on 90% DM content). The latter replaces the previous recommendation for straw and fodder (dry) of cereal grains (5 mg/kg).

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

The Meeting received information on the hydrolysis of <sup>14</sup>C-labelled-kresoxim-methyl as well as processing studies using unlabelled kresoxim-methyl on apples, grapes, gherkin and olive for oil production.

In a hydrolysis study using radiolabelled kresoxim-methyl typical processing conditions were simulated (pH 4.5 and 6 with 90 °C, 100 °C and 120 °C for 20, 60 and 20 minutes). Significant hydrolysis of kresoxim-methyl to kresoxim acid (490M1) was observed at the conditions of sterilisation at up to 71%, while 24% of parent kresoxim-methyl remained.

The Meeting concluded that kresoxim-methyl is stable under the conditions of pasteurisation, boiling, baking and brewing, but not under condition of sterilisation.

For the estimation of maximum residue levels, processing factor according to the residue definition (*kresoxim-methyl*) are summarised below.

Raw commodity	Processed commodity	Individual processing factors	Median or best estimate processing factor	RAC MRL (mg/kg)	RAC MRL × PF (mg/kg)
Grapes	Raisins	1.6, 1.6, 2.2	1.6	1.5	2.4
Olives	Virgin oil	4.5	4.5	0.2	0.9

The Meeting estimated a maximum residue level of 1 mg/kg for virgin oil and 3 mg/kg in raisins. The latter replaces the previous recommendation for raisin (2 mg/kg).

For the estimation of dietary intake of processed commodities, processing factor according to the residue definition (*Sum of kresoxim-methyl and metabolites 490M1 and 490M9 including their conjugates expressed as kresoxim-methyl*) are summarised below.

Raw commodity	Processed commodity	Individual processing factors	Median or best estimate processing factor	STMR <sub>RAC</sub> (mg/kg)	STMR-P = STMR <sub>RAC</sub> × PF (mg/kg)
Grapes	Wine	0.12, 0.20, 0.31, 0.46	0.26	0.365	0.095
	Juice	0.10, 0.48, 0.68	0.48	0.365	0.18
	Must, cold	0.27, 0.30, 0.31, 0.64	0.31	0.365	0.11
	Raisins	1.5, 1.6, 1.8	1.6	0.365	0.58
	Wet pomace	0.94, 2.0, 2.4, 2.6	2.2	0.365	0.80
Olives	Virgin oil	3.4	3.4	0.10	0.34

### ***Residues in animal commodities***

#### ***Farm animal feeding studies***

The Meeting received one feeding study involving kresoxim-methyl on lactating cows. No poultry feeding study was submitted.

The study was conducted with parent kresoxim-methyl at treatment rates of 7, 21 and 70 ppm. In milk, skim milk and cream residues of metabolites 490M2 and 490M9 were <LOQ (0.002 mg/kg) in all dosing groups throughout the study.

In the 7 ppm treatment group no residues >LOQ (0.01 mg/kg) were detected in tissues, except for 490M1 in kidney at up to 0.034 mg/kg (mean: 0.030 mg/kg).

In the 21 ppm treatment group residues were < 0.01 mg/kg in muscle. However, in liver, 490M1 and 490M9 were found at up to 0.037 mg/kg (mean: 0.027 mg/kg) and 0.020 mg/kg (mean: 0.016 mg/kg), respectively. In kidney, 490M1 and 490M9 were found at up to 0.16 mg/kg (mean: 0.010 mg/kg) and 0.019 mg/kg (mean: 0.014 mg/kg), respectively. In fat, 490M1 was found at up to 0.041 mg/kg (mean: 0.030 mg/kg).

In the 70 ppm treatment group residues were < 0.01 mg/kg in muscle. In liver, 490M1 and 490M9 were found at up to 0.040 mg/kg (mean: 0.032 mg/kg) and 0.021 mg/kg (mean: 0.015 mg/kg), respectively. In kidney, 490M1 and 490M9 were found at up to 0.39 mg/kg (mean: 0.020 mg/kg) and 0.047 mg/kg (mean: 0.022 mg/kg), respectively. In fat only, 490M1 was found at up to 0.13 mg/kg (mean: 0.089 mg/kg).

It was noted that 490M9 was not measured in muscle. However, since in the lactating goat metabolism studies 490M9 occurred in muscle at levels half of 490M1, it is assumed that 490M9 in the feeding study is < 0.01 mg/kg as well.

### ***Estimated maximum and mean dietary burdens of livestock***

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR. 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

<b>Livestock dietary burden, Sum of kresoxim-methyl, 490M1 and 490M9, ppm of dry matter diet</b>								
	US-Canada		EU		Australia		Japan	
	max.	Mean	max.	mean	max.	Mean	max.	Mean
Beef cattle	0.28	0.077	0.87	0.20	3.2 <sup>a</sup>	1.5 <sup>b</sup>	0.028	0.028
Dairy cattle	0.31	0.075	0.86	0.19	3.1 <sup>ab</sup>	1.5 <sup>b</sup>	0.15	0.044
Poultry – broiler	0.030	0.030	0.061	0.028	0.025	0.025	0.004	0.004
Poultry – layer	0.030	0.030	0.33 <sup>c</sup>	0.093 <sup>d</sup>	0.015	0.015	none	none

<sup>a</sup> Highest maximum beef or dairy cattle burden suitable for maximum residue level estimates for mammalian tissues

<sup>ab</sup> Highest maximum dairy cattle burden suitable for maximum residue level estimates for mammalian milk

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

<sup>c</sup> Highest maximum broiler or laying hen burden suitable for maximum residue level estimates for poultry products and eggs

<sup>d</sup> Highest mean broiler or laying hen burden suitable for STMR estimates for poultry products and eggs

none no relevant feed items

### ***Animal commodities maximum residue levels***

For beef and dairy cattle, a maximum and mean dietary burden of 3.2 ppm and 1.5 ppm were estimated, respectively. The estimated dietary burdens are evaluated against a lactating cow feeding study involving administration of kresoxim-methyl at 7, 21 and 70 ppm.

For maximum residue level estimation, the high residues in the tissues were calculated by taking the maximum dietary burden (3.2 ppm) as a proportion of the lowest feeding level (7 ppm) multiplied with the highest tissue concentrations from individual animals within this feeding group.

The STMR values for the tissues were calculated by taking the mean dietary burden (1.5 ppm) as a proportion of the lowest feeding level (7 ppm) multiplied by the feeding-level mean residue.

Maximum residue level beef or dairy cattle	Feed level (ppm) for milk residues	Sum of 490M1 and 490M9 as parent equivalents in milk (mg/kg)	Feed level (ppm) for tissue residues	Sum of 490M1 and 490M9 as parent equivalents <sup>a</sup> (mg/kg)			
				Liver	Kidney	Muscle	Fat
Feeding study	7.0	< 0.004	7.0	< 0.02	0.044	< 0.02	< 0.02
Dietary burden and highest residue	3.2	< 0.002	3.2	< 0.01	0.020	< 0.01	< 0.01

<sup>a</sup> Metabolite 490M9 in muscle was estimated at < 0.01 mg/kg.

STMR beef or dairy cattle	Feed level (ppm) for milk residues	Sum of 490M1 and 490M9 as parent equivalents in milk (mg/kg)	Feed level (ppm) for tissue residues	Sum of 490M1 and 490M9 as parent equivalents <sup>a</sup> (mg/kg)			
				Liver	Kidney	Muscle	Fat
Feeding study	7.0	< 0.004	7.0	< 0.02	0.040	< 0.02	< 0.02
Dietary burden and mean residue	1.5	< 0.001	1.5	< 0.004	0.009	< 0.004	< 0.004

<sup>a</sup> Metabolite 490M9 in muscle was estimated at < 0.01 mg/kg.

The Meeting concluded that residues >0.01 mg/kg are expected in kidney and estimated maximum residues levels of 0.05 mg/kg and a STMR of 0.009 mg/kg edible offal (mammalian). For all other tissues and milk the Meeting concluded that no residues > 0.01 mg/kg are expected and estimated maximum residue levels of 0.02(\*) mg/kg for mammalian meat, milks, fat and as well as STMR value of 0.

For poultry a maximum and mean dietary burden of 0.33 ppm and 0.093 ppm were estimated, respectively. However, no farm animal feeding studies were provided. Laying hen metabolism studies involved administration of 180 ppm kresoxim-methyl in the diet, which is about 500 times overdosed compared to the expected maximum dietary burden. Extrapolation of the highest residue found in poultry tissues and egg (metabolite 490M9 at 1.4 mg eq/kg) to the maximum dietary burden would result in residues at up to 0.003 mg/kg. Therefore, the Meeting concluded that no residues > 0.01 mg/kg are expected in eggs and poultry tissues and estimated maximum residues levels of 0.02(\*) mg/kg for poultry meat, eggs, fat and edible offal of as well as STMR value of 0.

## 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 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.*

The Meeting concluded that if future uses of kresoxim-methyl result in an increase of the exposure for metabolite 490M2, a reconsideration of the residue definition for dietary exposure purposes may become necessary.

## DIETARY RISK ASSESSMENT

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

The ADI for kresoxim-methyl 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 2018 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.

## 5.16 LAMBDA-CYHALOTHRIN (146)

### TOXICOLOGY

Lambda-cyhalothrin was previously evaluated by JMPR for toxicology in 1984 and 2007. In the 2007 evaluation, an ADI of 0–0.02 mg/kg bw and an ARfD of 0.02 mg/kg bw were established.

Following a request for additional maximum residue levels by CCPR, lambda-cyhalothrin was placed on the agenda of the present Meeting, which assessed additional toxicological information on lambda-cyhalothrin available since the last review.

The new studies with lambda-cyhalothrin consisted of a biliary elimination and biotransformation study, a 21-day dermal toxicity study, a 21-day inhalation toxicity study, two bacterial gene mutation studies and a preliminary developmental neurotoxicity study.

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 the biliary elimination and biotransformation study in rats, oral absorption was 19–24% following administration of [phenoxy-<sup>14</sup>C] lambda-cyhalothrin at the low dose of 1 mg/kg bw and 11% at the high dose of 12.5 mg/kg bw, based on the radioactivity in urine, bile, cage wash and carcass. The majority of the administered dose was found in faeces (83–84% at the low dose and 88–90% at the high dose), largely as lambda-cyhalothrin, and the majority of the radioactivity (>90%) was excreted by 48 hours post-dosing. There was 1.2% or less radioactivity remaining in the carcass or gastrointestinal tract in all treatment groups, indicating that excretion was essentially complete by 96 hours post-dosing.

No individual unconjugated metabolite accounted for more than 1% of the administered dose in urine or bile samples. The most abundant metabolites of lambda-cyhalothrin in samples hydrolysed with glucuronidase and sulfatase were R119890 (up to 2.1% of the administered dose in bile), R175447 (up to 9.3% of the administered dose in urine and bile) and R211133 (up to 3.2% of the administered dose in bile).

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

Two additional bacterial gene mutation studies were provided, which were both negative.

A preliminary developmental toxicity study in rats, which was the basis for the doses selected for the main study that was previously evaluated by the 2007 Meeting, was submitted. The Meeting noted that the effects seen in this preliminary study were consistent with those seen in the main study.

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

In rats, R119890 (plant metabolite) was not acutely toxic after oral ( $LD_{50} > 4990$  mg/kg bw), dermal ( $LD_{50} > 2000$  mg/kg bw) or inhalation ( $LC_{50} > 1.1$  mg/L) exposure. Metabolite R119890 was slightly irritating to skin of rabbits, moderately irritating to eyes of rabbits and not sensitizing to skin of guinea-pigs. The compound was negative in an Ames test.

R41207 (plant metabolite) was not acutely toxic in rats after oral exposure ( $LD_{50} > 3000$  mg/kg bw).

R79406 (plant metabolite) was tested in a study that evaluated its acute oral toxicity in rats, acute dermal toxicity in rats and skin and eye irritation in rabbits. The study was considered to be of unacceptable quality, with only limited information provided on the conduct of the study and on the study results.

The acute oral LD<sub>50</sub> of metabolite R110649 (plant metabolite) in rats was 1889 mg/kg bw.

It is concluded that the metabolites for which reliable acute oral toxicity data are available (R119890, R41207, R110649) are of lower acute oral toxicity than the parent compound (oral LD<sub>50</sub> of 56 mg/kg bw).

### ***Human data***

In total, 2252 cases were reported describing adverse effects relating to the use of lambda-cyhalothrin. In general, occupational and accidental exposure mainly caused temporary health effects of minor severity. The severe cases were related to intentional misuse. There is no indication of concern for dietary risk assessment.

### **Toxicological evaluation**

The Meeting concluded that the new studies do not have any impact on the ADI of 0–0.02 mg/kg bw or the ARfD of 0.02 mg/kg bw established in 2007.

The Meeting also concluded that on the basis of available data, the metabolites evaluated appear to be less acutely toxic orally than the parent compound.

An addendum to the toxicological monograph was prepared.



## 5.17 LUFENURON (286)

### RESIDUE AND ANALYTICAL ASPECTS

Lufenuron is an insect growth inhibitor that is active against larvae of Lepidoptera and Coleoptera. When ingested, lufenuron interferes with chitin synthesis, and prevents larvae from moulting.

Lufenuron was first evaluated by the 2015 JMPR where an ADI of 0–0.02 mg/kg bw was established. An ARfD was determined to be unnecessary.

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

The residue is fat-soluble.

Lufenuron was scheduled by the Forty-ninth Session of the CCPR for the evaluation of additional use patterns by the 2018 JMPR. The current Meeting received new GAP information and supervised field trials on citrus fruit, pome fruit, peaches, carambola, maize, sweet corn, and coffee along with processing studies on oranges and apples.

#### **Methods of analysis**

An HPLC-UV method, used to analyse all carambola samples collected from the supervised field trials, with a validated LOQ of 0.05 mg/kg, was determined to be acceptable.

Methods used for analysis of residues in citrus fruit, pome fruit, peaches, maize, sweet corn and coffee were previously reviewed by the 2015 JMPR (REM 118.07 citrus, apple, coffee; POPIT MET.153 maize) with LOQs of 0.01 mg/kg.

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

The stability of lufenuron residues during frozen storage (-18 °C) was evaluated by the 2015 JMPR. Lufenuron is stable for at least 24 months in commodities with high water (cabbage), high acid (orange) and high oil (cotton seed) content.

The current Meeting received frozen storage stability data for dry beans and potatoes. Lufenuron was determined to be stable for at least 12 months in commodities with high protein (dry beans) and high starch (potato) content.

The periods of demonstrated stability cover the frozen storage intervals used in the supervised field trials considered by the current Meeting.

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

##### *Citrus fruits*

The critical GAP in Brazil for citrus fruit is one application at 3.75 g ai/hL with a 28-day PHI.

Residues in trials from Brazil on oranges conducted according to the critical GAP were (n = 8): 0.05 (2), 0.07, 0.09 (3), 0.11 and 0.15 mg/kg.

The Meeting estimated a maximum residue level and STMR for the subgroup of oranges sweet, sour of 0.3 mg/kg and 0.09 mg/kg, respectively

In trials from Brazil on limes matching the critical GAP, residues were (n = 4): 0.09 (2), 0.10 and 0.17 mg/kg.

The Meeting estimated a maximum residue level and STMR for limes of 0.4 mg/kg and 0.10 mg/kg, respectively.

#### *Pome fruit*

The critical GAP in Chile for pome fruit is three applications at 5 g ai/hL with an 18-day PHI.

Residue trials were reported from Chile where three applications were made at 5 g ai/hL with sampling at 0, 7, 14, 21 and 28 days after application.

The Meeting noted there was little decline in residues and agreed that residues in samples collected at 14 or 21 days reflect critical GAP. Residues in 8 trials approximating critical GAP in Chile were: 0.20, 0.28 (2), 0.29, 0.30, 0.31, 0.38 and 0.43 mg/kg.

The Meeting estimated a maximum residue level and STMR for apples of 1 mg/kg and 0.29 mg/kg, respectively. Noting the use in Chile is for pome fruit, the Meeting agreed to extrapolate the recommendation to the pome fruit crop group.

#### *Peaches*

In Algeria, the critical GAP for lufenuron on tree fruit is for foliar application at 50 g ai/ha and a 28-day PHI with a maximum number of applications not specified.

Trials were available from Italy and Spain where trees received two foliar applications at 50 g ai/ha. As lufenuron is a persistent residue (t<sub>1/2</sub> 28 days), the Meeting was unable to determine whether additional sprays or shorter intervals between sprays would make a significant contribution to the terminal residues, therefore, a maximum residue level was not estimated.

#### *Carambola*

In Malaysia, the critical GAP for lufenuron on carambola is a maximum of 2 foliar spray applications at 50 g ai/ha and a PHI of 3 days.

In the supervised field trials, fruits were wrapped with papers during the growing stage to protect against fruit flies. As the Malaysian GAP does not specify the requirement to wrap/cover the fruit, the Meeting concluded that a maximum residue level could not be estimated in the absence of trials conducted in accordance with the critical GAP (unwrapped fruit).

#### *Maize*

The critical GAP for lufenuron on maize is in Brazil with a single foliar application at 15 g ai/ha and a 35-day PHI.

In trials from Brazil matching the critical GAP, residues were (n = 4) : < 0.01 (4) mg/kg. In addition, four trials were reported by the 2015 JMPR on maize, where two foliar applications were made with harvest at 35 days (immature corn=sweet corn) and at approximately 50 days after the last application (maize), residues were < 0.01 mg/kg for both immature and mature maize.

The Meeting concluded there is no expectation of residues above the LOQ of 0.01 mg/kg and estimated a maximum residue level and STMR of 0.01 mg/kg and 0.01 mg/kg, respectively, for maize.

#### *Coffee beans*

The critical GAP in Brazil for lufenuron on coffee is two foliar applications at 40 g ai/ha at an interval of 30 days with a 7-day PHI.

In trials from Brazil matching the critical GAP, residues in green coffee beans were ( $n = 8$ )  $< 0.01$  (4), 0.01 (1), 0.03 (2) and 0.04 mg/kg.

The Meeting estimated a maximum residue level and STMR of 0.07 mg/kg and 0.01 mg/kg, respectively, for coffee beans.

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

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

Processing studies on oranges were reviewed by the Meeting. A summary of relevant lufenuron processing factors is provided below.

	Processed Fraction	Processing Factor (PF) <sup>a</sup>	Best estimate PF	RAC STMR or median	STMR×PF= STMR-P (mg/kg)	Highest residue-P (mg/kg)
Orange MRL 0.3	Peel	1.4, 2.0	1.7	0.09	0.153	0.51
	Juice	$< 0.02$ , $< 0.04$	$< 0.02$		0.01*	
	Dried pulp	0.11, 0.18	0.145		0.013	
	Oil	19, 29	24		2.16	
Apple MRL 1	Pomace, wet	4.8	4.8	0.29	1.42	17.6
	Pomace, dry	17.6	17.6		5.19	
	Juice	$< 0.2$	$< 0.2$		0.06	
	Purée	$< 0.2$	$< 0.2$		0.06	

<sup>a</sup> PF = residues lufenuron in processed commodity divided by lufenuron in RAC

STMR-P for juice is from actual supervised trials where residues were measured.

Residues of lufenuron concentrated in orange peel, orange oil and apple dry pomace.

The Meeting recommended a maximum residue level of 8 mg/kg for orange oil.

### ***Residues in animal commodities***

#### ***Estimation of livestock dietary burdens***

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 OECD diets listed in Appendix IX of the 2016 edition of the FAO manual, are presented in Annex 6 and summarised below.

Potential cattle feed items include: citrus pulp, apple pomace, potato culls, maize grain, soya beans and tomato pomace.

#### **Summary of livestock dietary burden (ppm)**

	US-Canada		EU		Australia		Japan	
	Max	mean	Max	Mean	max	Mean	Max	Mean
Beef cattle	0.02	0.02	1.17	1.17	1.17 <sup>a</sup>	1.17 <sup>c</sup>	0.008	0.008
Dairy cattle	0.59	0.59	0.6 <sup>b</sup>	0.6 <sup>d</sup>	0.59	0.59	0.009	0.009
Broilers	0.01	0.01	0.013	0.013	-	-	0.008	0.008
Layers	0.009	0.009	0.013 <sup>e</sup>	0.013 <sup>f</sup>	-	-	0.009	0.009

<sup>a</sup> Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimates for mammalian tissues

<sup>b</sup> Highest maximum dairy cattle dietary burden suitable for maximum residue level 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 maximum residue level estimates for poultry meat and eggs

<sup>f</sup> Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs

### ***Animal commodity maximum residue levels***

As noted by the 2015 JMPR, two feeding studies on lactating cows and steers were available. Since no accumulation of residues in steers compared to dairy cows was observed, the Meeting decided to base its recommendations for mammalian products on the lactating cow feeding study, generally showing higher residues at identical intake levels.

The calculations used in estimating maximum residue levels and STMR values are shown below.

	Feed level (ppm) for milk residues	Residues (mg/kg) in milk	Feed level (ppm) for tissue residues	Residues (mg/kg) in			
				Muscle	Liver	Kidney	Fat
maximum residue level beef or dairy cattle							
Feeding study <sup>a</sup>	0.82	0.16 (cream 3.1)	4.3	0.26	0.39	0.23	5.3
			0.82	0.04	0.07	0.04	1.2
Dietary burden and high residue	0.6	0.117 (cream 2.29)	1.17	0.06	0.10	0.06	1.61
STMR beef or dairy cattle							
Feeding study <sup>b</sup>	0.82	0.16 (cream 3.1)	4.3	0.125	0.37	0.22	4.1
			0.82	0.03	0.06	0.03	0.73
Dietary burden and median residue estimate	0.6	0.117 (cream 2.29)	1.17	0.04	0.09	0.05	1.07

<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 replaces its previous recommendations of 0.7 mg/kg for mammalian fats and meat (from mammals other than marine mammals), 0.04 mg/kg for edible offal, 0.1 mg/kg for milks and 2 mg/kg for milk fats with the following estimated maximum residue levels: milk, 0.15 mg/kg; milk fat, 5 mg/kg (based on cream assuming it contains 50% fat); meat (mammalian except marine mammals), 2 mg/kg; mammalian fat (except milk fat), 2 mg/kg and edible offal 0.15 mg/kg (based on liver). The Meeting estimated the following STMRs: milk 0.117 mg/kg; milk fat 4.58 mg/kg; meat (mammalian except marine mammals) 0.04 mg/kg; mammalian fat (except milk fat) 1.07 mg/kg; liver 0.09 mg/kg and kidney 0.05 mg/kg.

## **RECOMMENDATIONS**

On the basis of the data from supervised field 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 for dietary risk assessment for plant and animal commodities: *lufenuron*

*The residue is fat soluble.*

**DIETARY RISK ASSESSMENT*****Long-term dietary exposure***

The ADI for lufenuron is 0–0.02 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for lufenuron 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 2018 JMPR Report. The IEDIs ranged from 2–10% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of lufenuron from uses considered by the JMPR is unlikely to present a public health concern.

***Acute dietary exposure***

The 2015 JMPR decided that an ARfD for lufenuron was unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of lufenuron resulting from uses that have been considered by the current Meeting is unlikely to present a public health concern.



## 5.18 MANDESTROBIN (307)

### TOXICOLOGY

Mandestrobin is the ISO-approved common name for 2-[2-[(2,5-dimethylphenoxy)methyl]phenyl]-2-methoxy-*N*-methylacetamide (IUPAC), with the CAS number 173662-97-0.

Mandestrobin is a fungicide that is marketed as a racemic mixture (50:50) consisting of the *R*-isomer and the *S*-isomer. The fungicidal mode of action is inhibition of mitochondrial respiration via binding to complex III.

Mandestrobin 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 metabolism studies in which rats were administered racemic [<sup>14</sup>C]mandestrobin labelled at either the benzyl or phenoxy ring as a single dose of 5 or 1000 mg/kg bw, excretion was approximately 90% (>70% within 48 hours). The major routes of excretion were through the faeces (66–74%) and urine (16–20%). There were no significant sex-, dose- or radiolabel-related differences in either the rates or routes of excretion. In bile duct cannulated rats, elimination of radioactivity after a single low dose of 5 mg/kg bw was rapid, with more than 95% of the dose eliminated within 24 hours. About 80% of the excreted radioactivity was eliminated via the bile, and the amount recovered in faeces of the cannulated rats accounted for less than 2% of the total radioactivity. Elimination via urine was comparable to that of intact animals. For both low and high doses, there were no significant sex differences in the pharmacokinetic parameters. Mean plasma elimination half-lives were approximately 20 and 27 hours at the low and high doses, respectively. *C*<sub>max</sub> was observed within 3 and 10 hours post-dosing for the low and high doses, respectively. At the high dose, additional plasma concentration peaks were observed, which were particularly prominent during the first 12 hours post-dosing. The multiple peaks could possibly reflect enterohepatic recirculation, which is supported by the enhanced rapidity of elimination in bile duct cannulated animals. At the high dose, systemic exposure (AUC) was subproportional, indicating saturation of absorption processes following administration.

Following repeated administration of a low dose of radiolabelled compound at 5 mg/kg bw for up to 14 consecutive days, radioactivity was primarily excreted in the faeces (50–57%), with urine containing 13–15% of the administered dose. There were no significant sex differences. In a metabolism study conducted with the *R*- or *S*-isomer, after a single low dose of 5 mg/kg bw, the excretion of *R*-isomer (>95% at 72 hours) was more rapid than excretion of the *S*-isomer (>94% at 120 hours), likely due to enterohepatic recirculation. The majority of radioactivity was excreted in faeces (up to 73% *R*-isomer; up to 77% *S*-isomer). Urinary excretion was higher in female rats (32% *R*-isomer; 25% *S*-isomer) than in male rats (22% *R*-isomer; 15% *S*-isomer).

Mandestrobin was widely distributed throughout the body. No major differences in distribution were observed, regardless of dose, sex or label position. The major tissue residues were seen in the gastrointestinal tract, liver, kidney, uterus and ovaries at 168 hours after dosing. A similar distribution of radioactivity into tissues was observed following repeated dosing. There was evidence of accumulation in tissues, but no persistence.

Mandestrobin was extensively metabolized to numerous metabolites. Unchanged parent was found in faeces at less than 0.2% and less than 6% of the administered dose after a single low and single high dose, respectively. The primary routes of metabolism were by oxidation and subsequent conjugation with glucuronic acid, demethylation with subsequent oxidation, or oxidation with subsequent demethylation. The metabolic profile was generally independent of sex, dose, label position or whether the animals were bile duct cannulated or not. Metabolite fractions in plasma, liver and kidney were identified. There was generally no discernible shift in metabolism at high or repeated doses except in the kidney. Metabolic profiles in the kidney exhibited differences in the type and number of metabolites observed depending on both sex and dosing regimen (single versus repeated dosing). In an investigation of the absorption, distribution, metabolism and excretion of the isomers, 12 metabolites were identified and quantified; 5-CA-S-2200-NHM was the predominant metabolite of the *R*-isomer, and 4-OH-S-2200 followed by 5-COOH-S-2200 were the most abundant metabolites of the *S*-isomer. However, the same metabolites were identified for both the *R*-isomer and the *S*-isomer. 4-OH-S-2200-glucuronide A is likely to be subject to enterohepatic circulation. This metabolic pathway is likely to occur more commonly with the *S*-isomer, because the rate of radiolabel excretion was slower (delayed presumably by enterohepatic recirculation) than that for the *R*-isomer.

### ***Toxicological data***

In rats, the acute oral and dermal LD<sub>50</sub> values were greater than 2000 mg/kg bw, and the acute inhalation LC<sub>50</sub> was greater than 4.96 mg/L. Mandestrobin was not irritating to the skin of rabbits, but was mildly irritating to the eyes of rabbits. Mandestrobin was not sensitizing to the skin of guinea-pigs.

The short-term toxicity of mandestrobin was tested in mice, rats and dogs, and the long-term toxicity and carcinogenicity were tested in mice and rats. The target organ in all species was the liver, with the dog being the most sensitive species. In the rat, thyroid follicular hypertrophy was also observed, concurrently with or at higher doses than effects on the liver.

In a 90-day study in mice in which mandestrobin was administered at a dietary concentration of 0, 1750, 3500 or 7000 ppm (equal to 0, 204, 405 and 807 mg/kg bw per day for males and 0, 252, 529 and 1111 mg/kg bw per day for females, respectively), the NOAEL was 3500 ppm (equal to 529 mg/kg bw per day), based on reduced body weight gain in females at 7000 ppm (equal to 1111 mg/kg bw per day).

In a 90-day study in rats in which mandestrobin was administered at a dietary concentration of 0, 800, 4000, 10 000 or 20 000 ppm (equal to 0, 54, 283, 743 and 1545 mg/kg bw per day for males and 0, 62, 320, 788 and 1886 mg/kg bw per day for females, respectively), the NOAEL was 4000 ppm (equal to 283 mg/kg bw per day), based on increased liver weights accompanied by hepatocyte hypertrophy, increased total cholesterol and thyroid follicular hypertrophy in both sexes at 10 000 ppm (equal to 743 mg/kg bw per day).

In a 90-day study in dogs in which mandestrobin was administered at a dietary concentration of 0, 4000, 12 000 or 40 000 ppm (equal to 0, 90.9, 267.8 and 933.1 mg/kg bw per day for males and 0, 102.7, 304.4 and 820.4 mg/kg bw per day for females, respectively), the NOAEL was 4000 ppm (equal to 90.9 mg/kg bw per day), based on increased liver weights, histopathological changes in the liver and increased ALP activity in blood in both sexes at 12 000 ppm (equal to 267.8 mg/kg bw per day).

In a 1-year study in dogs in which mandestrobin was administered at a dietary concentration of 0, 200, 800, 4000 or 8000 ppm (equal to 0, 4.3, 19.2, 92.0 and 180.7 mg/kg bw per day for males and 0, 4.5, 20.4, 92.0 and 225.7 mg/kg bw per day for females, respectively), the NOAEL was 800 ppm (equal to 19.2 mg/kg bw per day), based on increased relative liver weights, hepatocyte hypertrophy and hepatocyte pigment and disturbances to clinical biochemistry parameters (increased ALP, GGT and triglycerides) in males at 4000 ppm (equal to 92.0 mg/kg bw per day).



In an 18-month toxicity and carcinogenicity study in mice, mandestrobin was administered at a dietary concentration of 0, 700, 2000 or 7000 ppm (equal to 0, 82.5, 238.8 and 823.9 mg/kg bw per day for males and 0, 99.2, 280.3 and 994.0 mg/kg bw per day for females, respectively). The NOAEL for toxicity was 7000 ppm (equal to 823.9 mg/kg bw per day), the highest tested dose. No treatment-related increases in tumour incidence were observed in this study.

In a 2-year toxicity and carcinogenicity study in rats, mandestrobin was administered at a dietary concentration of 0, 400, 2000, 7000 or 15 000 ppm (equal to 0, 21.0, 105.1, 375.6 and 804.3 mg/kg bw per day for males and 0, 26.7, 135.2, 475.0 and 1016.2 mg/kg bw per day for females, respectively). The NOAEL for toxicity was 400 ppm (equal to 26.7 mg/kg bw per day), based on effects on body weight and liver (histopathological changes and increased liver weights) in females at 2000 ppm (equal to 135.2 mg/kg bw per day). The NOAEL for carcinogenicity was 7000 ppm (equal to 375.6 mg/kg bw per day), based on an equivocal increase in the incidence of tumours (ovarian sex cord stromal adenomas and testicular interstitial cell adenomas) at the highest dose.

Mandestrobin 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 mandestrobin is unlikely to be genotoxic.

In view of the lack of genotoxicity, the absence of carcinogenicity in mice and the fact that only an equivocal increase in testicular interstitial cell and ovarian sex cord stromal adenomas was seen in rats at the highest dose tested, the Meeting concluded that mandestrobin is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation reproductive toxicity study in which rats were given mandestrobin at a dietary concentration of 0, 1000, 3000 or 10 000 ppm (equal to 0, 47.77, 145.7 and 511.7 mg/kg bw per day for males and 0, 65.68, 200.3 and 672.0 mg/kg bw per day for females, respectively), the NOAEL for parental toxicity was 1000 ppm (equal to 47.77 mg/kg bw per day), based on reduced liver weights, brown pigment in the bile duct/periportal area in both sexes and periductular inflammatory cell infiltration in F<sub>1</sub> females at 3000 ppm (equal to 145.7 mg/kg bw per day). The NOAEL for offspring toxicity was 1000 ppm (equal to 47.77 mg/kg bw per day), based on decreased spleen weights in F<sub>1</sub> male and F<sub>2</sub> female pups. The NOAEL for reproductive toxicity was 10 000 ppm (equal to 511.7 mg/kg bw per day), the highest dose tested.

In a developmental toxicity study in rats given mandestrobin by gavage at 0, 100, 300 or 1000 mg/kg bw per day from gestation days 6 to 19, the NOAEL for maternal toxicity was 300 mg/kg bw per day, based on reduced feed consumption at 1000 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 300 mg/kg bw per day, based on an increase in a limited number of visceral and skeletal malformations at 1000 mg/kg bw per day.

In a developmental toxicity study in rabbits given mandestrobin by gavage at 0, 100, 300 or 1000 mg/kg bw per day from gestation days 7 to 28, the maternal and embryo/fetal NOAEL was 1000 mg/kg bw per day, the highest dose tested.

The Meeting concluded that mandestrobin is teratogenic in rats, but not in rabbits.

In an acute neurotoxicity study, mandestrobin was given to rats by gavage at a dose of 0, 500, 1000 or 2000 mg/kg bw. The NOAEL for neurotoxicity was 1000 mg/kg bw, based on decreased overall locomotor activity (total and/or ambulatory counts) at 2000 mg/kg bw. The NOAEL for systemic toxicity was 2000 mg/kg bw, the highest dose tested.

In a 90-day neurotoxicity study in rats given mandestrobin at a dietary concentration of 0, 1500, 5000 or 15 000 ppm (equal to 0, 99, 338 and 1024 mg/kg bw per day for males and 0, 122, 415 and 1223 mg/kg bw per day for females, respectively), the NOAEL for systemic toxicity was 5000 ppm (equal to 338 mg/kg bw per day), based on decreases in body weight, body weight gain and feed consumption in

males at 15 000 ppm (equal to 1024 mg/kg bw per day). The NOAEL for neurotoxicity was 15 000 ppm (equal to 1024 mg/kg bw per day), the highest dose tested.

Although there were no indications of neuropathological effects of mandestrobin, the Meeting concluded that mandestrobin may cause transient, acute neurobehavioural effects at high doses.

In a 28-day immunotoxicity study in female rats given mandestrobin at a dietary concentration of 0, 1500, 5000 or 15 000 ppm (equal to 0, 147, 471 and 1419 mg/kg bw per day, respectively), the NOAEL for immunotoxicity (splenic antibody-forming cell) was 15 000 ppm (equal to 1419 mg/kg bw per day), the highest dose tested.

Two in vivo studies (one in rats, one in mice) to gain insight into the mechanistic basis of the liver and thyroid effects observed in the main studies in rats were provided. The effects observed indicated a CAR-mediated induction of liver enzymes and subsequent perturbations of thyroid hormones, similar to a phenobarbital-like mode of action.

In an in vitro non-GLP-compliant human estrogen and androgen receptor transactivation assay, mandestrobin and its metabolites (5-COOH-S-2200, 4-OH-S-2200, 5-CH<sub>2</sub>OH-S-2200 and 5-CA-S-2200-NHM) did not show agonistic or antagonistic effects on human estrogen receptor alpha (hER $\alpha$ ) or human androgen receptor (hAR). In a second in vitro non-GLP-compliant study, a steroidogenesis assay in H295R cells, mandestrobin did not influence testosterone or estradiol production.

No information on the potential effects of mandestrobin on the microbiome of the human gastrointestinal tract is available.

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

##### ***Metabolite 2-CH<sub>2</sub>OH-S-2200 (free and conjugated)***

The free form of metabolite 2-CH<sub>2</sub>OH-S-2200 ((*2RS*)-2-[2-(5-hydroxymethyl-2-methylphenoxy-methyl)phenyl]-2-methoxy-*N*-methylacetamide) is a rat (<1% of the applied dose in urine), hen, goat and plant metabolite. The conjugate form is also a plant and animal metabolite. The submitted studies were performed with the free form of the metabolite only.

The acute oral LD<sub>50</sub> of metabolite 2-CH<sub>2</sub>OH-S-2200 in rats was greater than 2000 mg/kg bw.

Metabolite 2-CH<sub>2</sub>OH-S-2200 was tested in a gene mutation assay in bacteria. There was no evidence of mutagenicity.

The acute toxicity of the free and conjugated 2-CH<sub>2</sub>OH-S-2200 metabolite is considered to be similar to that of the parent compound. For chronic toxicity, the TTC approach could be applied using Cramer class III.

##### ***Metabolite 4-OH-S-2200 (free and conjugated)***

Both the free and conjugated forms of metabolite 4-OH-S-2200 ((*2RS*)-2-[2-(4-hydroxy-2,5-dimethylphenoxy-methyl)phenyl]-2-methoxy-*N*-methylacetamide) are rat (free form <1% of the applied dose in urine; conjugated form >30% of the applied dose in bile; present in plasma), hen, goat and plant metabolites. Submitted studies were performed with the free form of the metabolite only.

The acute oral LD<sub>50</sub> of metabolite 4-OH-S-2200 in rats was greater than 2000 mg/kg bw.

Metabolite 4-OH-S-2200 was tested in a gene mutation assay in bacteria. There was no evidence of mutagenicity.

Based on the high levels in bile, the toxicity of the free and conjugated 4-OH-S-2200 metabolite is considered to be covered by the parent compound.

*Metabolite De-Xy-S-2200*

Metabolite De-Xy-S-2200 ((2*RS*)-2-(2-hydroxymethylphenyl)-2-methoxy-*N*-methylacetamide) is a rat (<1% of the applied dose in urine; present in liver and kidney), hen, goat and plant metabolite.

The acute oral LD<sub>50</sub> of metabolite De-Xy-S-2200 in rats was greater than 2000 mg/kg bw.

Metabolite De-Xy-S-2200 was tested in a gene mutation assay in bacteria. There was no evidence of mutagenicity.

The acute toxicity of metabolite De-Xy-S-2200 is considered to be similar to that of the parent compound. For chronic toxicity, the TTC approach could be applied using Cramer class III.

*Metabolite 2-COOH-S-2200*

Metabolite 2-COOH-S-2200 (2-({2-[(1*RS*)-1-methoxy-2-(methylamino)-2-oxoethyl]benzyl}oxy)-4-methylbenzoic acid) is a rat (<1% of the applied dose in urine and bile; present in plasma and kidney), hen and goat metabolite.

The acute oral LD<sub>50</sub> of metabolite 2-COOH-S-2200 in rats was greater than 2000 mg/kg bw.

Metabolite 2-COOH-S-2200 was tested in an adequate range of in vitro and in vivo assays. Negative results were obtained in gene mutation assays and an in vivo micronucleus assay. A weak positive response was seen in an in vitro chromosomal aberration assay.

The acute toxicity of metabolite 2-COOH-S-2200 is considered to be similar to that of the parent compound. For chronic toxicity, the TTC approach could be applied using Cramer class III.

*Metabolite 5-COOH-S-2200*

Metabolite 5-COOH-S-2200 (3-({2-[(1*RS*)-1-methoxy-2-(methylamino)-2-oxoethyl]benzyl}oxy)-4-methylbenzoic acid) is a rat (1.3% of the applied dose in urine and faeces; present in plasma, liver and kidney), hen and goat metabolite.

The acute oral LD<sub>50</sub> of metabolite 5-COOH-S-2200 in rats was greater than 300 mg/kg bw and less than 2000 mg/kg bw.

Metabolite 5-COOH-S-2200 was tested in an adequate range of in vitro assays. There was no evidence of genotoxicity.

The acute toxicity of metabolite 5-COOH-S-2200 is considered to be similar to that of the parent compound. For chronic toxicity, the TTC approach could be applied using Cramer class III.

**Human data**

In reports on manufacturing plant personnel, no adverse effects were noted. No information on accidental or intentional poisoning in humans is available.

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

**Toxicological evaluation**

The Meeting established an ADI for mandestrobin of 0–0.2 mg/kg bw, based on a NOAEL of 19.2 mg/kg bw per day for increased liver weights, histopathological changes in the liver and associated disturbance of blood biochemistry parameters in a 1-year dog study and using a safety factor of 100. This ADI provides a margin of about 4000 relative to the LOAEL for equivocal carcinogenic effects in rats.

The Meeting established an ARfD of 3 mg/kg bw, based on a NOAEL of 300 mg/kg bw per day for malformations observed in a developmental toxicity study in rats and using a safety factor of 100. This ARfD is applicable to women of childbearing age only.

The Meeting concluded that it was not necessary to establish an ARfD for mandestrobin for the remainder of the population in view of its low acute oral toxicity and the absence of any other toxicological effects that would be likely to be elicited by a single dose.

A toxicological monograph was prepared.

#### ***Levels relevant to risk assessment of mandestrobin***

Species	Study	Effect	NOAEL	LOAEL
Mouse	Seventy-eight-week study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	7 000 ppm, equal to 823.9 mg/kg bw per day <sup>b</sup>	–
		Carcinogenicity	7 000 ppm, equal to 823.9 mg/kg bw per day <sup>b</sup>	–
Rat	Two-year study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	400 ppm, equal to 26.7 mg/kg bw per day	2 000 ppm, equal to 135.2 mg/kg bw per day
		Carcinogenicity	7 000 ppm, equal to 375.6 mg/kg bw per day	15 000 ppm, equal to 804.3 mg/kg bw per day <sup>c</sup>
	Two-generation study of reproductive toxicity <sup>a</sup>	Reproductive toxicity	10 000 ppm, equal to 511.7 mg/kg bw per day <sup>b</sup>	–
		Parental toxicity	1 000 ppm, equal to 47.77 mg/kg bw per day	3 000 ppm, equal to 145.7 mg/kg bw per day
		Offspring toxicity	1 000 ppm, equal to 47.77 mg/kg bw per day	3 000 ppm, equal to 145.7 mg/kg bw per day
	Developmental toxicity study <sup>d</sup>	Maternal toxicity	300 mg/kg bw per day	1 000 mg/kg bw per day
		Embryo and fetal toxicity	300 mg/kg bw per day	1 000 mg/kg bw per day
	Acute neurotoxicity study <sup>d</sup>	Neurotoxicity	1 000 mg/kg bw	2 000 mg/kg bw
	Developmental toxicity study <sup>d</sup>	Maternal toxicity	1 000 mg/kg bw per day <sup>b</sup>	–
		Embryo and fetal toxicity	1 000 mg/kg bw per day <sup>b</sup>	–
Dog	Ninety-day toxicity study <sup>a</sup>	Toxicity	4 000 ppm, equal to 90.9 mg/kg bw per day	12 000 ppm, equal to 267.8 mg/kg bw per day
	One-year toxicity study <sup>a</sup>	Toxicity	800 ppm, equal to 19.2 mg/kg bw per day	4 000 ppm, equal to 92.0 mg/kg bw per day

<sup>a</sup> Dietary administration.

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

<sup>c</sup> Based on an equivocal increase in the incidence of tumours.

<sup>d</sup> Gavage administration.

*Acceptable daily intake (ADI)*

0–0.2 mg/kg bw

*Acute reference dose (ARfD)*

3 mg/kg bw (applies to women of childbearing age only)

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

Rate and extent of oral absorption	>95% based on urinary and biliary excretion within 24 hours
Dermal absorption	No information provided
Distribution	Extensively distributed throughout the body (mainly in gastrointestinal tract, liver and kidneys)
Potential for accumulation	Evidence of accumulation, but not persistence
Rate and extent of excretion	Faecal elimination, via the bile, was the primary route of elimination (~80%); urinary excretion up to ~15%
Metabolism in animals	Extensively metabolized to numerous metabolites; primary routes of metabolism are oxidation and subsequent conjugation with glucuronic acid, demethylation with subsequent oxidation, oxidation with subsequent demethylation
Toxicologically significant compounds in animals and plants	Mandestrobin

*Acute toxicity*

Rat, LD <sub>50</sub> , oral	>2 000 mg/kg bw
Rat, LD <sub>50</sub> , dermal	>2 000 mg/kg bw
Rat, LC <sub>50</sub> , inhalation	>4.96 mg/L air (maximal attainable concentration)
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Mildly irritating
Guinea-pig, dermal sensitization	Not sensitizing (Magnusson & Kligman)

*Short-term studies of toxicity*

Target/critical effect	Liver and clinical chemistry
Lowest relevant oral NOAEL	19.2 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	1 000 mg/kg bw per day, highest dose tested (rat)
Lowest relevant inhalation NOAEC	Not available

*Long-term studies of toxicity and carcinogenicity*

Target/critical effect	Liver
Lowest relevant NOAEL	26.7 mg/kg bw per day (rat)

Carcinogenicity	Not carcinogenic in mice; equivocal increases in testicular interstitial cell and ovarian sex cord stromal adenomas in rats <sup>a</sup>
<i>Genotoxicity</i>	
	No evidence of genotoxicity <sup>a</sup>
<i>Reproductive toxicity</i>	
Target/critical effect	Parental: increased liver weights and pigment in the bile duct, periductal inflammatory cell infiltration Offspring: lower spleen weights
Lowest relevant parental NOAEL	47.77 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	47.77 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	511.7 mg/kg bw per day, highest dose tested (rat)
<i>Developmental toxicity</i>	
Target/critical effect	Maternal effects: decreased feed consumption Developmental effects: visceral and skeletal malformations
Lowest relevant maternal NOAEL	300 mg/kg bw per day (rat)
Lowest relevant embryo/fetal NOAEL	300 mg/kg bw per day (rat)
<i>Neurotoxicity</i>	
Acute neurotoxicity NOAEL	1 000 mg/kg bw (rat)
Subchronic neurotoxicity NOAEL	1 024 mg/kg bw per day, highest dose tested (rat)
Developmental neurotoxicity NOAEL	Not available
<i>Other toxicological studies</i>	
Immunotoxicity NOAEL	1 419 mg/kg bw per day, highest dose tested (rat)
<i>Studies on toxicologically relevant metabolites</i>	
2-COOH-S-2200	Oral LD <sub>50</sub> > 2 000 mg/kg bw Not genotoxic in vivo
5-COOH-S-2200	300 < LD <sub>50</sub> < 2 000 mg/kg bw Not genotoxic in vitro
2-CH <sub>2</sub> OH-S-2200	LD <sub>50</sub> > 2 000 mg/kg bw Not genotoxic in vitro
4-OH-S-2200	LD <sub>50</sub> > 2 000 mg/kg bw Not genotoxic in vitro
De-Xy-S-2200	LD <sub>50</sub> > 2 000 mg/kg bw Not genotoxic in vitro
<i>Human data</i>	
	No detrimental health effects in manufacturing personnel

<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	One-year toxicity study in dogs	100
ARfD	3 mg/kg bw <sup>a</sup>	Developmental toxicity study in rats	100

<sup>a</sup> Applies to women of childbearing age only.

**RESIDUE AND ANALYTICAL ASPECTS**

The Meeting was unable to complete an evaluation for residues - refer to section 2.2





## 5.19 MANDIPROPAMID (231)

### TOXICOLOGY

Mandipropamid was reviewed by JMPR for the first time in 2008, when an ADI of 0–0.2 mg/kg bw was established and it was concluded that an ARfD was not necessary.

Following a request for additional maximum residue levels by CCPR, mandipropamid was placed on the agenda of the present Meeting, which assessed additional toxicological information available since the last review.

A 90-day feeding study in mice, an immunotoxicity study in mice and several mechanistic studies performed with the parent compound were submitted. In addition, a number of toxicological and genotoxicity studies with the metabolite (4-chlorophenyl)-prop-2-ynyloxy-acetic acid (SYN500003) were provided.

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

In a 90-day feeding study in mice, target organs were the liver and the erythropoietic system, with possible involvement of the spleen. The NOAEL was 800 ppm (equal to 98.0 mg/kg bw per day), based on evidence of slight anaemia, higher liver and spleen weights and cytoplasmic eosinophilia of hepatocytes at 2000 ppm (equal to 247.6 mg/kg bw per day). The effects resembled those observed in other species, and the NOAEL was higher than in rats or dogs.

In a 28-day study in female mice, the T-cell-mediated immunological response was not affected by administration of mandipropamid up to the highest dose of 3000 ppm (equal to 649 mg/kg bw per day).

The Meeting considered that the mechanistic studies submitted did not provide any information relevant to the evaluation of mandipropamid.

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

The potato metabolite of mandipropamid, SYN500003, was more toxic than the parent compound in an acute oral toxicity study in rats, with an LD<sub>50</sub> of 1049 mg/kg bw, compared with greater than 5000 mg/kg bw for the parent compound.

SYN500003 gave negative results in gene mutation tests in bacteria as well as in mammalian cells. However, it gave a positive response in a chromosomal aberration study in human lymphocytes. A negative result was seen in a micronucleus assay in mouse bone marrow in which 2000 mg/kg bw, the highest dose tested, produced clinical signs of toxicity; one possibly treatment-related death was also noted. In a “proof of exposure” study, high concentrations of the metabolite were detected in plasma following oral administration of 1000 mg/kg bw to rats. The abundance of SYN500003 in plasma can be considered as evidence that a sufficient amount had reached the bone marrow in the micronucleus test.

The Meeting concluded that SYN500003 is unlikely to be genotoxic in vivo.

### **Toxicological evaluation**

The Meeting concluded that no revision of the ADI for mandipropamid was necessary.

For the metabolite SYN500003, the ADI for mandipropamid is not applicable, as the metabolite is structurally different from the parent and is more acutely toxic. No separate ADI or ARfD can be established for the metabolite, as the database is not sufficient for this purpose.

For chronic toxicity, the TTC concept for non-genotoxic substances (Cramer class III) is applicable to this metabolite.

An addendum to the toxicological monograph was prepared.

### RESIDUE AND ANALYTICAL ASPECTS

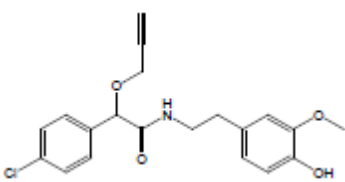
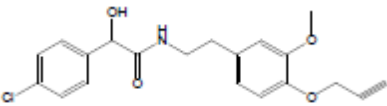
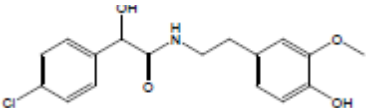
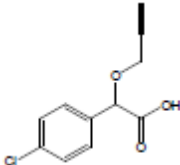
Mandipropamid is a fungicide in the mandelamide class used for the control of foliar oomycete pathogens in a range of crops, including *Plasmopara viticola* in grapes, *Phytophthora infestans* in potatoes and tomatoes, and *Pseudoperonospora cubensis* in cucurbits. Mandipropamid was first evaluated by the JMPR in 2008 when an ADI of 0–0.2 mg/kg bw was established, and maximum residue levels were recommended for various crops. An ARfD was considered unnecessary. The 2008 JMPR agreed on the following residue definition for mandipropamid:

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

The residue is not fat-soluble.

Mandipropamid was listed by the Forty-ninth Session of the CCPR for the evaluation of additional uses. The current Meeting received metabolism studies on potato (seed treatment) and on laying hens, registered labels, analytical method, sample storage stability data, and supervised residue trials for beans, potato and cacao beans.

The following abbreviated names are used for the metabolites discussed below.

Compound Name/Code	Structure	Occurrence in metabolism studies
NOA458422 2-(4-Chlorophenyl)-N-[2-(4-hydroxy-3-methoxyphenyl)-ethyl]-2-prop-2-ynyloxy-acetamide		Plant, animal
CGA380778 2-(4-Chlorophenyl)-2-hydroxy-N-[2-(3-methoxy-4-prop-2-ynyloxyphenyl)-ethyl]-acetamide		Plant, animal
CGA380775 2-(4-Chlorophenyl)-2-hydroxy-N-[2-(4-hydroxy-3-methoxyphenyl)-ethyl]-acetamide		Animal
SYN500003 (4-Chloro-phenyl)-prop-2-ynyloxy-acetic acid		Plant

Compound Name/Code	Structure	Occurrence in metabolism studies
SYN521195 2-(4-Chlorophenyl)-N-[2-(3-hydroxy-4-prop-2-ynyloxyphenyl)-ethyl]-2-prop-2-ynyloxy-acetamide		Animal
M186/1 [2-(4-chlorophenyl)-2-hydroxyacetic acid]		Animal
M401/1		Animal
M415/1		Animal
M431/1		Animal
M439/1		Animal
M453/1		Animal
SYN505503 2-(4-Chlorophenyl)-N-[2-(3,4-dihydroxyphenyl)-ethyl]-2-prop-2-ynyloxy-acetamide		Animal

### Plant metabolism

#### Potato

Potato seeds were treated with chlorophenyl- or methoxyphenyl- $^{14}\text{C}$ mandipropamid at rates of 6.1 and 6.3 mg ai/seed piece, respectively. This application rate was equivalent to 0.1 kg ai/t potato seed pieces. Treated potato seed was planted in outdoor raised beds and harvested at maturity, 183 days after the application.

TRR levels in potato tuber ranged from 0.024 to 0.054 mg eq/kg for the methoxyphenyl- and chlorophenyl- $^{14}\text{C}$ mandipropamid labelled experiments, respectively.

Tuber residues, extractable in acetonitrile: water (4:1) and acetonitrile, were 50% and > 76% TRR for the methoxyphenyl- and chlorophenyl-[<sup>14</sup>C]mandipropamid labels, respectively. Unextracted residues were not further characterised since residues were  $\leq 0.013$  mg eq/kg. The identification of the radioactive residues revealed the metabolite SYN500003 was the only major metabolite identified (40% TRR, up to 0.022 mg eq/kg), with parent being present at low proportions up to 11% TRR (0.003 mg eq/kg). Two other metabolites were found at very low levels  $\leq 0.001$  mg eq/kg).

In summary, residues of parent mandipropamid in potatoes following seed treatment were low. The major metabolite SYN500003 was formed by hydrolysis of the amide bond to the corresponding carboxylic acid.

At the 2008 JMPR, the metabolism of mandipropamid in plants (grapes, lettuce, potatoes and tomatoes) following foliar treatment was investigated. Unchanged mandipropamid was the major residue in all crops, except potato tubers, making up 40–94% TRR. The major metabolite in potato tubers after foliar treatment was SYN500003 accounting for up to 13% TRR however it was present at low levels ( $\leq 0.006$  mg/kg).

### **Animal metabolism**

#### *Laying hens*

The Meeting received information on a feeding study in which laying hens were orally dosed with chlorophenyl- or methoxyphenyl-[<sup>14</sup>C]mandipropamid, at a dose equivalent to 22–24 ppm in dry feed for 14 consecutive days. The majority of the administered dose was recovered in excreta (83–88%) of both labels.

The highest TRR was observed in the liver. The TRR levels in liver were 0.31–0.32 mg eq/kg, in egg yolk (Day 9) 0.083–0.12 mg eq/kg, in egg white (Day 9) 0.046–0.05 mg eq/kg, in muscle < 0.01–0.016 mg eq/kg and in fat 0.021–0.022 mg eq/kg. Residues in the egg whites and yolks reached a plateau within 9 days for both radiolabels.

Eggs, liver and muscle were extracted with acetonitrile and acetonitrile:water (80:20, v/v and 30:70, v/v).

In egg white 94–95% TRR was extractable (0.044–0.047 mg eq/kg). In egg yolk 31–38% TRR was extracted (0.031–0.038 mg eq/kg). Parent mandipropamid was identified as the major component in egg white, accounting for 309–33% TRR (0.015 mg/kg). The metabolite CGA380778 was detected as a major metabolite in egg white, accounting for 14–16% TRR (0.007–0.008 mg/kg).

In liver 29–35% TRR was extractable (0.107 and 0.095 mg eq/kg). NOA458422 conjugated was the major component in liver, accounting for 6.3–14.8% TRR (0.02–0.045 mg eq/kg).

In muscle 62% TRR was extractable (0.010 mg/kg). Mandipropamid was a minor component, accounting for 2.3% TRR (< 0.001 mg/kg). M186/1, CGA380775 and NOA458422 were also detected, but at lower levels ( $\leq 0.002$  mg/kg).

In fat residues extractable with hexane, hexane/diethyl ether (1:1, v/v) and acetonitrile were 45–64% TRR (0.01–0.014 mg eq/kg). Unchanged mandipropamid was a major component accounting for 28–37% TRR (0.006–0.008 mg eq/kg).

In summary, mandipropamid was detected in egg whites, but was minor in all other tissues. CGA380778 was detected at low level in egg whites and egg yolk. Conjugated NOA458422 was detected as the major component in liver.

### **Methods of analysis**

The current Meeting received description and validation data for additional or extended analytical methods

for mandipropamid and its metabolite SYN500003 in plant commodities (beans, potato tuber and processed and cacao bean and processed).

Crop samples were extracted with acetonitrile: water (80:20 v/v), cleaned-up using solid-phase extraction. Residues of mandipropamid and SYN500003 were quantified with HPLC-MS/MS. LOQ values are at 0.01 and 0.005 mg/kg for mandipropamid and SYN500003, respectively, in various plant matrices.

The methods are suitable for the analysis of mandipropamid and the metabolite SYN500003 in plants matrices.

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

The current Meeting received information on the freezer storage stability of residues of mandipropamid in plant commodities. Residues were stable (at least 70% remaining) in various plant matrices and processed commodities: tomatoes, grapes, lettuce, cucumbers, wheat and soya bean for at least 24 months, in beans (with pod and forage) for at least 12 months and in potato for at least 32 months when stored frozen at -20 °C.

The Meeting received information on the freezer storage stability of residues of SYN500003 in potato tuber and processed potato commodities. Results demonstrated that residues of SYN500003 were stable in potato tubers, potato granules/flakes, potato chips and potato wet peel when stored under freezer storage conditions for up to 32 months.

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

The 2008 JMPR concluded that for plant, mandipropamid was the major component following foliar treatment with <sup>14</sup>C-mandipropamid in grapes, lettuce, potatoes and tomatoes, except potato tuber. The major metabolite (SYN500003) in potato tubers following foliar treatment accounted for up to 13% TRR but was present at very low levels ( $\leq 0.006$  mg/kg).

In a potato metabolism study reviewed by the current Meeting (seed piece treatment), SYN500003 was the only major metabolite identified (40% TRR, up to 0.022 mg eq/kg), with parent being present at up to 11% TRR (0.003 mg eq/kg) in the tubers.

The Meeting concluded that the parent is an appropriate marker for the use of mandipropamid in potatoes after seed treatment, and confirms the previous residue definition for enforcement in plants as mandipropamid.

For dietary risk assessment, the Meeting noted that as no specific data were available on the toxicity of metabolite SYN500003, the TTC approach was applied<sup>25</sup>. The estimated exposure based on potatoes was up to 0.027 µg/kg bw, below the respective threshold of toxicological concern.

The Meeting concluded that dietary exposure to SYN500003 from the uses evaluated by the current Meeting is unlikely to present a public health concern, and confirms its previous residue definition for dietary intake assessment in plants as mandipropamid.

The 2008 JMPR concluded that mandipropamid comprised the majority of the residue in goat fat, and only a small proportion of the residue in goat milk and liver, and was not detected in kidney. The metabolite NOA 458422 was a significant residue in kidney but was a minor residue in liver.

In a hen metabolism study submitted to the current Meeting, mandipropamid was detected in egg whites, but was minor in egg yolk and tissues. CGA380778 was detected at low level (3–17% TRR, 0.002–0.008 mg eq/kg) in eggs and conjugated NOA458422 was detected in liver at low levels (6.3–14.8% TRR, 0.02–0.045 mg eq/kg).

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<sup>25</sup> See toxicology section for further details

The Meeting confirms its previous residue definition for compliance with the MRL and dietary risk assessment for animal commodities as mandipropamid.

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

The residue is not fat-soluble.

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

The Meeting received supervised trials data for mandipropamid uses on beans, cacao beans and potatoes.

#### ***Beans with pod***

The registered GAP in Canada for beans with pods allows 4 foliar applications at 150 g ai/ha, with a PHI of 1 day.

In 10 trials conducted in the USA on snap beans matching the critical GAP of Canada (4 × 146 g ai/ha; PHI: 1 day) residues of mandipropamid were (n = 10): 0.10, 0.11(2), 0.13, 0.19, 0.25(2), 0.40, 0.45 and 0.58 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg and a STMR of 0.22 mg/kg for mandipropamid in the subgroup of beans with pods. The highest residue is 0.58 mg/kg.

#### ***Potato***

The critical GAP for potato is from Canada and the USA, which allows one seed treatment application at 100 g ai/t seed potato followed by up to three foliar applications at 146 g ai/ha with a PHI of 14 days.

In 18 field trials from Canada and the USA matching critical GAP (100 g ai/t seed potato + 3 × 146 g ai/ha, PHI 14-days) residues of mandipropamid in potato harvested at maturity were (n = 18): < 0.01 (5), 0.014, 0.015, 0.016, 0.017, 0.020 (3), 0.021, 0.031, 0.043, 0.056, 0.058 and 0.073 mg/kg.

Based on the trials on potato from Canada and the USA, the Meeting estimated a maximum residue level of 0.1 mg/kg and a STMR of 0.0185 mg/kg for mandipropamid in potato. This estimation replaces the previous recommendation of a maximum residue level of 0.01(\*) mg/kg.

As noted the TTC approach was applied in relation to the metabolite SYN500003. In performing the TTC assessment of this compound, the following residue levels were identified in potato tubers (n = 18): < 0.005(10), 0.0051, 0.0058, 0.0059, 0.0089, 0.098, 0.01, 0.013 and 0.013 mg/kg.

The Meeting estimated a median residue of 0.005 mg/kg for (4-Chloro-phenyl)-prop-2-ynyloxy-acetic acid (SYN500003) in potato tubers to estimate exposure for TTC consideration.

#### ***Cacao Bean***

The critical GAP in Cameroon for cacao beans is 6 x 90 g ai/ha, PHI 14 day.

In eight field trials from Ghana and the Ivory Coast matching critical GAP (6 × 90 g ai/ha with a PHI of 14 days) residues of mandipropamid in cacao beans were (n = 8): < 0.01, 0.01 (4), 0.02 and 0.03 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.06 mg/kg and a STMR of 0.01 mg/kg in cacao beans.

### ***Animal feedstuffs***

#### ***Bean forage (green)***

Data were available from supervised trials on bean forage (green) in the USA. In 10 field trials on beans from

the USA matching critical GAP ( $4 \times 146$  g ai/ha; PHI: 1 day) the residues of mandipropamid in bean forage were ( $n = 10$ ) 1.27, 1.36, 2.21, 3.32, 4.20, 4.49, 4.54, 5.03, 7.05 and 9.27 mg/kg.

Based on the residues in bean forage from trials in the USA, the Meeting estimated a median residue value of 4.35 mg/kg (as received) and a highest residue value of 9.27 mg/kg (as received) for mandipropamid in bean forage (green).

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

The current Meeting received information on the fate of mandipropamid residues during the processing of potato and cacao beans. Based on the results of processing studies in combination with the residues from supervised trials, the estimated processing factors and the derived STMR-Ps are summarised in the table below.

Mandipropamid processing factors, STMR-P and HR-P for food and feed

Crop	Residue value (mg/kg) in raw commodity		Processed Commodity	Calculated PF	PF (Mean or best estimated)*	Residue value (mg/kg) in processed commodity	
	MRL	STMR				MRL**	STMR-P
Potato	0.1	0.0185	Flakes	<0.11, < 0.027	< 0.027	-	-
			Chip (crisp)	<0.11, < 0.027	< 0.027	-	-
			Peel (wet)	3.0, 1.1	2.1	-	0.04
			Fries (chips)	<0.11, 0.045	0.045	-	-
Cocoa bean	0.06	0.01	Roasted nibs	0.4, 0.56	0.48	-	0.005
			Cocoa powder	0.4, 0.56	0.48	-	0.005
			Cocoa butter	0.4, 0.66	0.53	-	0.005
			Chocolate***	0.5, 0.71	0.61	-	0.006

\*The factor is the ratio of the total residue in processed commodity divided by the total residue in the RAC.

\*\* maximum residue levels in processed commodities are only proposed where they are higher than the maximum residue level in the RAC.

\*\*\* For 800 g cocoa liquor = 10 g of lecithin + 190 g of commercial sugar.

### ***Residues in animal commodities***

#### ***Farm animal dietary burden***

Dietary burden calculation 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 OECD diets listed in Appendix IX of the 2016 edition of the FAO manual, are presented in Annex 6 and summarised below. As mandipropamid is not registered for use on beans in Australia and Australia does not import any forage, the Meeting decided to refine the animal burden calculation (to exclude bean forage in Australia).

Region	Livestock dietary burden, mandipropamid, ppm of dry matter diet							
	US - Canada		EU		Australia		Japan	
	Maximum	Mean	Maximum	Mean	Maximum	Mean	Maximum	Mean
Beef cattle	0.21	0.13	7.98	4.89	1.58	1.56	-	-
Dairy cattle	0.07	0.04	13.24 <sup>a,b</sup>	7.34 <sup>c,d</sup>	1.58	1.56	-	-
Broiler poultry	-	-	0.04	0.01	-	-	-	-
Laying poultry	-	-	1.97 <sup>e</sup>	1.20 <sup>f</sup>	-	-	-	-

<sup>a</sup> Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimation for mammalian tissues

<sup>b</sup> Highest maximum dairy cattle dietary burden suitable for maximum residue level estimation for mammalian milk

<sup>c</sup> Highest mean beef or dairy cattle dietary burden suitable for STMR estimation for mammalian tissues.

<sup>d</sup> Highest mean dairy cattle dietary burden suitable for STMR estimation for milk.

<sup>e</sup> Highest maximum poultry dietary burden suitable for maximum residue level estimation for poultry tissues and eggs.

<sup>f</sup> Highest mean poultry dietary burden suitable for STMR estimation for poultry tissues and eggs.

### *Animal commodities maximum residue levels*

The maximum and mean estimated dietary burden for dairy cattle was 13.2 and 7.3 ppm, respectively. No animal feeding studies on ruminants are available, and the lactating goat metabolism study submitted to the 2008 JMPR was used to estimate residues of mandipropamid in mammalian commodities, in line with the approach in 2008.

Lactating goats were fed for 7 days with [<sup>14</sup>C] mandipropamid equivalent to 27–49 ppm in the diet. At 30 ppm, the highest residue of parent mandipropamid was found in fat (0.019 mg/kg), with residues being < 0.01 mg/kg in milk and other tissues. The Meeting agreed that no residues of mandipropamid are expected in ruminant commodities at the calculated dietary burden

The Meeting estimated a maximum residue level of 0.01(\*) mg/kg and a STMR of 0 for mandipropamid in milks, edible offal (mammalian), mammalian fats (except milk fats) and meat (from mammals other than marine mammals).

The maximum and mean estimated dietary burdens for poultry were 2 and 1.2 ppm, respectively. No animal feeding studies on poultry are available, and the poultry metabolism study was used to estimate the residues of mandipropamid in poultry commodities.

Laying hens received [<sup>14</sup>C] mandipropamid for 14 days at 22–24 ppm in the diet. The highest residue of parent mandipropamid was 0.018 mg/kg, found in egg white, and residues were < 0.01 mg/kg in egg yolk and in hen tissues. The Meeting agreed that no residues of mandipropamid are expected in poultry commodities at the calculated dietary burden

The Meeting estimated maximum residue levels of 0.01(\*) mg/kg and a STMR of 0 for poultry meat, poultry fat, poultry edible offal and eggs.

## RECOMMENDATION

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 for dietary risk assessment for plant and animal commodities: *mandipropamid*

The residue is not fat-soluble.

## DIETARY RISK ASSESSMENT

### *Long-term dietary exposure*

The ADI for mandipropamid is 0–0.2 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for mandipropamid 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 2018 JMPR Report. The IEDIs ranged from 0–6% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of mandipropamid from uses considered by the JMPR is unlikely to present a public health concern.



***Acute dietary exposure***

The 2008 JMPR decided that an ARfD for mandipropamid was unnecessary. Therefore, the Meeting concluded that the acute dietary exposure to residues of mandipropamid from the uses considered is unlikely to present a public health concern.



## 5.20 NORFLURAZON (308)

### TOXICOLOGY

Norflurazon is the ISO-approved common name for 4-chloro-5-(methlamino)-2-( $\alpha,\alpha,\alpha$ -trifluoro-*m*-tolyl)-3-(2*H*)-pyridazinone (IUPAC), with the CAS number 27314-13-2.

Norflurazon is a fluorinated pyridazinone compound that is applied as a pre-emergence herbicide for selective control of annual grasses and broadleaf weeds in a number of crops, mostly in fruit, but also in cotton, hops, almonds and walnuts. In susceptible plant species, it inhibits carotenoid biosynthesis by inhibition of phytoene desaturase, resulting in chlorophyll photodegradation and eventually chlorosis.

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

Even though all relevant toxicological end-points are covered by submitted studies, it should be noted that most studies are very old, were not performed under GLP and did not follow current test guidelines, except where otherwise specified. Published literature has been taken into consideration, but is generally very limited.

#### **Biochemical aspects**

Following oral administration of a single dose of  $^{14}\text{C}$ -labelled norflurazon at 2 mg/kg bw to female rats, more than 90% of the administered dose was absorbed, based on a comparison of excretion following oral and intravenous dosing. Absorption after administration of a single high dose of 110 mg/kg bw was similar. Elimination was nearly complete within 96 hours. The major route of excretion was the faeces, with approximately 20% excreted via the urine. Tissue residues were generally low, with the highest relative radioactivity observed in liver and kidneys.

Biotransformation was extensive, with only 2% or less of the administered doses excreted as unchanged parent. The main metabolic pathways were *N*-demethylation and glutathione conjugation. Numerous metabolites were found in urine and faeces, nine of which could be identified. Only one of them (metabolite 5, a sulfoxide) accounted for more than 10% of the applied dose (up to 39% in urine, following intravenous administration), whereas the others represented only 1–2%.

An older study provided some evidence that excretion and metabolism are similar in male and female rats.

#### **Toxicological data**

Where no reliable information was available on the active ingredient, toxicological data on the 80% formulation have been evaluated.

In rats, the acute oral  $\text{LD}_{50}$  of an 80% formulation was 1080 mg/kg bw, and the acute dermal  $\text{LD}_{50}$  was greater than 2000 mg/kg bw. Although these studies were performed under GLP, there is no reliable information on the acute oral or dermal toxicity of the active ingredient itself.

In a GLP- and guideline-compliant study of the active substance in rats, the acute inhalation  $\text{LC}_{50}$  was greater than 2.4 mg/L.

In a study of limited reliability, norflurazon active ingredient did not cause skin or eye irritation in rabbits. In contrast, the 80% formulation was slightly irritating to the eyes and the skin of rabbits. For the same formulation, there was no evidence of skin sensitization in a Buehler test in guinea-pigs, whereas an older study with the active ingredient was inconclusive.

Short-term toxicity feeding studies were performed in rats, dogs and, to a lesser extent, mice. In all three species, the liver was a common target organ. Adverse effects on the kidney, thyroid and haematopoietic system (some evidence of anaemia in dogs) were also observed, but did not occur consistently across species and studies.

A poorly reported 28-day study in the mouse was performed as a range-finding experiment. Dietary concentrations were 0, 70, 210, 420 and 2520 ppm (equivalent to 0, 1, 21, 42 and 250 mg/kg bw per day, respectively). Liver and kidney weights were increased in males from 210 ppm onwards, and a liver weight increase was also observed in females at the highest dose. In high-dose males and females, gross appearance of the liver suggested some fatty degeneration.

In a 28-day feeding study in rats, the dietary concentrations were 0, 500, 1000 and 5000 ppm (equal to 0, 52, 105 and 517 mg/kg bw per day for males and 0, 70, 140 and 717 mg/kg bw per day for females, respectively). The NOAEL was 500 ppm (equal to 52 mg/kg bw per day), based on relative liver and kidney weight increases at 1000 ppm (equal to 105 mg/kg bw per day) and above, accompanied by histopathological lesions in these organs.

In a 90-day feeding study in rats, the dietary concentrations were 0, 250, 500 and 2500 ppm (equal to 0, 24, 45 and 248 mg/kg bw per day for males and 0, 26, 52 and 275 mg/kg bw per day for females, respectively). Body weight was slightly reduced in both sexes at the highest dose. In the same groups, liver and kidney weights were increased, but no concomitant histopathological lesions were noted. In contrast, a higher thyroid weight in high-dose males was accompanied by moderate follicular cell hypertrophy, moderate depletion of colloid and a slight to moderate increase in interstitial vascularity, suggesting some stimulation of thyroid activity. The NOAEL was 500 ppm (equal to 45 mg/kg bw per day).

In a 6-month study, dogs were fed norflurazon at a concentration of 0, 50, 150 or 450 ppm (equal to 0, 1.5, 5 and 14.3 mg/kg bw per day for males and 0, 1.6, 4.8 and 17.8 mg/kg bw per day for females, respectively). The NOAEL was 50 ppm (equal to 1.5 mg/kg bw per day), based on liver weight increase, minor histopathological findings in liver and thyroid and increases in cholesterol and ALP at 150 ppm (equal to 4.8 mg/kg bw per day).

In a guideline- and GLP-compliant toxicological study with norflurazon, dogs were administered a dietary concentration of 0, 50, 200 or 800 ppm (equal to 0, 1.7, 6.2 and 27 mg/kg bw per day for males and 0, 1.5, 6.3 and 23 mg/kg bw per day for females, respectively) for 1 year. The NOAEL was 50 ppm (equal to 1.5 mg/kg bw per day), based on impairment of nutritional parameters, such as body weight (gain), feed consumption and feed efficiency, in females and alterations in clinical chemistry suggestive of liver toxicity and increased liver weights in both sexes at 200 ppm (equal to 6.2 mg/kg bw per day). Kidney findings of equivocal toxicological significance, including renal tubular pigmentation, were noted in males at 200 ppm and above.

The overall NOAEL for the two dog studies was 50 ppm (equal to 1.5 mg/kg bw per day), and the overall LOAEL was 150 ppm (equal to 4.8 mg/kg bw per day).

In a combined long-term toxicity and carcinogenicity study in mice with in utero exposure, norflurazon was administered at a dietary concentration of 85, 340 or 1360 ppm (equivalent to 13, 51 and 200 mg/kg bw per day, respectively) for up to 2 years. Two control groups were included. The study suffered from many deficiencies, and there is good reason to exclude one of the control groups and the low-dose group, as the animals were not treated in parallel with the other groups. The parents of the animals under investigation had already been exposed to norflurazon as part of a reproduction study. Except for a slight reduction in body weight in high-dose males, there were no in-life observations that could be attributed to treatment. Liver weight was increased in all male groups and in mid- and high-dose females, showing a clear dose-response relationship. In females, there was no increase either in neoplastic or in non-neoplastic liver findings in any group.

Histopathology of the livers in male mice was evaluated independently by three pathologists and subject to an additional statistical reanalysis. Based on the evaluation considered most appropriate by the Meeting, there was a clear increase only in liver cell adenoma at 1360 ppm (equivalent to 200 mg/kg bw per day), with a NOAEL for carcinogenicity of 340 ppm (equivalent to 51 mg/kg bw per day). No NOAEL could be identified for non-neoplastic effects, as the lower dose levels were not sufficiently investigated. The LOAEL was 340 ppm (equivalent to 51 mg/kg bw per day), the lowest dose for which reliable data were available, based on non-neoplastic liver lesions in males, increases in liver weight in both sexes and non-neoplastic microscopic lesions in organs other than the liver (i.e. kidneys, spleen, pancreas, ovaries and bone marrow) mainly in females at the highest dose.

The Meeting concluded that norflurazon at a dose of 200 mg/kg bw per day caused an increase in benign liver tumours in male mice that was preceded by non-neoplastic changes at lower doses. No increase in the incidence of carcinomas was observed in this study. No information on the mode of action is available; thus, human relevance cannot be excluded.

In a combined long-term toxicity and carcinogenicity study in rats, norflurazon was administered at a dietary concentration of 125, 375 or 1025 ppm (equivalent to 6, 19 and 50 mg/kg bw per day, respectively) for 2 years. Two control groups of the same size were included and fed on untreated basal diet. Again, there were a number of deficiencies in this study, including the unusual study design, in which the parents had previously been treated with equal or lower concentrations of the test substance. There was no evidence of carcinogenicity in this study. There were no in-life observations attributable to treatment. The NOAEL was 125 ppm (equivalent to 6 mg/kg bw per day), based on increased kidney weights and histopathological changes (increased hyaline casts and nephritis) in the kidneys of females at 375 ppm (equivalent to 19 mg/kg bw per day). The uterus was identified as an additional target organ, as there was a higher incidence of squamous metaplasia and endometritis at least in top-dose females. In low- and mid-dose females, the uteri were not subject to histopathological examination.

The Meeting concluded that norflurazon is carcinogenic in male mice, but not in female mice or rats.

Norflurazon was tested for genotoxicity in a limited range of in vitro assays. There was no evidence of genotoxicity in the Ames test or the rec assay in bacteria or of chromosomal aberrations in mammalian (Chinese hamster ovary) cells. The substance gave negative results for unscheduled DNA synthesis in primary rat hepatocytes, but was positive in a recently published comet assay in an aquatic bioindicator organism, but only at cytotoxic concentrations.

In spite of the generally poor database, the Meeting concluded, on the weight of evidence, that norflurazon is not genotoxic in vitro and that norflurazon is unlikely to be genotoxic in vivo.

In view of the limited evidence of genotoxicity in vitro and taking into account the tumour spectrum of this compound (i.e. adenoma in one sex and one species only at the highest dose), the Meeting concluded that norflurazon is unlikely to pose a carcinogenic risk to humans from the diet.

The reproductive toxicity of norflurazon was investigated in one of the few studies that was performed under GLP and broadly complied with modern test guidelines. In a two-generation study in rats, the test substance was administered at a dietary concentration of 0, 150, 750 or 1500 ppm (equal to 0, 10.2, 51.0 and 102.5 mg/kg bw per day, respectively). No adverse effects on fertility or reproductive performance were observed. Accordingly, the NOAEL for reproductive toxicity was 1500 ppm (equal to 102.5 mg/kg bw per day), the highest dose tested. Parental effects in the adult animals comprised decreases in body weight and body weight gain, but also higher organ weights and histopathological findings in liver and kidney, at 750 ppm (equal to 51.0 mg/kg bw per day), with a NOAEL for parental toxicity of 150 ppm (equal to 10.2 mg/kg bw per day). The same NOAEL was identified for offspring toxicity, as body weight development

was impaired and organ weights of liver and kidney were increased at 750 ppm (equal to 51.0 mg/kg bw per day). In addition, there was an equivocal impact on viability (lactation index) in the F<sub>2B</sub> litters at the LOAEL.

It was noted that developmental landmarks were not investigated in this study. However, relevant information was available from recent studies from the Endocrine Disruptor Screening Program of the USEPA.

In a prepubertal assay in intact young female rats, a delay in vaginal opening was observed at the highest dose of 500 mg/kg bw per day, but not at 250 mg/kg bw per day. This effect was attributed to lower body weight gain in this group. Estrous cycle was not affected. An impact on the thyroid was evident, with lower thyroxine (T<sub>4</sub>) levels at both doses and histological findings (smaller follicles, lower amount of colloid) in the animals receiving the higher dose.

In a similar study in intact young male rats, balanopreputial separation was slightly delayed at the highest dose of 375 mg/kg bw per day. Again, this observation was made in parallel to a decrease in body weight gain. Testosterone, T<sub>4</sub> and TSH levels were not affected.

In a developmental toxicity study in rats, norflurazon was administered by gavage at a dose of 0, 100, 200 or 400 mg/kg bw per day on gestation days 6 through 15. The NOAEL for maternal toxicity was 200 mg/kg bw per day, based on initial body weight loss and lower feed consumption at 400 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 400 mg/kg bw per day, the highest dose tested.

In a preliminary range-finding study, pregnant rabbits received norflurazon by oral gavage from gestation days 7 through 19 at a dose of 0, 10, 40, 80, 100 or 400 mg/kg bw per day. At 40 mg/kg bw per day, maternal toxicity was apparent as a result of body weight loss, which became more pronounced at higher dose levels. Resorption rate was increased at 80 mg/kg bw per day and higher. At 400 mg/kg bw per day, does aborted and eventually died or had to be killed on gestation day 15 or 16.

In the main developmental toxicity study, daily doses of 0, 10, 30 or 60 mg/kg bw per day were administered to pregnant rabbits from gestation days 7 through 19. The NOAEL for maternal toxicity was 30 mg/kg bw per day, based on abortions and body weight loss at the highest dose of 60 mg/kg bw per day. The latter finding was most marked during the first week of treatment and was considered by the Meeting to be an acute effect. The NOAEL for embryo and fetal toxicity was 10 mg/kg bw per day, based on an increase in skeletal variations, mainly ossification delay, at 30 mg/kg bw per day. A teratogenic potential at the highest dose cannot be excluded, as hydrocephalus was observed in one high-dose fetus (of 116 fetuses examined). This is a very rare malformation in New Zealand White rabbits (historical background 0.1%), the strain used in this study, and the extent could have been masked by the abortions.

The Meeting concluded that norflurazon is not teratogenic in rats, but it could not exclude the possibility that norflurazon was teratogenic in rabbits, based on the occurrence of hydrocephalus in rabbit fetuses.

No studies on neurotoxicity or immunotoxicity were submitted. There was no evidence for such effects in the routine toxicological studies, but it must be taken into consideration that the range of parameters in these mostly very old and preguideline studies was relatively limited. Therefore, the Meeting could not conclude on these end-points.

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

#### ***Desmethyl norflurazon***

The desmethyl metabolite of norflurazon (plant metabolite) was found in the urine (accounting for 2.9%). Desmethyl norflurazon was detected in urine of female rats receiving a single norflurazon dose of 2 mg/kg bw at a maximum of 7% (lower amounts found in other treatment groups). In faeces, the same metabolite

accounted for 2.2–5%, depending on the treatment group.

This metabolite and its conjugates are considered to be covered by studies of the parent compound.

#### *6-Methyl sulfoxide norflurazon*

The metabolite 6-methyl sulfoxide norflurazon appears in rat urine at greater than 10%.

This metabolite is considered to be covered by the studies of the parent compound.

#### *NOA-452075*

The metabolite 1-({5-chloro-6-oxo-1-[3-(trifluoromethyl)phenyl]hydropyridazin-4-yl}ureido)-4-hydroxy-butaneurea (i.e. NOA-452075) occurs in the rat only at trace concentrations.

For chronic toxicity, the TTC approach (Cramer class III) could be applied.

#### **Human data**

No data were submitted. A case of skin sensitization due to a commercial product containing norflurazon has been reported in the open literature.

The Meeting concluded that the existing database on norflurazon was adequate to identify 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 norflurazon, on the basis of an overall NOAEL of 1.5 mg/kg bw per day for liver changes in the 6-month and 1-year studies in dogs, using a safety factor of 300. An additional factor of 3 was used because of the poor quality of the database. The upper range of the ADI provides a margin of 40 000 relative to the LOAEL for liver adenomas in male mice.

The Meeting established an ARfD of 0.3 mg/kg bw from the NOAEL for maternal toxicity of 30 mg/kg bw per day in a developmental toxicity study in rabbits, based on abortions and reductions in maternal body weight at 60 mg/kg bw per day, using a safety factor of 100.

The ADI and ARfD apply to the metabolites desmethyl norflurazon and its conjugates and 6-methyl sulfoxide norflurazon.

A toxicological monograph was prepared.

#### **Levels relevant to risk assessment of norflurazon**

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	–	340 ppm, equivalent to 51 mg/kg bw per day <sup>b</sup>
		Carcinogenicity	340 ppm, equivalent to 51 mg/kg bw per day	1 360 ppm, equivalent to 200 mg/kg bw per day
Rat	Two-year study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	125 ppm, equivalent to 6 mg/kg bw per day	375 ppm, equivalent to 19 mg/kg bw per day
		Carcinogenicity	1 025 ppm, equivalent to 50 mg/kg bw per day <sup>c</sup>	–

Species	Study	Effect	NOAEL	LOAEL
	Two-generation study of reproductive toxicity <sup>a</sup>	Reproductive toxicity	1 500 ppm, equal to 102.5 mg/kg bw per day <sup>c</sup>	–
		Parental toxicity	150 ppm, equal to 10.2 mg/kg bw per day	750 ppm, equal to 51 mg/kg bw per day
		Offspring toxicity	150 ppm, equal to 10.2 mg/kg bw per day	750 ppm, equal to 51 mg/kg bw per day
	Developmental toxicity study <sup>d</sup>	Maternal toxicity	200 mg/kg bw per day	400 mg/kg bw per day
		Embryo and fetal toxicity	400 mg/kg bw per day <sup>c</sup>	–
Rabbit	Developmental toxicity study <sup>d</sup>	Maternal toxicity	30 mg/kg bw per day	60 mg/kg bw per day
		Embryo and fetal toxicity	10 mg/kg bw per day	30 mg/kg bw per day
Dog	Six-month and 1-year toxicity studies <sup>a,e</sup>	Toxicity	50 ppm, equal to 1.5 mg/kg bw per day	150 ppm, equal to 4.8 mg/kg bw per day

<sup>a</sup> Dietary administration.

<sup>b</sup> Lowest dose tested.

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

<sup>d</sup> Gavage administration.

<sup>e</sup> Two or more studies combined.

*Acceptable daily intake (ADI) (applies to norflurazon, desmethyl norflurazon and its conjugates and 6-methyl sulfoxide norflurazon, expressed as norflurazon)*

0–0.005 mg/kg bw

*Acute reference dose (ARfD) (applies to norflurazon, desmethyl norflurazon and its conjugates and 6-methyl sulfoxide norflurazon, expressed as norflurazon)*

0.3 mg/kg bw

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

Full evaluation of potential for genotoxicity in vivo, neurotoxicity and immunotoxicity; comparative metabolism study in toxicological species and humans; results from epidemiological, occupational health and other observational studies of human exposure

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

*Absorption, distribution, excretion and metabolism in mammals*

Rate and extent of oral absorption	>80%
Dermal absorption	No data
Distribution	Highest concentrations in liver and kidney
Potential for accumulation	Low



Rate and extent of excretion	Nearly complete via faeces (65–80%) and urine (19–27%) within 96 hours
Metabolism in animals	Extensive by a variety of pathways (e.g. N-demethylation and glutathione conjugation), resulting in numerous metabolites, of which only a sulfoxide accounted for more than 10% of the administered dose
Toxicologically significant compounds in animals and plants	Norflurazon
<i>Acute toxicity</i>	
Rat, LD <sub>50</sub> , oral	1 080 mg/kg bw (80% formulation)
Rat, LD <sub>50</sub> , dermal	>2 000 mg/kg bw (80% formulation)
Rat, LC <sub>50</sub> , inhalation	>2.4 mg/L (active substance)
Rabbit, dermal irritation	Slightly irritating (80% formulation)
Rabbit, ocular irritation	Slightly irritating (80% formulation)
Guinea-pig, dermal sensitization	Not sensitizing (Buehler, 80% formulation)
<i>Short-term studies of toxicity</i>	
Target/critical effect	Liver changes
Lowest relevant oral NOAEL	1.5 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEC	No data
<i>Long-term studies of toxicity and carcinogenicity</i>	
Target/critical effect	Decrease in body weight; liver weight increase, histological lesions in liver and kidney
Lowest relevant NOAEL	6 mg/kg bw per day (rat)
Carcinogenicity	Carcinogenic in male mice, but not in female mice or rats <sup>a</sup>
<i>Genotoxicity</i>	
	Negative in vitro <sup>a</sup>
<i>Reproductive toxicity</i>	
Target/critical effect	No effects on reproduction
Lowest relevant parental NOAEL	10.2 mg/kg bw per day
Lowest relevant offspring NOAEL	10.2 mg/kg bw per day
Lowest relevant reproductive NOAEL	102.5 mg/kg bw per day, highest dose tested
<i>Developmental toxicity</i>	
Target/critical effect	Abortions and body weight losses in does; skeletal variations and developmental delay in rabbit fetuses
Lowest relevant maternal NOAEL	30 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	10 mg/kg bw per day (rabbit)
<i>Neurotoxicity</i>	

Acute neurotoxicity NOAEL	No data
Subchronic neurotoxicity NOAEL	No data
Developmental neurotoxicity NOAEL	No data
<i>Other toxicological studies</i>	
Immunotoxicity	No data
<i>Studies on toxicologically relevant metabolites</i>	
No studies available on toxicologically relevant metabolites	
<i>Human data</i>	
Evidence of skin sensitization (case report)	

<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>	Short-term toxicity studies in dogs	300
ARfD	0.3 mg/kg bw <sup>a</sup>	Developmental toxicity study in rabbits	100

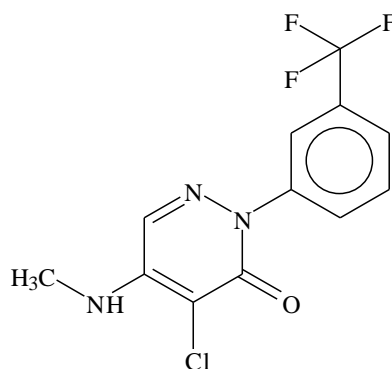
<sup>a</sup> Applies to norflurazon, desmethyl norflurazon and its conjugates and 6-methyl sulfoxide norflurazon, expressed as norflurazon.

### RESIDUE AND ANALYTICAL ASPECTS

Norflurazon is a pyridazinone selective, pre-emergent herbicide, absorbed by roots and translocated acropetally in xylem, blocking carotenoid synthesis and promoting photo-oxidative chlorosis in emerging susceptible annual grass and broad-leaf weed seedlings.

Norflurazon was scheduled by the Forty-ninth Session of the CCPR as a new compound for consideration by the 2018 JMPR. The manufacturer submitted studies on metabolism, analytical methods, supervised field trials, processing, freezer storage stability and environmental fate.

Authorisations exist in Australia and the USA for the use of norflurazon as a pre-plant (soil incorporated) or a post-plant pre-emergent soil treatment in cotton, soya bean, peanuts, a directed (inter-row) soil treatment in tree and vine crops and in established alfalfa and asparagus.

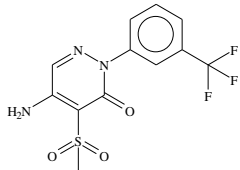


Norflurazon  
(MW 303.67)

Norflurazon is slightly soluble in water ( $\approx 34$  mg/L), stable to hydrolysis but susceptible to photolysis ( $DT_{50}$  of 1 hour). It has a low vapour pressure, is soluble in high-medium polarity organic solvents (e.g. ethanol, acetonitrile, acetone) and is not likely to bioaccumulate ( $\log P_{ow}$  2.2).

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

Code	Name and Matrix	Structure
desmethyl norflurazon	5-amino-4-chloro-2-[3-(trifluoromethyl) phenyl]-2-hydropyridazin-3-one  MW: 289.64  Rat, goat, hen, plants, soil, rotational crops	
deschloro desmethyl norflurazon	5-amino-2-[3-(trifluoromethyl)phenyl] pyridazin-3-one  255.2  Rat, goat, hen	
NOA-417010 (6-methyl sulfoxide) (‘ortho-sulfoxide’)	5-amino-4-chloro-2-[2-(methylsulfinyl) -5-(trifluoromethyl)phenyl]pyridazin-3-one  MW: 351.73  Rat, goat	
6-methylsulfone desmethyl norflurazon	5-amino-4-chloro-2-[2-(methylsulfinyl) -5-(trifluoromethyl)phenyl]-2-hydropyridazin-3-one  MW: 367.73  Rat, goat, hen	
5,6-dihydrodiol desmethyl norflurazon	5-amino-2-[2,3-dihydroxy-5-(trifluoromethyl)cyclohexa-1(6),4-dienyl]-4-chloro-2-hydropyridazin-3-one  MW: 323.66  Rat, goat	
NOA-452075 (ethanolamine)	1-((5-chloro-6-oxo-1-[3-(trifluoromethyl)phenyl]hydropyridazin-4-yl)ureido)-4-hydroxybutaneurea  MW: 376.72  Rat, goat	

Code	Name and Matrix	Structure
NOA-417373	5-amino-4-(methylsulfonyl)-2-[3-(trifluoromethyl)phenyl]pyridazin-3-one  MW: 333.29  Rat, goat	

### Plant metabolism

The Meeting received plant metabolism studies on alfalfa, maize, orange, cotton and soya bean following exposure to [ $^{14}\text{C}$ ]-norflurazon by planting in treated soil, exposing roots to fortified nutrient solution or by treatment of soil at the base of the growing crop.

#### Alfalfa – soil applications

Outdoor alfalfa plots were treated with [4,5- $^{14}\text{C}$ -pyridazinyl]-norflurazon at rates equivalent to 2.7 kg ai/ha or 5.4 kg ai/ha, applied to bare soil once established (3 years old) alfalfa plants had been cut to a height of 10 cm and the plots raked to remove all debris. Foliage samples were taken 31, 65 and 110 days after treatment (to reflect 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> cuts). Whole plants were also sampled at maturity and separated into foliage, crowns/stems and roots.

Norflurazon radioactivity was absorbed from soil into the lower parts of the alfalfa plant (crown/stems and roots) but poorly translocated into the mature foliage. About 64% of the whole-plant radioactivity was present in the crowns/stems (i.e. the first 10 cm above ground), 15–22% TRR was found in the roots and 14–20% TRR in foliage. Radioactivity in the '1<sup>st</sup> cut' foliage samples (31 DAT) were higher than in the '2<sup>nd</sup> cut' (65 DAT) and '3<sup>rd</sup> cut' (110 DAT) samples, with concentrations decreasing from 0.6 mg eq/kg to 0.24 mg eq/kg and to 0.18 mg eq/kg, respectively, in plants treated with 2.7 kg ai/ha.

Solvent (methanol, chloroform and methanol) extracts of the foliage samples from the plots treated with 5.4 kg ai/ha contained 44–59% TRR, and high temperature alkaline hydrolysis released a further 7–8% TRR. High temperature acid hydrolysis released a further 3–5% of the TRR. Acidic DMSO digestion (lignin solubilisation) released an additional 16–23% of the TRR. The identifiable components of the residues were norflurazon, desmethyl norflurazon and conjugated desmethyl norflurazon.

Norflurazon (free and conjugated) residues in foliage sampled 31 DAT ('1<sup>st</sup> cut') were 0.22 mg/kg, 13% TRR (7.4% TRR in the solvent extracts and 5.5% TRR released by high temperature alkaline hydrolysis). In the 65 DAT ('2<sup>nd</sup> cut') foliage, residues were 2.2% TRR (all solvent-extracted) and norflurazon was not found in the 110 DAT foliage. Residues in mature (whole plant) foliage were 0.5% TRR and only in the hydrolysed extracts.

Desmethyl norflurazon (free and conjugated) residues in the 1<sup>st</sup> cut foliage were also 0.22 mg eq/kg, 13% TRR (4.9% TRR being solvent-extracted, 6.8% TRR and 1.4% TRR released by high temperature alkaline and acid hydrolysis respectively). In the 2<sup>nd</sup> cut foliage, residues were 11% TRR (6% TRR in the solvent extracts and 4.9% TRR in the hydrolysed extracts) and in the 110 DAT foliage, residues were 8.4% TRR (all in the hydrolysed extracts). Desmethyl norflurazon (free and conjugated) residues in mature (whole plant) foliage were 12% TRR, mostly (10% TRR) in the hydrolysed extracts and 1.8% TRR in the solvent extracts.

In solvent extracts, residues of free norflurazon+desmethyl norflurazon averaged 12% TRR (0.21 mg eq/kg) and the combined residues of norflurazon and desmethyl norflurazon (conjugated) averaged 14% TRR (0.23 mg eq/kg).

*Orange – soil application*

In a confined study investigating the uptake of norflurazon from soil, [4,5-<sup>14</sup>C-pyridazinyl]-norflurazon was applied at a rate equivalent to 5.6 kg ai/ha to the soil in a pot containing a dwarf orange tree. Samples of one orange (peel and pulp, separately) and one tenth of the orange leaves were sampled 7 DAT and 28 DAT. The entire orange tree, separated into the three remaining fruits (peel and pulp, separately), foliage, stalk and root was sampled at the end of the 95-day study.

Radioactive residues were taken up from the soil into the lower parts of the tree but poorly translocated into the foliage, fruit peel and pulp. Radioactive residues at maturity (95 DAT) ranged from 11% AR (5.8 mg eq/kg) in roots to 0.01% AR (0.01 mg eq/kg) in fruit pulp. Most of the radioactivity (81% AR) remained in the soil, with 77% TRR being extracted. Sequential solvent extracts (methanol, chloroform and methanol) contained about 89–93% TRR (roots, peel and pulp), 82% TRR (foliage), and 66% TRR (trunk/branches). The identifiable components of the residues were norflurazon, desmethyl norflurazon and conjugated desmethyl norflurazon.

Norflurazon was the major residue in orange roots (71% TRR) and a significant component of the foliage residue (10% TRR, 0.09 mg/kg). In fruit, norflurazon residues were 14% TRR (0.012 mg/kg) in peel and 6% TRR (0.0008 mg/kg) in pulp. Based on a peel:pulp ratio of 30:70, estimated norflurazon residues in whole fruit are 0.0042 mg/kg (about 12% TRR).

Desmethyl norflurazon (free and conjugated) were the major residues in foliage and stalk (totalling 31–36% TRR) and made up about half the residue in fruit, 49% TRR (0.041 mg eq/kg) in peel and 50% TRR (0.0068 mg eq/kg) in pulp. Based on a peel:pulp ratio of 30:70, estimated free and conjugated desmethyl norflurazon residues in whole fruit totalled 0.017 mg eq/kg (about 50% TRR).

Numerous other components were present, but were each < 0.01 mg/kg or <6% TRR. In soil, extracted radioactivity was norflurazon (59% TRR) and desmethyl norflurazon (14% TRR).

*Cotton, soya bean – pre-plant soil applications*

In a confined study where six cotton seeds or 12 soya bean seeds were planted in soil treated with [4,5-<sup>14</sup>C-pyridazinyl]-norflurazon at a rate equivalent to 5.6 kg ai/ha, seedlings were sampled 14 DAT and mature plants were sampled 135 DAT.

In cotton plants, radioactivity was taken up from the soil into roots and leaves, but poorly translocated into the seeds and bolls. In seedlings (14 DAT), TRR in foliage was 1.0 mg eq/kg and in mature plants (135 DAT), TRRs were 1.5 mg eq/kg in roots, 1.1 mg eq/kg in stalks, 0.62 mg eq/kg in foliage and 0.02 mg eq/kg in seeds.

Extraction efficiencies (methanol-chloroform-methanol) were 88% TRR in seedlings, 78% in cotton roots and 43–63% in cotton stalks, foliage and seeds. High temperature alkaline hydrolysis of the cotton seed and mature soya bean foliage PES released the remaining 46% TRR in cotton seed.

The identifiable components of the residues were norflurazon, desmethyl norflurazon and a polar conjugate of desmethyl norflurazon. Norflurazon was the major residue in cotton seedlings (63% TRR), mature cotton roots (69% TRR) and stalks (21% TRR). Total desmethyl norflurazon residues (mostly conjugated) were the predominant residues in foliage (23% TRR, 0.14 mg eq/kg) and cotton seed (23% TRR, < 0.01 mg eq/kg). The 46% TRR released from the cotton seed PES was not able to be investigated further. Numerous unidentified metabolites were all individually less than 10% TRR, and generally present at 1–5% TRR.

In soya bean seedlings, radioactivity was taken up from the soil into roots and leaves, but poorly translocated into the seeds. In seedlings, the TRR was 3.9 mg eq/kg in foliage and in mature plants (135

DAT), TRRs were 3.8 mg eq/kg in roots, 0.56 mg eq/kg in foliage and 0.02 mg eq/kg in seeds. Radioactivity in whole plants at maturity was 0.82 mg eq/kg.

Sequential methanol, chloroform and methanol solvent extraction efficiencies were 86% TRR in seedlings, 87% TRR in pod hulls, 79% TRR in roots and 74% TRR in foliage. High temperature alkaline hydrolysis of the mature soya bean foliage PES released a further 16% TRR. The identifiable components of the residues were norflurazon, desmethyl norflurazon (free and conjugated).

Desmethyl norflurazon (free and conjugated) were the predominant residues in seedlings, totalling about 52% TRR, with norflurazon making up about 14% TRR. In mature plants (135 DAT), desmethyl norflurazon was the predominant residue in roots (19% TRR), foliage (32% TRR) and pod hulls (52% TRR). The solvent-extracted desmethyl norflurazon conjugate was also a significant component of the residue in roots, foliage and pod hulls (14–20% TRR). Other unidentified metabolites were all individually less than 4% TRR, and < 0.02 mg eq/kg.

Alkaline hydrolysis of the PES released about 16% TRR, including desmethyl norflurazon (8% TRR) and norflurazon (1% TRR). Radioactivity in soya bean seeds (relative to the extractable mass) was too low to allow further investigation.

#### *Cotton, Maize, Soya bean seedlings – root dip*

Root uptake of norflurazon was investigated in a confined study involving three-week old maize, cotton and soya bean seedlings grown in a nutrient solution containing 1.0 mg/mL [<sup>3</sup>H-phenyl]-norflurazon for five days.

Radiolabelled norflurazon was absorbed from the nutrient solution into all parts of the cotton, maize and soya bean seedlings but distribution between the roots and the foliage varied. In maize and soya bean seedlings, 87–88% of the whole plant radioactivity was found in the foliage while in cotton seedlings about 54% TRR was found in foliage.

Most of the radioactivity in the seedlings (85–96% TRR) was readily extracted by the chloroform/ethanol mixture. These residues mostly remained in the chloroform extracts (78–93% TRR) with 2.1–8.4% TRR present in the aqueous extracts. Unextracted residues ranged from 4.4–14% TRR.

In maize and soya bean seedlings, norflurazon made up about 31–33% TRR (mostly in the foliage) and close to 83% TRR in cotton seedlings (equally distributed between the roots and foliage). Desmethyl-norflurazon was the major metabolite, making up about 43% TRR and 30% TRR in maize and soya bean seedlings, respectively, but only about 4% TRR in cotton seedlings.

#### *Cotton – pre-plant soil application*

In a confined study where cotton seeds were planted in soil treated with [<sup>3</sup>H-phenyl]-norflurazon at a rate equivalent to 4.5 kg ai/ha, the radio-label was readily taken up into the roots, stems and foliage (3.5–5.0 mg eq/kg) but poorly translocated into the seeds (0.01–0.02 mg eq/kg).

At maturity (32 weeks after planting), about 65% TRR in foliage was extracted with ethanol:chloroform (38% TRR in the chloroform phase and 27% TRR in the aqueous phase). High temperature acid and alkaline hydrolysis of the PES released 10% and 14% of the TRR, respectively, but further clean-up and characterisation was not successful.

In the mature foliage, the identifiable residues were norflurazon (about 21% TRR), desmethyl norflurazon (11% TRR) and conjugated desmethyl norflurazon (6.6% TRR) released from the solvent extracts by high temperature acid hydrolysis. Unidentified fractions made up 15% TRR in the solvent extracts and 34% TRR in the PES (with 26% TRR being released by high temperature hydrolysis).

In summary, norflurazon is absorbed from treated soil, mostly into the roots and lower plant parts, and poorly translocated to foliage and reproductive parts. Norflurazon (parent), its desmethyl metabolite

(free and conjugated) are the predominant residues, with other (unidentified) metabolites only present at low levels. Following uptake from soil, metabolism proceeds by demethylation to form desmethyl-norflurazon and the subsequent formation of polar metabolites and conjugation with plant components.

### ***Environmental fate***

The Meeting received information on the environmental fate and behaviour of norflurazon, including hydrolytic stability, photochemical degradation in water and soil, and aerobic soil metabolism studies. Soil degradation field studies were also provided.

#### ***Hydrolysis***

Radiolabelled norflurazon incubated in the dark in sterile aqueous buffered solutions at pH 5, 7, and 9 for 30 days at 25 °C was stable (97–99% AR remaining) with no major transformation products being detected. Norflurazon can be considered hydrolytically stable.

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

In an aqueous photolysis study, where [<sup>14</sup>C]-norflurazon (buffered to pH 7) was incubated at 25 ± 1 °C under natural sunlight for up to 10 days, norflurazon was readily photolysed, with an estimated half-life of 2 days. The predominant photoproduct was a dimer of norflurazon (up to 16% AR) with four other degradates increasing over time to 1–8% AR.

In a soil photolysis study where [<sup>14</sup>C]-norflurazon in acetone was applied to a thin layer (3 mm) of loam soil (at a rate equivalent to about 5.6 kg ai/ha), norflurazon was readily photolysed, decreasing from 97% AR (Day-1) to 45% AR (Day 43), with the associated increase in residues of desmethyl norflurazon (up to 7% AR after 24 days). No other photodegradation product exceeded 4% AR. The estimated photolysis half-life in loam soil was 12 days.

#### ***Aerobic soil metabolism***

The biotransformation of [<sup>14</sup>C]-norflurazon in soil was investigated in a loam soil, where the equivalent of 5.6 kg ai/ha [<sup>14</sup>C]-norflurazon was mixed with soil to a depth of 6.7 cm and incubated at 22 °C for up to 365 days.

During the first 30 days, more than 88% AR was able to be solvent-extracted, with about 50% AR being extracted after 365 days incubation. Mineralisation accounted for 30% AR in the 365-day sample. Norflurazon residues decreased to 83% AR after 30 days, to 42% AR after 180 days and about 12% AR after 365 days. Desmethyl norflurazon residues increased over the study period, making up 4.5% AR after 30 days, 28% AR after 180 days and about 34% AR in the 365-day sample. Residues in the PES made up 10–12% AR. In the 180-day incubation flask, alkaline hydrolysis was able to liberate 4% AR as norflurazon and 2% AR as desmethyl norflurazon. The estimated half-life for norflurazon in aerobic soil was about 130 days.

#### ***Soil degradation (field studies)***

In soil degradation field studies conducted in the USA, norflurazon was applied to sandy loam or silt loam soils (0.5–1.9% organic matter) as inter-row soil treatments in peach orchards and in vineyards (2.3 kg ai/ha) and as pre-plant/pre-emergent treatments in cotton and peanut fields (1.7–2.8 kg ai/ha). Soil samples (to a depth of at least 60 cm) were taken at intervals up to 20 months after treatment and analysed for norflurazon and desmethyl norflurazon (free and conjugated).

Residues of norflurazon and desmethyl norflurazon generally remained in the top 30 cm soil layers and calculated half-lives were 163 days (norflurazon) and 163–340 days for the combined residues of norflurazon and desmethyl norflurazon.

In summary, norflurazon is slightly soluble in water, stable to hydrolysis but susceptible to photolysis. It is moderately persistent in soil, with the major soil degradate being desmethyl norflurazon.

### ***Rotational crop metabolism***

The Meeting received information on the metabolism of norflurazon in soya bean, wheat, spinach, beet and radish grown as confined rotational crops and in a range of representative field crops grown in norflurazon-treated soil.

### ***Confined rotational crop studies***

In a confined rotational crop study, a sandy loam soil was treated with [ $^{14}\text{C}$ ]-norflurazon at a rate equivalent to 1.12 kg ai/ha and planted with soya bean, wheat, spinach, beet and radish seeds at plant-back intervals ranging from 45 days to 270 days.

Plant matrices (foliage, pods, seeds, straw and roots) were sequentially extracted with chloroform and methanol, with the methanol eluates and the 180-day PBI wheat grain PES subjected to high temperature hydrolysis. Solvent extraction efficiencies ranged from 64–83% in soya bean matrices, 51–78% in wheat matrices, 87–89% in spinach and 63–97% in beet and radish roots and tops.

The predominant residue in all matrices (except beet roots) at all PBIs was desmethyl norflurazon (free and conjugated), with norflurazon (and in some matrices, KOH-released norflurazon) being the only compounds identified.

In wheat grain, norflurazon residues were 23% TRR (90-day PBI) and 21% TRR, 0.021 mg/kg in the 180-day PBI samples. Desmethyl norflurazon (free and conjugated) residues increased from 24% TRR (90-day PBI) to 30% TRR, 0.03 mg eq/kg (180-day PBI).

In soya bean seed, by contrast, norflurazon was not found at any PBI and desmethyl norflurazon (free and conjugated) made up 46% TRR (0.009 mg eq/kg) in both the 45-day and 180-day PBI samples. The ratio of free and conjugated desmethyl norflurazon was about 50:50 in the 180-day PBI samples.

In spinach, norflurazon residues made up 10% TRR, 0.077 mg/kg in the 180-day PBI samples and 8% TRR in the 270-day PBI samples. Residues of desmethyl norflurazon (free and conjugated) increased from 35% TRR (180-day PBI) to 48% TRR, 0.24 mg eq/kg in the 270-day PBI sample.

Soya bean foliage from the 45-day and 180-day PBI samples contained low levels of norflurazon (4% TRR and 1% TRR, respectively). Residues of desmethyl norflurazon (free and conjugated) remained constant, at 33% TRR (0.17 mg eq/kg).

In wheat forage, residues of norflurazon remained constant at 8% TRR in both the 90-day and 180-day PBI samples with residues of desmethyl norflurazon (free and conjugated) increasing from 22% TRR to 30% TRR (1.0 mg eq/kg).

In beet roots (180-day PBI) and radish roots (210-day PBI), residues of norflurazon were about 29% TRR and desmethyl norflurazon (free and conjugated) made up 15% TRR in the beet roots and 51% TRR in the radish roots (45% TRR being conjugated).

In beet tops (180-day PBI) and radish tops (210-day PBI), residues of norflurazon were about 8% TRR and desmethyl norflurazon (free and conjugated) made up 47–54% TRR, mostly (44–45% TRR) in conjugated form.

In summary, residues in the crops tested were lower in grains, seeds and roots than in foliage and did not decrease significantly in samples from the longer plant-back intervals. The nature of the residues in soya bean, wheat, spinach, radish and beet grown as rotational crops was similar, consisting mainly of desmethyl norflurazon (free and conjugated) and norflurazon.



### Field rotational crop studies

In a series of rotational crop field trials conducted in the USA, norflurazon was applied either as pre-plant soil incorporated treatments or a pre-emergent spray of 1.1–2.24 kg ai/ha to cotton, soya bean and peanut crops. After harvest and soil cultivation, representative leafy, small grain and root crops were planted (5–18 months after treatment).

The rotational crops were sampled at maturity and analysed for norflurazon and desmethyl norflurazon using methods involving dichloromethane extraction and high temperature alkaline hydrolysis (to release bound residues). LOQs for both analytes were 0.02 mg/kg.

Soils were also analysed for norflurazon and desmethyl norflurazon in two of the earlier studies. Residues of norflurazon and desmethyl norflurazon were found predominantly in the top 0–10 cm soil layer and generally did not show any significant decline between the 12-month and 18-month plantings.

Median and highest residues of norflurazon, desmethyl norflurazon (free and bound) and total residues at any application rate and any PBI up to 18 months (but mostly up to 12 months) are summarised below.

Matrix	Norflurazon		Desmethyl norflurazon (free and conjugated)		Norflurazon + Desmethyl norflurazon (free and conjugated)	
	max (mg/kg)	median mg/kg	max (mg/kg)	median mg/kg	max (mg/kg)	median mg/kg
Cereal grains						
wheat, maize	< 0.02	< 0.02	0.057	< 0.02	0.059	< 0.04
sorghum, rice	0.16	< 0.02	0.13	< 0.02	0.23	0.044
Leafy crops	0.11	< 0.02	0.51	0.041	0.53	0.053
Root crops	0.13	< 0.02	0.09	< 0.02	0.21	< 0.02
Cereal forage	0.23	0.023	0.6	0.093	0.94	0.13
Cereal fodder	0.45	0.042	1.3	0.155	1.5	0.22

### Animal metabolism

The Meeting received animal metabolism studies on rats, lactating goats and laying hens where animals were dosed with norflurazon radiolabelled in the phenyl ring or the pyridazinyl ring.

#### Rats

The metabolism of norflurazon in rats was reviewed in the framework of the toxicological evaluation by the WHO Core Assessment Group of the 2018 JMPR.

Following oral administration of a single dose of [<sup>14</sup>C]-radiolabelled norflurazon at 2 mg/kg bw to female rats, more than 90% of the administered dose was absorbed, based on a comparison of excretion following oral and intravenous application of the same dose. Absorption after administration of a single high dose of 110 mg/kg bw was similar. Elimination was nearly complete within 96 hours. The major route of excretion was the faeces, with approx. 20% via the urine. Tissue residues were generally low with the highest relative radioactivity observed in liver and kidneys.

Biotransformation was extensive, with only 2% or less of the administered doses excreted as unchanged parent. The main metabolic pathways were N-demethylation and glutathione conjugation. Numerous metabolites were found in urine and faeces of which 9 could be identified. Only one of them (metabolite 5, a sulfoxide) accounted for more than 10% of the applied dose (up to 39% in urine, following

i.v. administration) whereas the others represented only 1 to 2%. An older study provided some evidence that excretion and metabolism in male rats are similar to what was observed in females.

#### *Lactating goats – Study 1*

Single lactating goats were dosed orally once each morning for four days (after feeding and milk, urine and faeces collection) with [ $^{14}\text{C}$ ]-norflurazon at rates equivalent to 12 or 15 ppm in the diet and were killed 24 hours after the last dose.

Most of the radioactivity was excreted in the faeces (54–60% AD) and urine (14–18% AD). The highest levels of radioactivity were found in liver (0.9–1.0 mg eq/kg) and kidney (0.1–0.2 mg eq/kg). Radioactivity in milk averaged 0.03–0.07 mg eq/kg and were 0.003–0.009 mg eq/kg in fat. Radioactivity in muscle and fat was too low to investigate further.

The milk samples contained higher residues in the 7 hours immediately after each dose than in the remaining 7–24 hours after each dose and appeared to reach a plateau within 24–48 hours after the first dose.

Sequential solvent extraction (hexane, acetone/ethyl acetate, methanol) was able to extract about 79% TRR in milk, 24% TRR in liver and 34% TRR in kidney. High temperature acid and alkaline hydrolysis released a further 4.4–12.5% TRR from milk (alkaline hydrolysis only) and 50–55% TRR from liver and kidney.

Norflurazon was not found in any of the milk or tissue samples. In liver, most of the identified residues were desmethyl norflurazon (3.6–7.9% TRR, < 0.01 mg eq/kg) and conjugated desmethyl norflurazon released by alkaline and acid hydrolysis (10–16% TRR, 0.09–0.16 mg eq/kg). Combined residues of desmethyl norflurazon (free and conjugated) were 14–24% TRR, 0.12–0.24 mg eq/kg. Low levels of deschloro desmethyl norflurazon (free and conjugated) were present, at 4.3% TRR, 0.05 mg eq/kg.

In kidney, most of the identified residues were desmethyl norflurazon (5.1–8.3% TRR, < 0.01 mg eq/kg), with desmethyl norflurazon conjugates making up 6.5–12% TRR, 0.01–0.012 mg eq/kg. Combined residues of free and conjugated desmethyl norflurazon made up 12–20% TRR (0.02 mg eq/kg). Deschloro desmethyl norflurazon (free and conjugated) residues were 9% TRR, < 0.03 mg eq/kg.

In milk, the major residue was a co-elution of 6-methyl-sulfoxide norflurazon and an ethanolamine conjugate, present at 20–24% TRR, 0.01–0.016 mg eq/kg. Desmethyl norflurazon (free and conjugated) made up not more than 7% TRR (< 0.005 mg eq/kg) and residues of deschloro desmethyl norflurazon (free and conjugated) were 0.5–1.3% TRR, < 0.001 mg eq/kg.

#### *Lactating goats – Study 2*

Two lactating goats were dosed orally once each morning for four days (after feeding and milk, urine and faeces collection) with the equivalent of about 150 ppm in the feed and were killed six hours after the last dose. The purpose of the extremely high dose rate and the short sampling interval was to measure low level and transitory residues in order to clarify the metabolic pathway.

Most of the radioactivity was excreted in the faeces (46% AD) and urine (23% AD), with about 3% AD present in liver, 0.54% AD in muscle, 0.48% AD in milk, 0.08% AD in kidney and 0.04% AD in fat. Radioactivity was higher in milk samples taken 7 hours after each dose than in the subsequent sample taken 24 hours after each dose and residues reached a plateau within 24 hours.

The majority of the radioactivity in milk (92% TRR) and tissues (66–91% TRR) was able to be extracted. Norflurazon was a significant component in fat (9% TRR, 0.011 mg/kg) but only present in minor amounts in other tissues and milk (0.2–1.8% TRR).

Milk samples were extracted with methanol; liver, kidney and muscle samples were extracted with 80:20 methanol:water; and fat samples were extracted with 80:20 methanol:hexane. Post-extraction solids were treated with more aggressive extraction techniques, including microwave, acid hydrolysis (2 M HCl for 6 hours at 60 °C) and enzyme hydrolysis (protease, collagenase, phospholipase).

In milk, the major metabolites were 5,6-dihydrodiol desmethyl norflurazon (22% TRR, 0.26 mg eq/kg) and NOA-452075 (ethanolamine conjugate), accounting for 17% TRR. Other identified metabolites in milk were desmethyl norflurazon sulfate (9.0% TRR), 5,6-dihydrodiol ethanolamine conjugate (7.8% TRR), and 6-methyl sulfoxide norflurazon (5.2% TRR).

In muscle, 6-methylsulfone desmethyl norflurazon (15% TRR, 0.027 mg eq/kg) and 6-methyl sulfoxide norflurazon (11% TRR) were the major metabolites.

In fat, the predominant metabolites were desmethyl norflurazon (23% TRR, 0.028 mg eq/kg) and NOA-417373 (18% TRR).

In liver, polar fractions containing glutathione conjugates (totalling 20% TRR, 4.6 mg eq/kg) were major components. Phospholipids linked to norflurazon via ethanolamine were also significant components (14%) and desmethyl norflurazon (mostly released following microwave extraction) represented 9.5% TRR.

In kidney, a polar acidic fraction characterised by anion exchange chromatography and  $\beta$ -glucuronidase hydrolysis as multiple glucuronide conjugates made up 13% TRR (0.53 mg eq/kg) and phospholipids represented 8.5% TRR.

Numerous other identified or characterised metabolites were found in milk and tissues, mostly at levels below 5% TRR or < 0.01 mg eq/kg.

The proposed norflurazon metabolic pathways include:

- the epoxidation of the phenyl ring and the subsequent formation of glutathione and cysteine conjugates, and methylation to form the 6-methyl sulfoxide and the corresponding 6-methylsulfone
- oxidation and demethylation of the pyridazinyl ring (to desmethyl norflurazon) or conjugation with ethanolamine or glutathione
- dechlorination of the pyridazinyl ring and sulphate conjugation.

#### *Laying hens*

Laying hens were dosed orally once a day for four days with the equivalent of about 10 ppm [ $^{14}\text{C}$ ]-norflurazon in the diet. Eggs were collected twice daily and the animals were killed 24 hours after the last dose.

The majority of the radioactivity (80–84%) was found in the excreta, with only low levels present in tissues (about 1% AD) and eggs (<0.5% AD). Liver contained the highest tissue residues (about 0.45 mg eq/kg, 0.46% AD). Egg yolk contained up to 0.6 mg eq/kg (0.4% AD). Muscle, fat and egg white residues were about 0.01–0.03 mg eq/kg (0.08–0.32% AD).

Liver and muscle samples were extracted with ethyl acetate and egg fractions were extracted with ethyl acetate, hexane and acetonitrile. The liver and muscle extract aqueous and solid phases and the egg PES were subjected to high temperature alkaline and acid hydrolysis.

Solvent extraction efficiencies were 11–15% (0.011–0.018 mg eq/kg) in eggs, 19–25% (0.092–0.11 mg eq/kg) in liver, about 51% (0.015 mg eq/kg) in muscle and about 92% (0.021 mg eq/kg) in fat. High temperature hydrolysis released a further 60% TRR (0.066–0.094 mg eq/kg) in eggs, about 69% TRR (0.31 mg eq/kg) in liver and about 37% TRR (0.011 mg eq/kg) in muscle.

Norflurazon was only found at trace levels in eggs and not found in the edible tissues. In addition to the following, up to 30 unknown metabolites were found in various samples, each not more than 10% TRR but mostly less than 5% TRR.

In eggs, desmethyl norflurazon was the predominant residue, found in solvent extracts at 4.6–6.6% TRR, with a further 9% TRR present as conjugates. Total (free and conjugated) desmethyl norflurazon residues were about 15% TRR (0.016 mg eq/kg). Deschloro desmethyl norflurazon (free and conjugated) made up about 10% TRR (0.012 mg eq/kg).

In liver, desmethyl norflurazon was a major residue (with 2–3% TRR as free desmethyl norflurazon and a further 12–20% TRR present as conjugates). Total (free and conjugated) desmethyl norflurazon residues were 15–22% TRR (0.06–0.1 mg eq/kg). The 6-methyl-sulfone desmethyl norflurazon (from glutathione conjugation) was also a major residue (7–16% TRR in the solvent extracts and about 8% TRR in the hydrolysed extracts). Total (free and conjugated) residues were 15–24% TRR (0.07–0.1 mg eq/kg). A minor residue was conjugated deschloro desmethyl norflurazon, making up 4–5% TRR (0.016–0.017 mg eq/kg).

In muscle, the 6-methyl-sulfone desmethyl norflurazon was the predominant residue, making up 40–43% TRR in the solvent extracts and 4.8–7.9% TRR in the hydrolysed extracts. Total (free and bound) residues were 44–47% TRR (0.011–0.016 mg eq/kg). While desmethyl norflurazon (free and bound) residues made up 13% TRR, concentrations were < 0.005 mg eq/kg.

In fat, the only identified residue was the 6-methyl-sulfone desmethyl norflurazon, making up 28–47% TRR and 0.006–0.012 mg eq/kg.

The proposed norflurazon metabolic pathway in hens involves initial N-demethylation to desmethyl norflurazon, followed by reductive dechlorination (to deschloro-desmethyl norflurazon) or glutathione conjugation leading to a sulfone metabolite (on the pyridazinyl ring).

In summary, norflurazon is readily absorbed and extensively metabolized in goats and hens. Most of the administered radioactivity was excreted, with <5% AD remaining in tissues, mostly in liver (0.46–3% AD) and less than 0.5% AD in milk and eggs. Residues in milk reached a plateau within 24 hours.

Norflurazon (parent) was present in goat fat (9% TRR) but found only at low levels (< 2% TRR) in eggs and other tissues. Desmethyl norflurazon (free and conjugated) was the predominant residue in most tissues (about 10–25% TRR in liver, kidney and poultry muscle).

Other metabolites present at more than 10% TRR and above 0.01 mg eq/kg include 6-methyl sulfoxide norflurazon (milk – 22% TRR), free and conjugated deschloro desmethyl norflurazon (eggs – 10% TRR) and free and conjugated 6-methylsulfone desmethyl norflurazon (poultry muscle – 45% TRR, poultry liver – 20% TRR, poultry fat – 38% TRR).

### **Methods of analysis**

For plant matrices, methods for measuring residues of norflurazon and desmethyl norflurazon generally involved extraction with methanol, methanol: acetone or methanol: chloroform followed by sequential partitioning steps (e.g. dichloromethane, acetonitrile), TLC or column clean-up and GC-ECD analysis to measure residues of norflurazon and desmethyl norflurazon.

Limits of quantification were generally 0.08–0.1 mg/kg for norflurazon and desmethyl norflurazon (0.025–0.05 mg/kg for peanut fractions and alfalfa). Mean recovery rates generally ranged from 72–108% (RSDs < 20%) but were 61–63% in peanut soap stock.

Methods for measuring norflurazon and desmethyl norflurazon (free and conjugated) in plant and animal matrices added an initial hydrolysis step (0.5 M KOH at 90–95 °C for 1 hour) before the solvent extractions, partitioning, and column clean-up steps described above, with analysis by GC-ECD.

For plant matrices, limits of quantification for both analytes ranged from 0.02 mg/kg to 0.1 mg/kg and for animal matrices were 0.01 mg/kg. Mean recovery rates were mostly within the 70–120% range (RSDs < 20%).

The meeting noted that a modified version of the QuEChERS multi-residue method has been confirmed by the USDA in their Pesticides Data Programme (PDP) as being a suitable enforcement method for norflurazon and desmethyl norflurazon, with acceptable recovery rates at fortification levels down to 0.01 mg/kg for each analyte.

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

Residues of norflurazon and desmethyl norflurazon were stable in analytical samples stored frozen (at -12 °C or below) for at least the storage intervals used in the supervised residue trials, with residues in the stored samples usually more than 80% of the spiked sample levels. In general, residue stability was shown for at least 19 months in representative commodities with high water content (apples, asparagus, forages, peach), high oil content (tree nuts, cotton seed, peanut and soya bean seeds), high acid content (cranberry, grape, orange), hays, juices (orange, grape), oils (cotton seed, soya bean) and animal tissues.

### ***Residue definition***

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

In the plant metabolism studies involving soil, pre-plant and pre-emergent applications and in the rotational crop metabolism study, norflurazon and desmethyl norflurazon were the only residues of significance. In the plant and rotational crop metabolism studies and in the field trials (where residues were found), concentrations of desmethyl norflurazon in food and feed commodities were equal or higher than the norflurazon concentrations (except in beetroot grown as a rotational crop).

Suitable analytical methods are available for measuring norflurazon and desmethyl norflurazon residues in plant matrices.

The Meeting considered that for plant commodities, a suitable residue definition for compliance with the MRL would be the sum of norflurazon and desmethyl norflurazon.

For dietary risk assessment, the plant and rotational crop metabolism studies indicate that a significant component of the residue is conjugated desmethyl norflurazon (released by high temperature hydrolysis).

The Meeting noted that desmethyl norflurazon (free and conjugated) was identified in the rat metabolism study, included in the toxicological profile and considered to be no more toxic than norflurazon.

For plant commodities, the Meeting considered a suitable residue definition for dietary risk assessment would be the sum of norflurazon and desmethyl norflurazon (free and conjugated).

#### ***Animal commodities***

In the goat and hen metabolism studies, norflurazon was found at trace levels in eggs but not present in other animal matrices except in the extremely high dose (150 ppm) goat study, with a short (6 hour) sampling interval, where norflurazon made up only 9% TRR in fat, <2% TRR in muscle and <0.5% TRR in other tissues.

Desmethyl norflurazon (free and bound) was a predominant residue in most tissues, making up about 10–25% TRR in liver, kidney, poultry muscle and eggs but a minor residue in milk (2% TRR).

Suitable analytical methods (including a high temperature hydrolysis step) are available for measuring norflurazon and desmethyl norflurazon (free and conjugated) residues in animal matrices.

The Meeting considered that a suitable residue definition for compliance with the MRL for animal commodities would be the sum of norflurazon and desmethyl norflurazon (free and conjugated).

For dietary risk assessment, based on the goat and poultry metabolism studies, and taking into account the extremely high dose rate and the relatively short sampling interval used in one of the goat studies, desmethyl norflurazon (free and conjugated) is the predominant residue in liver, kidney and eggs, and is also present in goat fat.

The 6-methyl sulfoxide metabolite (free and conjugated) and NOA-452075 (ethanolamine conjugate), co-eluting in the first goat study but subsequently identified in the second goat study, are the predominant residues in milk and are also present at low levels in muscle.

In the poultry metabolism study (10 ppm dose rate), 6-methylsulfone desmethyl norflurazon is a significant component of the residues in poultry liver, muscle and fat. Concentrations are < 0.02 mg eq/kg in muscle and fat, and up to 0.1 mg eq/kg in liver. Deschloro desmethyl norflurazon is a minor residue in eggs (10% TRR) found at low concentrations < 0.02 mg eq/kg.

Noting that the anticipated dietary burden for poultry is 70-fold lower than the dose used in the poultry metabolism study, the Meeting agreed that 6-methylsulfone desmethyl norflurazon and deschloro desmethyl norflurazon need not be included in the residue definition for estimating dietary exposure for animal commodities.

Norflurazon (parent) was not found in any tissues or milk, only present at trace levels in eggs and the Meeting agreed that norflurazon need not be included in the residue definition.

Based on the above, the Meeting considered that in addition to desmethyl norflurazon (free and conjugated), the residue definition for dietary exposure estimation should include 6-methyl sulfoxide norflurazon and NOA-452075 (ethanolamine conjugate).

The Meeting noted that desmethyl norflurazon (free and conjugated) and 6-methyl sulfoxide norflurazon were identified in the rat metabolism study, included in the toxicological profile and were considered to be no more toxic than norflurazon.

For NOA-452075 (ethanolamine conjugate), as no specific data were available on the toxicity, the TTC approach was applied<sup>26</sup>. The estimated long term exposure for the total residues of desmethyl norflurazon (free and conjugated), 6-methyl sulfoxide norflurazon and NOA-452075 in all animal commodities is 0.91 µg/kg bw. Since the NOA-452075 metabolite was only a significant residue in milk (< 17% TRR), the Meeting concluded that the estimated exposure to NOA-452075 would be well below the 1.5 µg/kg bw threshold of concern. The Meeting agreed that NOA-452075 need not be included in the residue definition for dietary risk assessment for animal commodities.

The Meeting noted that the octanol/water partition coefficient (Log  $P_{ow}$ ) for norflurazon was 2.2, suggesting a limited potential for norflurazon to be fat-soluble. Information on relative concentrations in muscle and fat in the animal metabolism studies suggested that residues of norflurazon and desmethyl norflurazon in fat were only about 3-fold higher than in muscle, and the Meeting concluded that the residue is not fat-soluble.

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<sup>26</sup> Refer to section on Toxicology section for further details

The definition of the residue for compliance with the MRL for plant commodities: *Sum of norflurazon and desmethyl norflurazon, expressed as norflurazon*

The definition of the residue for dietary risk assessment for plant commodities: *Sum of norflurazon and desmethyl norflurazon (free and conjugated), expressed as norflurazon.*

The definition of the residue for compliance with the MRL for animal commodities: *Sum of norflurazon and desmethyl norflurazon (free and conjugated), expressed as norflurazon.*

The definition of the residue for dietary risk assessment for animal commodities: *Sum of desmethyl norflurazon (free and conjugated) and 6-methyl sulfoxide norflurazon, expressed as norflurazon.*

The residue is not fat-soluble.

### ***Residues in rotational crops***

The Meeting noted that in rotational crops, significant residues of norflurazon and desmethyl norflurazon (free and conjugated) could be expected in root crops, leafy vegetables and cereal crops.

In a series of rotational crop field trials conducted at rates reflecting the recommended maximum application rates in the USA for field crops (up to 2.24 kg ai/ha) and at plant-back intervals up to 12 months (18 months for leafy vegetables), residues of norflurazon and desmethyl norflurazon (free and conjugated) were measured in a number of crops, representing root vegetables, leafy vegetables and cereals.

The GAP in Australia does not include uses on annual crops. However, the USA GAP specifies minimum plant-back intervals of 24 months for all crops except alfalfa, cotton, peanuts and soya beans (for which label claims exist). The Meeting concluded that the available data were not sufficient to allow extrapolation from the 12-month PBI data to estimate residue concentrations in 24-month PBI crops.

In addition, since the analytical methods used in these trials included a high temperature hydrolysis step to release conjugated residues, a significant component of the total residues, the trial results are likely to overestimate levels of the norflurazon+desmethyl norflurazon residues.

The Meeting agreed the data were not sufficient to estimate maximum residue levels for rotational crops.

However, for estimating dietary exposure and livestock dietary burdens, the Meeting agreed that the results of these studies (with PBIs shorter than the 24-months permitted in the USA GAP) could be used to estimate conservative maximum and median residues of total norflurazon+desmethyl norflurazon (free and conjugated) for rotational crops.

Highest residues of total norflurazon+desmethyl norflurazon (free and conjugated) in rotational crops were less than 0.06 mg/kg in wheat, maize and sorghum, 0.23 mg/kg in rice, 0.53 mg/kg in leafy crops and 0.21 mg/kg in root crops. In cereal forages and hays, maximum total residues were 0.94 mg/kg and 1.5 mg/kg, respectively.

Median residues of total norflurazon+desmethyl norflurazon (free and conjugated) in rotational crops were up to 0.04 mg/kg in wheat, maize and sorghum, up to 0.1 mg/kg in rice, 0.053 mg/kg in leafy crops and < 0.04 mg/kg in root crops. In cereal forages and hays, the median total residues were 0.13 mg/kg and 0.22 mg/kg, respectively.

Based on the field rotational crop study results for the following commodity subgroups, the Meeting estimated median and highest residues of total norflurazon+desmethyl norflurazon (free and conjugated), for estimating dietary exposure and livestock dietary burdens.

Commodity	Median residue (mg/kg)	Maximum residue (mg/kg)
Subgroup of Wheat (20A)	< 0.04	
Subgroup of Maize cereals (20E)	< 0.04	
Subgroup of Sorghum grain and Millet (20C)	0.04	
Subgroup of Rice cereals (20C)	0.1	
Subgroup of Leafy greens (13A)	0.053	0.53
Subgroup of Leaves of Brassicacea (13B)	0.096	0.22
Subgroup of Root vegetables (16A)	< 0.04	0.21
Wheat forage (green)	0.082	0.59
Maize forage	<b>0.19</b>	<b>0.94</b>
Sorghum forage (green)	0.13	0.42
Wheat straw and fodder, dry	<b>0.31</b>	<b>1.5</b>
Rice straw and fodder, dry	0.27	0.65
Maize fodder	0.19	0.9
Sorghum straw and fodder, dry	0.15	0.6
Sugar beet leaves or tops	0.13	0.36

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

The Meeting received information on supervised field trials involving soil directed (inter-row) treatments of norflurazon in a range of perennial crops (citrus, pome fruit, stone fruit, berry fruit, avocado, tree nuts and hops) and as a pre-plant, pre-emergent or post-emergent broadcast soil treatment in a number of field crops (soya bean, cotton, peanut and alfalfa). These trials were conducted in the USA. GAP information was available from Australia and the USA.

The supervised trial information provided for pome fruit, stone fruit, grapes (1981 trials), almonds, hazel nuts and walnuts was available only in summary form, with inadequate information on the trial designs and analytical methods. The Meeting was unable to use the data from these trials to estimate maximum residue levels.

#### ***Citrus fruits***

The critical GAP in the USA, for citrus fruit is for one ring-drench soil application of 9 kg ai/treated ha or up to two directed (inter-row) soil applications of 4.5 kg ai/ha within a 4-month period. The PHI is 30 days. No trials matched this GAP.

The GAP for grapefruit, lemon, mandarin and orange in Australia is for a single directed (inter-row) soil application of 4.0 kg ai/ha, either in early autumn or mid spring, with no specified PHI.

In trials from the USA on lemons (4), lime (1), oranges (4), tangerines (2) and grapefruit (3) matching the Australian GAP, norflurazon+desmethyl norflurazon residues were < 0.16 (14) mg/kg.

The Meeting noted that the analytical method used in these trials did not include a high temperature hydrolysis step to release conjugated residues. Since the residue definition for dietary risk assessment includes these conjugates, the Meeting was not able to estimate a STMR or a HR. The Meeting therefore did not estimate a maximum residue level for norflurazon on citrus.

#### ***Berries and small fruit***

Results from supervised field trials on blackberries, raspberries, blueberries and grapes conducted in the USA were provided to the Meeting.



*Blackberries, blueberries, raspberries*

The critical GAP in the USA, is for blackberries, raspberries and blueberries is for one directed (inter-row) soil application of 4.5 kg ai/ha, not more than 4.5 kg ai/ha/year and a PHI of 60 days. In two raspberry trials matching this GAP, residues of norflurazon+desmethyl norflurazon were < 0.16(2) mg/kg.

The Meeting agreed there were insufficient data to estimate maximum residue levels for norflurazon on blackberries, raspberries and blueberries.

*Grapes*

The critical GAP in the USA for grapes, is for one directed (inter-row) soil application of 4.5 kg ai/ha, not more than 4.5 kg ai/ha/year and a PHI of 60 days. No trials matched this GAP.

The GAP for grapes in Australia is for a single directed (inter-row) soil application of 4.0 kg ai/ha, either in early autumn or mid spring, with no specified PHI.

In eight trials conducted in the USA and matching the Australian GAP, norflurazon+desmethyl norflurazon residues were: < 0.16(8) mg/kg.

The Meeting noted that the analytical method used in these trials did not include a high temperature hydrolysis step to release conjugated residues. Since the residue definition for dietary risk assessment includes these conjugates, the Meeting was not able to estimate a STMR or a HR. The Meeting therefore did not estimate a maximum residue level for norflurazon in grapes.

*Avocado*

The critical GAP in the USA for avocado is for one directed (inter-row) soil application of 4.5 kg ai/ha, not more than 4.5 kg ai/ha/year and a PHI of 60 days. No trials matched this GAP.

*Soya bean (dry)*

The critical GAP for soya bean in the USA is for a pre-emergent broadcast application of 2.2 kg ai/ha.

In six trials conducted in the USA and matching this GAP, norflurazon+desmethyl norflurazon residues were < 0.16(6) mg/kg.

The Meeting noted that the analytical method used in these trials did not include a high temperature hydrolysis step to release conjugated residues. Since the residue definition for dietary risk assessment includes these conjugates, the Meeting was unable to estimate a STMR or a HR. The Meeting therefore did not estimate a maximum residue level for norflurazon on soya bean (dry).

*Asparagus*

The critical GAP in the USA for asparagus is for one pre-emergent broadcast application of 4.5 kg ai/ha, a maximum application rate of 4.5 kg ai/ha/year and a 14-day PHI.

In three trials conducted in the USA and matching this GAP, norflurazon+desmethyl norflurazon residues were < 0.2(3) mg/kg.

The Meeting agreed there were insufficient data to estimate a maximum residue level for norflurazon in asparagus.

*Oilseeds**Cotton seed*

The critical GAP in the USA for cotton is for a pre-plant (soil incorporated) or a pre-emergent broadcast soil

application of 2.2 kg ai/ha, up to 4 weeks before planting.

In three trials conducted in the USA and matching this GAP, norflurazon+desmethyl norflurazon residues were < 0.16(3) mg/kg.

The Meeting agreed there were insufficient data to estimate a maximum residue level for norflurazon in cotton seed.

#### *Peanut*

The critical GAP in the USA for peanuts is for a pre-emergent broadcast application of 1.6 kg ai/ha (at planting). In two trials matching this GAP, residues of norflurazon+desmethyl norflurazon were < 0.2(2) mg/kg. Since the analytical method used in these trials did not include a high temperature hydrolysis step (to release conjugated residues), the results were not suitable for estimating dietary exposure.

In four additional trials matching this GAP, total norflurazon+desmethyl norflurazon (free and conjugated) residues were < 0.2(4) mg/kg.

The Meeting agreed there were insufficient data to estimate a maximum residue level for norflurazon in peanut.

#### *Hops*

The critical GAP in the USA for hops is for one directed (inter-row) soil application of 4.5 kg ai/ha with a PHI of 60 days and not more than 4.5 kg ai/ha/year. No trials matched this GAP.

### ***Legume animal feeds***

#### *Alfalfa forage*

The critical GAP in the USA for alfalfa is for broadcast applications of 2.2 kg ai/ha during dormancy or after cutting (and removal of forage/hay), with a PHI of 28 days and not more than 2.2 kg ai/ha/year.

As both free and conjugated residues can be expected in some treated and rotational crops used as animal feed, and may contribute to the livestock dietary burden, the Meeting agreed that desmethyl norflurazon (free and conjugated) should be included in the livestock dietary burden calculation.

In two trials matching the GAP in the USA, total residues of norflurazon+desmethyl norflurazon (free and conjugated) in alfalfa forage were: 0.18 and 0.78 mg/kg.

In three trials matching the GAP in the USA, free norflurazon+desmethyl norflurazon residues in alfalfa forage were: 0.77, 1.3 and 1.6 mg/kg. Noting that in the alfalfa metabolism study, conjugated norflurazon and desmethyl norflurazon concentrations averaged 14% TRR and free norflurazon+desmethyl norflurazon concentrations averaged 12% TRR, the Meeting applied a conversion factor of 2.2 to these trial results to reflect residues of total norflurazon+desmethyl norflurazon (free and conjugated). The adjusted data set is: 1.7, 2.9, and 3.5 mg/kg.

The combined data set of total (free and conjugated) residues is: 0.18, 0.78, 1.7, 2.9 and 3.5 mg/kg (n = 5).

For calculating the norflurazon livestock dietary burden, the Meeting estimated a fresh weight median residue of 1.7 mg/kg and a fresh weight highest residue of 3.5 mg/kg for total norflurazon+desmethyl norflurazon (free and conjugated) for alfalfa forage as a primary crop.

In field studies on rotational crops, the highest median and maximum residues of total norflurazon+desmethyl norflurazon (free and conjugated) in forage crops were 0.19 mg/kg and 0.94 mg/kg

respectively. To account for previous applications to alfalfa, the Meeting agreed to add the median residue found in the rotated forage crops to the median residue from the residue trials to estimate a fresh weight median residue of 1.9 mg/kg for total norflurazon+desmethyl norflurazon (free and conjugated) in alfalfa forage.

The Meeting also agreed to add the highest residue found in the rotated forage crops to the highest residue from the residue trials to estimate a fresh weight highest residue of 4.4 mg/kg for total norflurazon+desmethyl norflurazon (free and conjugated) in alfalfa forage.

#### *Alfalfa fodder*

In four trials matching the GAP in the USA for alfalfa, norflurazon+desmethyl norflurazon residues in alfalfa fodder were: 0.81, 1.6, 3.0 and 4.3 mg/kg.

In a further four trials, involving higher application rates (3.4 kg ai/ha), norflurazon+desmethyl norflurazon residues were 0.68, 1.5, 2.0 and 2.85 mg/kg. Using the proportionality approach, scaled residues (0.65×) were 0.44, 0.975, 1.3 and 1.9 mg/kg.

The data set for the norflurazon+desmethyl norflurazon residues is: 0.44, 0.81, 0.975, 1.3, 1.6, 1.9, 3.0 and 4.3 mg/kg (n = 8).

After correction for an average 89% dry matter, the Meeting estimated a maximum residue level of 7 mg/kg (dry weight) for norflurazon on alfalfa fodder.

For calculating the livestock dietary burden, residues of total norflurazon+desmethyl norflurazon (free and conjugated) in 2 trials matching the USA GAP for alfalfa, were: 0.62 and 1.6 mg/kg.

In four trials matching this GAP, norflurazon+desmethyl norflurazon residues in alfalfa fodder were: 0.81, 1.6, 3.0 and 4.3 mg/kg. The Meeting applied the conversion factor of 2.2 to these trial results to reflect residues of total norflurazon+desmethyl norflurazon (free and conjugated). The adjusted data set is: 1.8, 3.5, 6.6 and 9.5 mg/kg.

The combined data set of total norflurazon+desmethyl norflurazon (free and conjugated) residues matching the GAP in the USA is: 0.62, 1.6, 1.8, 3.5, 6.6 and 9.5 mg/kg (n = 6).

For calculating the norflurazon livestock dietary burden, the Meeting estimated a median residue of 2.65 mg/kg (as received) and a highest residue of 9.5 mg/kg (as received) for total norflurazon+desmethyl norflurazon (free and conjugated) for alfalfa fodder as a primary crop.

To account for rotational crop residues in alfalfa fodder, the Meeting agreed to add the highest median residue found in the rotated fodder crops (0.31 mg/kg) to the median residue from the residue trials to estimate a fresh weight median residue of 3.0 mg/kg for total norflurazon+desmethyl norflurazon (free and conjugated) in alfalfa fodder.

The Meeting also agreed to add the highest residue found in the rotated fodder crops (1.5 mg/kg) to the highest residue from the residue trials to estimate a fresh weight highest residue of 11 mg/kg for total norflurazon+desmethyl norflurazon (free and conjugated) in alfalfa fodder.

#### *Peanut forage (green)*

The critical GAP for peanuts in the USA is for a single pre-emergent broadcast application of 1.6 kg ai/ha.

In four trials matching this GAP, total residues of norflurazon+desmethyl norflurazon (free and conjugated) in forage were: < 0.1 (4) mg/kg.

For calculating the livestock dietary burden, the Meeting estimated a median residue of < 0.1 mg/kg and a highest residue of < 0.1 mg/kg for total residues of norflurazon+desmethyl norflurazon (free and conjugated) in peanut forage as a primary crop.

To account for rotational crop residues in peanut forage, the Meeting agreed to add the highest median residue found in the rotated forage crops (0.19 mg/kg) to the median residue from the residue trials to estimate a fresh weight median residue of 0.29 mg/kg for total norflurazon+desmethyl norflurazon (free and conjugated) in peanut forage.

The Meeting also agreed to add the highest residue found in the rotated forage crops (0.94 mg/kg) to the highest residue from the residue trials to estimate a fresh weight highest residue of 1.0 mg/kg for total norflurazon+desmethyl norflurazon (free and conjugated) in peanut forage.

#### *Soya bean forage*

The critical GAP for soya bean in the USA is for a pre-emergent broadcast application of 2.2 kg ai/ha with a 90-day PHI for forage and hay.

In five trials conducted in the USA and matching cGAP, norflurazon+desmethyl norflurazon residues in soya bean forage were: < 0.16, < 0.245, < 0.28, < 0.4 and < 0.54 mg/kg.

The analytical method used in these trials did not include a high temperature hydrolysis step to release conjugated residues. Since the levels of any conjugated residues need to be included in the livestock dietary burden, the Meeting agreed the data were not sufficient to estimate a median or highest residue for norflurazon in soya bean forage.

#### *Peanut fodder*

The critical GAP for peanuts in the USA is for a single pre-emergent broadcast application of 1.6 kg ai/ha.

In four trials matching this GAP, total residues of norflurazon+desmethyl norflurazon (free and conjugated) in hay were: < 0.2, < 0.2, 0.31 and 0.39 mg/kg.

Since no trials measuring norflurazon+desmethyl norflurazon were available, the Meeting was not able to estimate a maximum residue level for norflurazon in peanut hay.

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

The fate of norflurazon residues has been examined in a number of studies simulating commercial processing of citrus, grapes, soya beans and peanuts. Since the Meeting has not estimated maximum residue levels for these commodities, these processing studies were not considered further.

#### ***Residues in animal commodities***

##### *Farm animal feeding studies*

In a dairy cow feeding study, three groups of lactating Holstein cows (4 cows/group) were dosed orally twice daily (after milking) for 28 consecutive days with norflurazon at rates equivalent to 8, 24 and 80 ppm in the feed. Milk was collected twice daily and pooled samples were taken at intervals throughout the study period. Animals were killed within 24 hours after the last dose and samples of liver, kidney, muscle, and fat were collected for analysis. Samples were stored frozen for about 2 months before analysis for norflurazon and desmethyl norflurazon (free and conjugated). Milk samples were also analysed for 6-methyl-sulfoxide norflurazon.

No residues of norflurazon were detected above the LOQ of 0.02 mg/kg in milk or any tissues from any of the dose groups.

Residues of desmethyl norflurazon (free and conjugated) were also < 0.02 mg/kg in milk and tissues except liver, where mean and maximum residues were 0.3 mg/kg and 0.31 mg/kg, respectively, in animals from the 8 ppm dose group, increasing to 2.4 mg/kg and 2.8 mg/kg, respectively, in animals from the 80 ppm dose group.

Total residues of norflurazon+desmethyl norflurazon (free and conjugated) were < 0.04 mg/kg in milk and tissues except liver, where mean and maximum residues were 0.32 mg/kg and 0.33 mg/kg, respectively, in animals from the 8 ppm dose group, increasing to 2.42 mg/kg and 2.82 mg/kg, respectively, in animals from the 80 ppm dose group.

Residues of 6-methyl-sulfoxide norflurazon were only found in the milk from the 80 ppm dose group, up to about 0.054 mg/kg and averaging 0.037 mg/kg.

In a laying hen feeding study, norflurazon was administered orally in gelatine capsules to three groups of 15 hens (23–24 weeks old) daily for 28 consecutive days. Dosing was targeted at treatment levels of 0.5, 1.5 and 5 ppm feed based on an average daily consumption of 200 g feed per dose group. Actual feed consumption ranged 121–147 g per dose group/day. Eggs were collected daily and samples taken at intervals throughout the study period. Samples of liver, muscle, and skin with fat were collected from all animals when they were killed (on the day of the last dose).

Samples were stored frozen for about 2 months before analysis for norflurazon and desmethyl norflurazon (i.e. without a high temperature alkaline hydrolysis step).

Residues of desmethyl norflurazon were all below the LOQ of 0.01 mg/kg in eggs from all dose groups and while norflurazon levels of 0.01 mg/kg were consistently reported in eggs from all dose groups, similar levels (0.01–0.02 mg/kg) were also reported in eggs from the control group.

Norflurazon residues were present in fat at levels of 0.02–0.03 mg/kg in all dose groups, in liver at up to 0.03 mg/kg in the low- and medium-dose groups and up to 0.08 mg/kg in the high-dose group and only found in muscle (up to 0.05 mg/kg) from the highest dose group.

Desmethyl norflurazon residues were not detected in any tissue from any dose group except in two hens from the low-dose group, where apparent residues of 0.02–0.03 mg/kg were reported. The lack of detectable residues in hens from the higher dose groups suggests that these were artefacts or interferences.

### ***Farm animal dietary burden***

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

Livestock feed commodities considered by the Meeting were alfalfa forage and hay, cereal grains, leafy forages and root crops.

With the exception of alfalfa forage and hay, the estimated median and highest residues in animal feed commodities were derived from rotational crops. GAP information available to the Meeting is from Australia and the USA, and since the Australian GAP is only for permanent crops, the Meeting agreed that the livestock dietary burdens should be estimated using the US-Canada diet for commodities that are not traded internationally (e.g. forages).

The Meeting also noted that no fodder crops are imported into Australia and agreed that alfalfa fodder need not be included in the Australian livestock dietary burden calculation.

**Estimated maximum and mean dietary burdens of farm animals**

	Animal dietary burden: desmethyl norflurazon (free and conjugated), ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	2.1	0.61	0.38	0.13	0.073	0.073	1.5	0.53
Dairy cattle	4.4	1.5 <sup>③④</sup>	4.9 <sup>①②</sup>	1.4	0.037	0.037	3.1	0.93
Poultry – broiler	0.06	0.06	0.046	0.046	0.08	0.08	0.046	0.046
Poultry – layer	0.06	0.06	0.21 <sup>⑤⑦</sup>	0.089 <sup>⑥⑧</sup>	0.08	0.08	0.046	0.046

- ① Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level /HR estimates for mammalian tissues
- ② Highest maximum dairy cattle dietary burden suitable for maximum residue level /HR estimates for mammalian milk
- ③ Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.
- ④ Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.
- ⑤ Highest maximum poultry dietary burden suitable for maximum residue level /HR estimates for poultry tissues.
- ⑥ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues.
- ⑦ Highest maximum poultry dietary burden suitable for maximum residue level/HR estimates for poultry eggs.
- ⑧ Highest mean poultry dietary burden suitable for STMR estimates for poultry eggs.

The Meeting used the calculated beef and dairy cattle maximum and mean dry weight dietary burdens of 4.9 ppm and 1.5 ppm for estimating residue levels in milk and ruminant tissues.

For poultry commodities, the calculated dry weight maximum dietary burden is 0.21 ppm and the calculated mean dietary burden is 0.089 ppm dry weight of feed.

**Animal commodity maximum residue levels****Cattle**

Residues in milk and tissues were derived by extrapolation, using the maximum (4.9 ppm) and mean (1.5 ppm) dietary burdens and the 8 ppm or 80 ppm dose groups in the dairy cow feeding study.

To account for residues of the norflurazon metabolites listed in the dietary risk assessment residue definition for animal commodities, the Meeting applied a conversion factor to estimate total residues in animal commodities, based on the relative proportions of the relevant metabolites reported in the goat metabolism studies. For each matrix, the conversion factor is:  $A+B/A$  where A and B relate to the columns in the following table.

Matrix				A	B		
	Dose group	Tissue residues <sup>(a)</sup>	Tissue residues <sup>(a)(b)</sup> (scaled)	desmethyl norflurazon <sup>(b)</sup>	6-methyl sulfoxide norflurazon <sup>(b)</sup>	conversion factor	Total residues <sup>(c)</sup> (mg/kg)
<b>Ruminant</b>	ppm	mg/kg	mg/kg	%TRR (mean)	%TRR (mean)		mg/kg
Milk (mean)	80	< 0.02	0.00038	2.0	5.2	3.6	0.0014
Muscle (max) <sup>(d)</sup>	80	< 0.02	0.0012	4.8	11	3.3	0.004
Muscle (mean) <sup>(d)</sup>	80	< 0.02	0.00038	4.8	11	3.3	0.0012
Fat (max) <sup>(d)</sup>	80	< 0.02	0.0012	23	3.3	1.1	0.0014
Fat (mean) <sup>(d)</sup>	80	< 0.02	0.00038	23	3.3	1.1	0.00043
Liver (max)	8	0.33	0.19	20	1.6	1.1	0.22

Matrix				A	B		
	Dose group	Tissue residues <sup>(a)</sup>	Tissue residues <sup>(a)(b)</sup> (scaled)	desmethyl norflurazon <sup>(b)</sup>	6-methyl sulfoxide norflurazon <sup>(b)</sup>	conversion factor	Total residues <sup>(c)</sup> (mg/kg)
Liver (mean)	8	0.32	0.06	20	1.6	1.1	0.065
Kidney (max)	80	< 0.02	0.0012	16	-	1.0	0.0012
Kidney (mean)	80	< 0.02	0.00038	16	-	1.0	0.00038

<sup>a</sup> total desmethyl norflurazon (free and conjugated)

<sup>b</sup> residue values scaled to the mean and maximum livestock dietary burdens

<sup>c</sup> total residues of desmethyl norflurazon (free and conjugated) and 6-methyl sulfoxide norflurazon (free and conjugated)

<sup>d</sup> %TRR values taken from the 150 ppm goat study

Residues of total norflurazon+desmethyl norflurazon (free and conjugated) calculated in milk and tissues for use in estimating maximum residue levels are: 0.0012 mg/kg for fat, muscle and kidney, 0.19 mg/kg for liver, and the mean residue for milk is 0.0012 mg/kg.

The Meeting estimated maximum residue levels of 0.02(\*) mg/kg for norflurazon in milk, meat (from mammals other than marine mammals), mammalian fats and 0.3 mg/kg for edible offal (mammalian).

For estimating dietary exposure to total residues, calculated HRs are: 0.0014 mg/kg for mammalian fat, 0.004 mg/kg for mammalian muscle and 0.22 mg/kg for edible offal. Calculated STMRs are: 0.00043 mg/kg for mammalian fat, 0.0012 mg/kg for mammalian muscle, 0.065 mg/kg for edible offal, and 0.0014 mg/kg for milk.

### Poultry

The meeting noted that in the poultry feeding study, the analytical method measured norflurazon and desmethyl norflurazon, but did not measure conjugates able to be released by high temperature hydrolysis. Since the residue definition for compliance with the MRL is for residues of total norflurazon+desmethyl norflurazon (free and conjugated), the Meeting used the results of the poultry metabolism study to estimate STMRs, HRs and maximum residue levels for poultry commodities.

For poultry commodities, the calculated dry weight maximum dietary burdens are 0.08 ppm and 0.21 ppm for poultry broilers and layers respectively. Mean dietary burdens were 0.08 mg/kg for broilers and 0.089 mg/kg for layers.

In the poultry feeding study, no residues of 6-methylsulfoxide norflurazon or NOA-452075 (ethanolamine conjugate) were detected, and the highest average concentration of desmethyl norflurazon (free and conjugated) was 0.085 mg/kg in liver. The Meeting agreed that since the highest dietary burden (0.21 ppm) was about 50-fold lower than the 10 ppm dose in the metabolism study, residues are not expected in poultry commodities.

The Meeting estimated maximum residue levels of 0.02 mg/kg (\*) for norflurazon in eggs, poultry muscle, poultry fat and poultry edible offal.

STMRs and HRs for estimating dietary exposure to total residues are: 0 mg/kg for poultry fat, poultry muscle, poultry edible offal and eggs.

## 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: *Sum of norflurazon and desmethyl norflurazon, expressed as norflurazon*

Definition of the residue for dietary risk assessment for plant commodities: *Sum of norflurazon and desmethyl norflurazon (free and conjugated) expressed as norflurazon.*

Definition of the residue for compliance with the MRL for animal commodities: *Sum of norflurazon and desmethyl norflurazon (free and conjugated), expressed as norflurazon*

Definition of the residue for dietary risk assessment for animal commodities: *Sum of desmethyl norflurazon (free and conjugated) and 6-methyl sulfoxide norflurazon, expressed as norflurazon.*

The residue is not fat-soluble

## DIETARY RISK ASSESSMENT

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

The 2018 JMPR established an ADI for norflurazon of 0–0.005 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for norflurazon were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the present JMPR. The results are shown in Annex 3 of the 2018 JMPR Report. The IEDIs ranged 0–20% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of norflurazon from uses considered by the JMPR is unlikely to present a public health concern.

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

The 2018 JMPR established as ARfD for norflurazon of 0.3 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for norflurazon 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 2018 JMPR Report. The IESTIs varied from 0–10% of the ARfD for children and 0–4% for the general population.

The Meeting concluded that acute dietary exposure to residues of norflurazon from uses considered by the present Meeting is unlikely to present a public health concern.



## 5.21 OXATHIPIPROLIN (291)

### RESIDUE AND ANALYTICAL ASPECTS

Oxathiapiprolin is a systemic piperidinyl thiazole isoxazoline fungicide. It was first evaluated by the JMPR in 2016 for toxicology and residues. The 2016 Meeting established an ADI of 0–4 mg/kg bw and decided that an ARfD was unnecessary. The 2016 Meeting concluded that the residue definition for enforcement in plant and animal commodities is oxathiapiprolin. The definition of the residue for dietary risk assessment for plants and animal commodities is the sum of oxathiapiprolin, 5-(Trifluoromethyl)-1*H*-pyrazole-3-carboxylic acid (IN-E8S72), and 1-β-*D*-Glucopyranosyl-3-(trifluoromethyl)-1*H*-pyrazole-5-carboxylic acid (IN-SXS67), expressed as parent. The 2016 Meeting further concluded that the residue is not fat-soluble.

Oxathiapiprolin was scheduled at the Forty-ninth Session of the CCPR for the evaluation of additional uses by the 2018 JMPR. The 2018 Meeting received GAP information on the registered uses and residue data on citrus fruits, cane berries, mustard greens, soya beans, potatoes, asparagus, maize, poppy seed, sunflower, and basil. Additional data were provided relating to analytical methods and processing.

#### ***Methods of analysis***

Residue analysis for all sample results submitted to the 2018 Meeting were performed using LC-MS/MS analytical methods DuPont-30422, DuPont-30422 Supplement No. 1 and multi-residue method DFG S 19. These methods were found to be acceptable by the 2016 JMPR.

For all matrices, validation data generated concurrently with each residue study demonstrated adequate method performance for the residues of interest (oxathiapiprolin, IN-E8S72, IN-SXS67; recoveries 72–114%, maximum ≤12% RSD). The LOQ was 0.01 mg/kg for all analytes and matrices, except for residues of IN-SXS67 in asparagus for which the Meeting determined that the limit of quantitation is 0.1 mg/kg.

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

New information on the stability of oxathiapiprolin was not provided to the current Meeting. The 2016 Meeting concluded that residues of oxathiapiprolin and metabolites IN-E8S72 and IN-SXS67 were stable for at least 18 months in representative commodities with high water content (wheat forage, tomato), high starch content (potato, wheat grain), high protein content (dry bean seed), high oil content (soya bean seed), high acid content (grape) and low moisture content (wheat straw, dry grape pomace).

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

The Meeting received supervised residue trial data for citrus fruits (orange, grapefruit, lemon), cane berries (blackberry, raspberry), mustard greens, soya bean, potato, asparagus, maize, oilseeds (poppy seed, sunflower seed), and herbs (basil (fresh and dried), hops (dried)).

Labels for end-use products containing oxathiapiprolin were available from Australia, Indonesia, and the USA describing the registered uses of oxathiapiprolin.

The majority of samples from residue trials submitted to the current Meeting were stored for less than 18 months. For five samples each of mustard greens and citrus (peel and pulp), the storage durations were up to approximately 22 months and 19 months, respectively. Based on results demonstrating stability of oxathiapiprolin residues of interest for at least 18 months in high-water and high-acid content commodities, the Meeting concluded that residues would be unlikely to undergo significant decline during the period between 18 and up to 22 months. Therefore, the results from those samples are suitable for consideration for making residue recommendations.

There are different residue definitions for enforcement (oxathiapiprolin) and dietary risk assessment (sum of oxathiapiprolin, IN-E8S72, and IN-SXS67) for plant and animal commodities. Therefore, the Meeting has summarised the residues separately for estimating maximum residue levels (identified as oxathiapiprolin, *per se*) and for dietary risk assessment purposes (identified as total oxathiapiprolin, where total is the sum of oxathiapiprolin, IN-E8S72, and IN-SXS67 in expressed in parent equivalents). Additionally, since residues of IN-E8S72 and IN-SXS67 are expected in some rotational crops, the Meeting has accounted for rotational residues in the recommendations for dietary exposure assessment.

The 2016 Meeting concluded that when oxathiapiprolin is applied as a foliar treatment, metabolite IN-SXS67 does not make a significant contribution to the total residue; however, it does contribute significantly in situations where uptake from soil is the dominant source of residues (e.g., soil and seed-treatment applications, rotational crops). For foliar-only applications (mustard greens, poppy seed, basil, and hops), samples were not analysed for residues of IN-SXS67 and the Meeting assumed no contribution of IN-SXS67 toward the total residue. Neither IN-SXS67 nor IN-E8S72 were analysed in maize samples derived from seed treatment. The Meeting assumed LOQ residues for IN-E8S72 and IN-SXS67 as a conservative assumption when calculating total residues.

When calculating total residues (oxathiapiprolin+IN-E8S72+IN-SXS67), values reported as below the LOQ were assumed to be at the LOQ.

Oxathiapiprolin, mg/kg		IN-E8S72, mg/kg		IN-SXS67, mg/kg		Total (for dietary), mg eq/kg
Reported	Assumed	Reported	Assumed	Reported	Assumed	
< 0.01	0.01	< 0.01	0.01	< 0.01	0.01	0.056
< 0.01	0.01	< 0.01	0.01	-	-	0.040
-	-	< 0.01	0.01	< 0.01	0.01	0.046
-	-	< 0.01	0.01	-	-	0.030

### ***Residues in rotational crops***

The 2016 Meeting noted that in rotational crops, significant residues of IN-E8S72 and/or its glucose conjugate (IN-SXS67) can be expected in various rotational commodities. The current Meeting noted that as a result, primary crops may contain residues of IN-E8S72 and IN-SXS67 due to previous applications of oxathiapiprolin (i.e., as a follow crop). Mean residues of oxathiapiprolin were <LOQ in rotational crops based on the metabolism studies reviewed by the 2016 Meeting.

The current Meeting considered the contributions from applications in the previous year to following primary crops and the contributions to rotational crops. To account for this in the dietary exposure assessment, the Meeting added previously estimated levels in rotational crops to the total residues (oxathiapiprolin+IN-E8S72+IN-SXS67) for primary treated crops. The following mean residues for the metabolites (expressed as oxathiapiprolin) were applied for the uses reviewed by the current Meeting: 0.33 mg/kg for leafy vegetables; 0.12 mg/kg for pulses; 0.060 mg/kg for root vegetables; 0.056 for stem vegetables; 0.062 mg/kg for oilseeds; 0.056 mg/kg for cereal grain; 0.14 mg/kg for legume forage; 0.30 mg/kg for legume hay; 0.21 mg/kg for cereal forage; and 0.18 mg/kg for cereal straw. Additionally, since oxathiapiprolin was measured in the legume hay rotational studies, the Meeting included the rotational maximum residue (0.014 mg/kg) when estimating the maximum residue level for soya bean hay.

### ***Residues for dietary burden calculations for livestock commodities***

There are different residue definitions for enforcement (oxathiapiprolin) and dietary risk assessment (oxathiapiprolin, IN-E8S72, and IN-SXS67) for animal commodities. Two lactating goat metabolism studies

were reviewed by the 2016 Meeting; one with oxathiapiprolin *per se* and one with metabolite IN-SXS67. The current Meeting calculated two livestock dietary burdens, one for oxathiapiprolin *per se* and one for IN-E8S72+IN-SXS67, and used these burdens, along with both metabolism studies, to estimate the maximum residue levels (oxathiapiprolin) and STMRs (sum of oxathiapiprolin, IN-E8S72, and IN-SXS67) for animal commodities.

To estimate the livestock dietary burdens for estimating the maximum residue levels for animal commodities, the Meeting estimated highest and median residues of oxathiapiprolin from the residue trials. Except for soya bean hay where oxathiapiprolin rotational residues were observed, the estimated maximum residue levels consider contributions from primary crops only since the residue of concern for enforcement is oxathiapiprolin. For estimating residues in animal commodities to estimate dietary exposure, the Meeting used median residues from the residue trials to estimate separate dietary burdens for oxathiapiprolin and IN-E8S72+IN-SXS67 and then combined the resulting residue estimates. Additionally, as noted by the 2016 Meeting, there may be substantial residues of IN-E8S72 and IN-SXS67 in the animal feeds of follow-on crops. To account for residues in rotational and follow crops, the current Meeting included previously estimated levels in rotational crops in the IN-E8S72+IN-SXS67 dietary burden. In cases where the primary crop uses of oxathiapiprolin result in residues of IN-E8S72+IN-SXS67 (expressed as oxathiapiprolin) that are  $\leq 10\%$  of the residues in rotational crops, the Meeting used the rotational crop residues alone for estimating dietary burden for those compounds.

Summary of how livestock dietary burdens, maximum residue levels, and STMRs were estimated

Estimation	Residues of Concern	Meta. Study <sup>a</sup>	Dietary Burden			Total <sup>c</sup>
			Calculated For	Residue Trial Data Used	Rotational <sup>b</sup>	
Maximum residue level	oxathiapiprolin	oxathiapiprolin	oxathiapiprolin	highest and median residues	No	oxathiapiprolin
STMR	oxathiapiprolin,	oxathiapiprolin	oxathiapiprolin	median residues	No	oxathiapiprolin +
	IN-E8S72, IN-SXS67	IN-SXS67	IN-E8S72 + IN-SXS67	median residues	Yes	IN-E8S72 + IN-SXS67

<sup>a</sup> This column indicates the compound used for dosing in the lactating goat metabolism studies.

<sup>b</sup> Indicates if rotational residues were included in the dietary burden estimation.

<sup>c</sup> Indicates residues that were combined to determine the maximum residue level or STMR.

### Citrus fruits

The cGAP for the Citrus crop group is from the USA and consists of a single foliar spray application at a nominal use rate of 35 g ai/ha with a 0-day PHI. Residue trials were submitted for soil-only applications and soil plus foliar applications in the USA; however, there were no residues observed from the soil application and the Meeting concluded that the residues observed in the soil plus foliar trials are from the foliar applications. Twenty-three trials using soil plus foliar applications were conducted in the USA resulting in 23 independent residue results (five lemon, six grapefruit, and 12 orange). Residue trials were not conducted in mandarins.

Residues of **oxathiapiprolin, *per se***, in whole fruit were:

Lemon (n = 5): < 0.01 (2), 0.015, 0.022, 0.033 mg/kg;

Grapefruit (n = 6): < 0.01 (3), 0.011, 0.012, 0.018 mg/kg; and

Orange (n = 12): < 0.01 (4), 0.01, 0.016, 0.020, 0.022 (2), 0.023 (2), 0.024 mg/kg.

Residues of **total oxathiapiprolin** in whole fruit were:

Lemon (n = 5): < 0.056 (2), 0.061, 0.068, 0.079 mg/kg;

Grapefruit (n = 6): < 0.056 (3), 0.057 (2), 0.064 mg/kg; and

Orange (n = 12): < 0.056 (4), 0.056, 0.062, 0.065, 0.067 (2), 0.069 (2), 0.070 mg/kg.

Residues of **total oxathiapiprolin** in pulp were <LOQ in all samples:

Lemon (n = 5): < 0.056 mg/kg;

Grapefruit (n = 6): < 0.056 mg/kg; and

Orange (n = 12): < 0.056 mg/kg.

Noting that the median residues of oxathiapiprolin, *per se*, for each fruit type are within a 5-fold range, and that there is no significant difference in the residue populations across the citrus types by the Kruskal-Wallis test ( $p = 0.193$ ), the Meeting decided to make a recommendation for the Group of Citrus Fruit.

Residues of **oxathiapiprolin, per se**, in whole fruit citrus were (n = 23): < 0.01 (9), 0.01, 0.012, 0.011, 0.015, 0.016, 0.018, 0.020, 0.022 (3), 0.023 (2), 0.024, 0.033 mg/kg.

Residues of **total oxathiapiprolin** in whole fruit citrus were (n = 23): < 0.056 (9), 0.056, 0.057 (2), 0.061, 0.062, 0.064, 0.065, 0.067 (2), 0.068, 0.069 (2), 0.070 and 0.079 mg/kg.

Residues of **total oxathiapiprolin** in citrus pulp were <LOQ in all samples were (n = 23): < 0.056 (23) mg/kg.

For the Group of Citrus Fruit, the Meeting estimated a maximum residue level of 0.05 mg/kg. For dietary exposure assessment, the Meeting estimated a STMR of 0.056 mg/kg for citrus pulp and a STMR of 0.057 mg/kg for whole fruit.

### *Cane berries*

The cGAP for the Cane berry subgroup is from the USA and consists of two soil applications at a 7-day interval, each at 281 g ai/ha, with a 1-day PHI. Four raspberry trials and one blackberry trial were conducted in Canada matching the cGAP.

Residues of oxathiapiprolin, *per se*, were:

Raspberry (n = 4): < 0.01 (2), 0.022, 0.22 mg/kg; and

Blackberry (n = 1): < 0.01 mg/kg

Residues of total oxathiapiprolin were:

Raspberry (n = 4): < 0.056 (2), 0.068, 0.27 mg/kg; and

Blackberry (n = 1): < 0.056 mg/kg

The number of trials is insufficient to make a recommendation for blackberry. However, noting that residues are likely to be similar between raspberry and blackberry and that the registration is for the subgroup of cane berries, the Meeting decided to combine the data from raspberry and blackberry and to extrapolate them to the subgroup of cane berries. The Meeting estimated a maximum residue level of 0.5 mg/kg for the subgroup of Cane berries. For dietary exposure assessment, the Meeting estimated a STMR of 0.056 mg/kg.

*Brassica leafy vegetables*

The cGAP for the Brassica leafy greens subgroup is from the USA and consists of four foliar applications at a 5-day interval, each at 35 g ai/ha, with a 0-day PHI. Ten mustard green trials were conducted in Canada and the USA matching the cGAP.

Residues of **oxathiapiprolin, per se**, were (n = 10): 1.5, 1.7, 2.7, 2.8, 2.9, 3.0, 3.7, 4.2 and 4.3 (2) mg/kg.

Residues of **total oxathiapiprolin** were (n = 10): 1.5, 1.8, 2.7, 2.9 (2), 3.0, 3.7 and 4.3 (3) mg/kg.

The Meeting estimated a maximum residue level of 10 mg/kg for residues of oxathiapiprolin in mustard greens and extrapolated it to the Subgroup 013B Brassica Leafy vegetables. For purposes of estimating the oxathiapiprolin livestock dietary burden, the Meeting estimated a highest residue of 4.3 and a median residue of 2.95 mg/kg for oxathiapiprolin.

For dietary exposure assessment (sum of oxathiapiprolin, IN-E8S72, and IN-SXS67) and livestock dietary burdens for IN-E8S72 and IN-SXS67, the Meeting considered residues in follow crops. In field studies on rotational crops, mean residues of oxathiapiprolin, IN-E8S72, and IN-SXS67 (expressed as parent equivalents) were 0.33 mg eq/kg in leafy vegetables. To account for residues in follow crops, the Meeting decided to add the mean residue found in the leafy vegetable rotational crop studies to the median residue from the mustard green (foliar application; 2.95 mg/kg) residue trials to estimate an overall STMR of 3.28 mg/kg for Subgroup 013B Brassica Leafy vegetables.

Residues of IN-E8S72 were <LOQ in all mustard green samples and residues of IN-SXS67 are not expected from foliar applications; therefore, the Meeting used 0.36 mg/kg (0.03 mg/kg STMR; 0.33 mg/kg rotational) as the median residue for kale in the IN-E8S72+IN-SXS67 livestock dietary burden.

*Soya bean (dry)*

The cGAP for soya bean is from the USA and consists of a seed treatment application of 12–24 µg ai/seed. Six independent soya bean trials were conducted in the USA at 3× (five trials) and 10× (one trial) of the cGAP.

Residues of **oxathiapiprolin, per se**, were (n = 6): < 0.01 (6) mg/kg.

Residues of **total oxathiapiprolin** were (n = 6): < 0.056 (6) mg/kg.

The Meeting estimated a maximum residue level of 0.01(\*) mg/kg for residues of oxathiapiprolin in soya bean (dry). For purposes of estimating the oxathiapiprolin livestock dietary burden, the Meeting estimated a median residue of 0.01 mg/kg for oxathiapiprolin.

For dietary exposure assessment (sum of oxathiapiprolin, IN-E8S72, and IN-SXS67) and livestock dietary burdens for IN-E8S72 and IN-SXS67, the Meeting considered residues in follow crops. In field studies on rotational crops, mean residues of oxathiapiprolin, IN-E8S72, and IN-SXS67 (expressed as parent equivalents) were 0.12 mg eq/kg in pulses. To account for residues in follow crops, the Meeting decided to add the mean residue found in the pulses rotational crop studies to the median residue from the soya bean (seed treatment application; 0.056 mg eq/kg) residue trials to estimate an overall STMR of 0.176 mg/kg for soya bean (dry).

Since residues of IN-E8S72 and IN-SXS67 were <LOQ in all samples, the Meeting estimated a median residue of 0.166 mg/kg (0.046 mg/kg STMR; 0.12 mg/kg rotational) for soya bean in the IN-E8S72+IN-SXS67 livestock dietary burden.

*Tuberous and corm vegetables*

The cGAP is from the USA and consists of two soil (in-furrow and soil-directed) applications at 10-day intervals at 140 g ai/ha. Sixteen potato trials were conducted in the USA matching the cGAP.

Residues of **oxathiapiprolin, per se**, were (n = 16): < 0.01 (10), 0.010 (2), 0.012, 0.013, 0.015 and 0.037 mg/kg.

Residues of **total oxathiapiprolin** were (n = 16): < 0.056 (9), 0.056 (2), 0.058 (3), 0.061 and 0.083 mg/kg.

Noting that the cGAP in the USA is for the tuberous and corm vegetable subgroup, the Meeting decided to extrapolate the data from potato to the Codex subgroup 16B tuberous and corm vegetables. The Meeting estimated a maximum residue level of 0.04 mg/kg for residues of oxathiapiprolin in the subgroup of tuberous and corm vegetables and withdraws its previous recommendations for potato (0.01(\*) mg/kg) and sweet potato (0.01(\*) mg/kg). For purposes of estimating the oxathiapiprolin livestock dietary burden, the Meeting estimated a highest residue of oxathiapiprolin in potato of 0.037 mg/kg and a median residue of 0.01 mg/kg.

For dietary exposure assessment (sum of oxathiapiprolin, IN-E8S72, and IN-SXS67) and livestock dietary burdens for IN-E8S72 and IN-SXS67, the Meeting considered residues in follow crops. In field studies on rotational crops, mean residues of oxathiapiprolin, IN-E8S72, and IN-SXS67 (expressed as parent equivalents) were 0.060 mg eq/kg in root vegetables. To account for residues in follow crops, the Meeting decided to add the mean residue found in the root vegetable rotational crop studies to the median residue from the potato (0.056 mg eq/kg) residue trials to estimate an overall STMR of 0.116 mg eq/kg for the subgroup 16B Tuberous and corm vegetables.

For IN-E8S72 and IN-SXS67, residues were <LOQ in potato except in one field trial where there were measurable residues of IN-E8S72 (0.011 mg/kg) and were also observed in the rotational crop studies; therefore, the Meeting used 0.106 mg/kg (0.046 mg/kg STMR; 0.06 mg/kg rotational) as the median residue for root and tuber vegetables in the IN-E8S72+IN-SXS67 livestock dietary burden.

*Stalk and stem vegetables*

The cGAP for the stalk and stem vegetable subgroup is from the USA and consists of two soil-directed applications at a 14-day interval, each at 281 g ai/ha, with a 0-day PHI. Eight asparagus trials were conducted in Canada and the USA matching the cGAP.

Residues of **oxathiapiprolin, per se**, were (n = 8): < 0.01 (2), 0.28, 0.35, 0.53, 0.58, 0.71 and 0.74 mg/kg.

Residues of **total oxathiapiprolin** were (n = 8): 0.20 (2), 0.46, 0.53, 0.72, 0.76, 0.90 and 0.93 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg for residues of oxathiapiprolin in asparagus and extrapolated it to the Subgroup 17B Stalk and stem vegetables - Young shoots.

For dietary exposure assessment (sum of oxathiapiprolin, IN-E8S72, and IN-SXS67), the Meeting considered residues in follow crops. In field studies on rotational crops, mean residues of oxathiapiprolin, IN-E8S72, and IN-SXS67 (expressed as parent equivalents) were < 0.056 mg eq/kg in stem vegetables. To account for residues in the following regrowth of asparagus, the Meeting decided to add the mean residue found in the stem vegetable rotational crop studies to the median residue from the asparagus (0.625 mg eq/kg) residue trials to estimate an overall STMR of 0.681 mg eq/kg.

### Maize

The cGAP for maize is from Indonesia and consists of a seed treatment application at 0.882 g ai/kg seed (equivalent to approximately 220 µg ai/seed). Eight maize trials were conducted in Indonesia and Thailand matching the cGAP.

Residues of **oxathiapiprolin, *per se***, were (n = 8): < 0.01 (8) mg/kg.

Residues of **total oxathiapiprolin** were (n = 8): < 0.056 (8) mg/kg.

The Meeting estimated a maximum residue level of 0.01(\*) mg/kg for residues of oxathiapiprolin in maize grain. For purposes of estimating the oxathiapiprolin livestock dietary burden, the Meeting used 0.01 mg/kg as the highest and median residues for oxathiapiprolin from seed treatment of maize.

For dietary exposure assessment (sum of oxathiapiprolin, IN-E8S72, and IN-SXS67) and livestock dietary burdens for IN-E8S72 and IN-SXS67, the Meeting considered residues in follow crops. In field studies on rotational crops, mean residues of oxathiapiprolin, IN-E8S72, and IN-SXS67 (expressed as parent equivalents) were < 0.056 mg eq/kg in cereal grain. Maize samples were not analysed for residues IN-E8S72 and IN-SXS67; the Meeting assumed that residues of IN-E8S72 and IN-SXS67 were <LOQ in all samples as a conservative assumption. To account for residues in follow crops, the Meeting decided to add the mean residue found in the cereal grain rotational crop studies to the median residue from the maize (0.056 mg eq/kg) residue trials to estimate an overall STMR of 0.112 mg eq/kg.

Since the Meeting assumed that residues of IN-E8S72 and IN-SXS67 were <LOQ in all samples, the Meeting estimated a median residue of 0.102 mg/kg (0.046 mg/kg STMR; 0.056 mg/kg rotational) for maize in the IN-E8S72+IN-SXS67 livestock dietary burden.

### Poppy Seed

The cGAP for poppy seed is from Australia and consists of one foliar application of 35 g ai/ha, with a 42-day PHI. Poppy seed trials were conducted in Australia at five different locations including rates of at 1× (four trials), 2× (four trials), and 4× (one trial) of the cGAP.

Residues of **oxathiapiprolin, *per se***, were (n = 5): < 0.01 (5) mg/kg.

Residues of **total oxathiapiprolin** were (n = 5): < 0.040 (5) mg/kg.

The Meeting estimated a maximum residue level of 0.01(\*) mg/kg for residues of oxathiapiprolin in poppy seed.

For dietary exposure assessment (sum of oxathiapiprolin, IN-E8S72, and IN-SXS67), the Meeting considered residues in follow crops. In field studies on rotational crops, mean residues of oxathiapiprolin, IN-E8S72, and IN-SXS67 (expressed as parent equivalents) were 0.062 mg eq/kg in oilseeds. To account for residues in follow crops, the Meeting decided to add the mean residue found in the rape seed rotational crop studies to the median residue from the poppy seed (0.040 mg eq/kg) residue trials to estimate an overall STMR of 0.102 mg/kg for poppy seed.

### Sunflower Seed

The cGAP for sunflower is from the USA and consists of one seed treatment application of 9.4–18.8 µg ai/seed. Eight sunflower seed trials were conducted in Canada and the USA matching the cGAP.

Residues of **oxathiapiprolin, *per se***, were (n = 8): < 0.01 (8) mg/kg.

Residues of **total oxathiapiprolin** were (n = 8): < 0.056 (8) mg/kg.

The Meeting estimated a maximum residue level of 0.01(\*) mg/kg for residues of oxathiapiprolin in sunflower seed. For purposes of estimating the oxathiapiprolin livestock dietary burden, the Meeting used 0.01 mg/kg as the median residue for oxathiapiprolin.

For dietary exposure assessment (sum of oxathiapiprolin, IN-E8S72, and IN-SXS67) and livestock dietary burdens for IN-E8S72 and IN-SXS67, the Meeting considered residues in follow crops. In field studies on rotational crops, mean residues of oxathiapiprolin, IN-E8S72, and IN-SXS67 (expressed as parent equivalents) were 0.062 mg eq/kg in oilseeds. To account for residues in follow crops, the Meeting decided to add the mean residue found in the rape seed rotational crop studies to the median residue from the sunflower seed (0.056 mg eq/kg) residue trials to estimate an overall STMR of 0.118 mg/kg for sunflower seed.

Since residues of IN-E8S72 and IN-SXS67 were <LOQ in all samples, the Meeting used 0.108 mg/kg (0.046 mg/kg STMR; 0.062 mg/kg rotational) from rotational residues as the median residue for sunflower in the IN-E8S72+IN-SXS67 livestock dietary burden.

#### *Basil, Fresh and Dried*

The cGAP for basil is from the USA (field and greenhouse) and consists of four applications at a 5-day interval, each at 35 g ai/ha, with a 0-day PHI. Eight basil residue trials (6 outdoors, 2 protected) were conducted in Canada and the USA matching the cGAP.

##### *Fresh Basil*

Residues of **oxathiapiprolin, per se**, in fresh basil were (n = 8): 1.8, 2.4 (2), 2.6, 2.8, 3.2, 3.8 and 5.4 mg/kg.

Residues of **total oxathiapiprolin** in fresh basil were (n = 8): 1.8, 2.4 (2), 2.6, 2.9, 3.2, 3.8 and 5.4 mg/kg.

The Meeting estimated a maximum residue level of 10 mg/kg for residues of oxathiapiprolin in fresh basil.

For dietary exposure assessment (sum of oxathiapiprolin, IN-E8S72, and IN-SXS67), the Meeting considered residues in follow crops. In field studies on rotational crops, mean residues of oxathiapiprolin, IN-E8S72, and IN-SXS67 (expressed as parent equivalents) were 0.33 mg eq/kg in leafy vegetables. To account for residues in follow crops, the Meeting decided to add the mean residue found in the leafy vegetable rotational crop studies to the median residue from the fresh basil (2.75 mg eq/kg) residue trials to estimate an overall STMR of 3.08 mg/kg for fresh basil.

##### *Dried Basil*

Samples of fresh basil from four of the trials described above were dehydrated to produce samples of dried basil.

Residues of **oxathiapiprolin, per se**, in dried basil were (n = 4): 24 (2), 28, 29 mg/kg.

Residues of **total oxathiapiprolin** in dried basil were (n = 4): 24 (2), 28, 29 (2) mg/kg.

The Meeting estimated a maximum residue level of 80 mg/kg for residues of oxathiapiprolin in dried basil.

For dietary exposure assessment (sum of oxathiapiprolin, IN-E8S72, and IN-SXS67), the Meeting considered residues in follow crops. In field studies on rotational crops, mean residues of oxathiapiprolin, IN-E8S72, and IN-SXS67 (expressed as parent equivalents) were 0.33 mg eq/kg in leafy vegetables. To account for residues in follow crops, the Meeting decided to add the mean residue found in the leafy



vegetable rotational crop studies to the median residue from the dried basil (26 mg eq/kg) residue trials to estimate an overall STMR of 26.33 mg/kg for dried basil.

#### *Hops, Dried*

Evidence of a registration for use of oxathiapiprolin on hops was not provided to the Meeting; therefore, no recommendation was made for residues in hops.

#### **Animal feeds**

##### *Soya bean*

The soya bean cGAP is from the USA and consists of a seed treatment application of 12–24 µg ai/seed. Six independent soya bean trials were conducted in the USA at 3× (five trials) and 10× (one trial) the cGAP.

##### *Soya Bean Forage*

Residues of **oxathiapiprolin, *per se***, were (n = 6): < 0.01 (6) mg/kg.

Residues of **total oxathiapiprolin** were (n = 6): < 0.056 mg/kg.

In field studies on rotational crops, the maximum residue of oxathiapiprolin was 0.038 mg/kg and the mean was < 0.01 mg/kg in legume forage; therefore, the Meeting considered the contribution of follow crops to the highest and median residues. For purposes of estimating the oxathiapiprolin livestock dietary burden, the Meeting used 0.048 mg/kg as the highest and 0.02 mg/kg as the median residues for oxathiapiprolin.

For livestock dietary burdens for IN-E8S72 and IN-SXS67, the Meeting considered residues in follow crops. In field studies on rotational crops, mean residues of oxathiapiprolin, IN-E8S72, and IN-SXS67 (expressed as parent equivalents) were 0.14 mg eq/kg in legume forage. Since residues of IN-E8S72 and IN-SXS67 were <LOQ in all samples, the Meeting used 0.186 mg/kg (0.046 mg/kg STMR; 0.14 mg/kg rotational) from rotational residues as the median residue in the IN-E8S72+IN-SXS67 livestock dietary burden.

##### *Soya bean hay*

Residues of **oxathiapiprolin, *per se***, were (n = 6): < 0.01 (6) mg/kg.

Residues of **total oxathiapiprolin** were (n = 6): < 0.056 mg/kg.

In field studies on rotational crops, the maximum residue of oxathiapiprolin was 0.014 mg/kg in legume hay and the median residue was < 0.01 mg/kg; therefore, the Meeting considered the contribution of follow crops to the maximum residue level, highest, and median residue estimates for soya bean hay. The Meeting estimated a maximum residue level of 0.02 mg/kg for residues of oxathiapiprolin in soya bean hay. For purposes of estimating the oxathiapiprolin livestock dietary burden, the Meeting used 0.02 mg/kg as the highest and median residues for oxathiapiprolin.

For livestock dietary burdens for IN-E8S72 and IN-SXS67, the Meeting considered residues in follow crops. In field studies on rotational crops, mean residues of oxathiapiprolin, IN-E8S72, and IN-SXS67 (expressed as parent equivalents) were 0.30 mg eq/kg in legume hay. Since residues of IN-E8S72 and IN-SXS67 were <LOQ in all samples, the Meeting used 0.346 mg/kg (0.046 mg/kg STMR; 0.30 mg/kg rotational) as the median residue in the IN-E8S72+IN-SXS67 livestock dietary burden.

### *Maize*

The cGAP is from Indonesia and consists of a seed treatment application at 0.882 g ai/kg seed (equivalent to approximately 220 µg ai/seed). Eight maize trials were conducted in Indonesia and Thailand matching the cGAP. Maize samples were not analysed for residues IN-E8S72 and IN-SXS67; the Meeting assumed that residues of IN-E8S72 and IN-SXS67 were <LOQ in all samples as a conservative assumption.

#### *Maize forage*

Residues of **oxathiapiprolin, per se**, were (n = 8): < 0.01 (8) mg/kg.

Residues of **total oxathiapiprolin** were (n = 8): < 0.056 (8) mg/kg.

For purposes of estimating the oxathiapiprolin livestock dietary burden, the Meeting used the 0.01 mg/kg as the highest and median residue of oxathiapiprolin.

For livestock dietary burdens for IN-E8S72 and IN-SXS67, the Meeting considered residues in follow crops. In field studies on rotational crops, mean residues of oxathiapiprolin, IN-E8S72, and IN-SXS67 (expressed as parent equivalents) were 0.21 mg eq/kg in cereal forage. Since the Meeting assumed that residues of IN-E8S72 and IN-SXS67 were <LOQ in all samples, the Meeting used 0.256 mg/kg (0.046 mg/kg STMR; 0.21 mg/kg rotational) from rotational residues as the median residue in the IN-E8S72+IN-SXS67 livestock dietary burden.

#### *Maize fodder (Stover)*

Residues of **oxathiapiprolin, per se**, were (n = 8): < 0.01 (8) mg/kg.

Residues of **total oxathiapiprolin** were (n = 8): < 0.056 (8) mg/kg.

The Meeting estimated a maximum residue level of 0.01(\*) mg/kg for residues of oxathiapiprolin in maize fodder. For purposes of estimating the oxathiapiprolin livestock dietary burden, the Meeting used the 0.01 mg/kg as the highest and median residue of oxathiapiprolin.

For livestock dietary burdens for IN-E8S72 and IN-SXS67, the Meeting considered residues in follow crops. In field studies on rotational crops, mean residues of oxathiapiprolin, IN-E8S72, and IN-SXS67 (expressed as parent equivalents) were 0.18 mg eq/kg in cereal straw. Since the Meeting assumed that residues of IN-E8S72 and IN-SXS67 were <LOQ in all samples, the Meeting used 0.226 mg/kg (0.046 mg/kg STMR; 0.18 mg/kg rotational) from rotational residues as the median residue in the IN-E8S72+IN-SXS67 livestock dietary burden.

### *Fate of residues during processing*

The Meeting received data from processing studies conducted in orange. Residues of oxathiapiprolin, IN-E8S72, and IN-SXS67 were not detected or <LOQ for all orange juice samples. Samples of dried pulp and oil were only analysed for residues of oxathiapiprolin. For orange oil, residues of parent alone were used to calculate the processing factor since both metabolites are acids and are not anticipated to partition into oil. Metabolite IN-E8S72 was not detected in fat samples from the [<sup>14</sup>C]-oxathiapiprolin lactating goat study, further supporting the rationale that this metabolite is not anticipated to partition into orange oil. For dried pulp, residues of parent alone were also used to calculate the processing factor. Metabolites IN-E8S72 and IN-SXS67 are not expected in dried pulp because residues of these metabolites were <LOQ or not detected in the field trials, and the available hydrolysis and high-temperature hydrolysis studies indicated that residues of oxathiapiprolin did not significantly decline over a 5-day period and were stable under conditions simulating pasteurization, baking, brewing, boiling, and sterilisation.

Processing factors calculated for oxathiapiprolin, per se, and total oxathiapiprolin, and estimates of STMR-P for studies evaluated by the current Meeting

Crop	Commodity	Oxathiapiprolin			Total oxathiapiprolin	
		PF <sub>ENF</sub> [best estimate]	maximum residue level Rec., mg/kg	Highest residue, mg/kg	PF <sub>RISK</sub> [best estimate]	STMR- P, mg/kg
Orange	Whole fruit	--	0.05	0.036 (whole fruit) < 0.01 (pulp)	--	0.057
	Dried pulp	1.7, 3.7 [2.7]	0.15	0.027	1.4, 2.2 [1.6]	0.10
	Juice	< 0.14, < 0.26 [< 0.2]	--	--	< 0.47, < 0.67 [< 0.57]	0.032
	Oil	50, 44 [47]	3	--	31, 20 [26]	1.5

The Meeting recommends a maximum residue limit of 0.15 mg/kg in citrus pulp, dry and 3 mg/kg in orange oil, edible and STMRs of 1.5 mg/kg and 0.10 mg/kg, respectively.

### ***Residues in animal commodities***

The current Meeting calculated dietary burdens based on residue estimates from previous meetings with updates to reflect feed commodities addressed by the current Meeting. Potential primary crop feed items include feedstuffs from cabbage, tomato, grape, citrus, kale, soya bean, potato, maize, and sunflower crops. For the IN-E8S72+IN-SXS67 burden, potential residues in rotated or follow crops were also considered. The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO manual, are presented in Annex 6 and summarised below.

Summary of animal dietary burdens, as ppm of dry matter, for oxathiapiprolin for maximum residue level setting

Livestock	Canada and US		European Union		Australia		Japan	
	Max.	Mean	Max.	Mean	Max.	Mean	Max.	Mean
Beef cattle	0.087	0.047	5.8	4.0	0.69	0.61	0.011	0.011
Dairy cattle	0.072	0.040	5.8	4.0	12 <sup>a,b</sup>	8.5 <sup>c,d</sup>	0.018	0.018
Broiler chickens	0.01	0.01	0.038	0.017	0.004	0.004	0.011	0.011
Layer hens	0.011	0.011	0.20 <sup>e</sup>	0.068 <sup>f</sup>	0.004	0.004	0.011	0.011

<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.

<sup>d</sup> Highest mean dietary burden for dairy cattle.

<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.

Summary of livestock dietary burdens, as ppm of dry matter, for IN-E8S72+IN-SXS67 for use in the dietary assessment

Livestock*	Canada and US		European Union		Australia		Japan	
	Max.	Mean	Max.	Mean	Max.	Mean	Max.	Mean
Beef cattle	--	0.70	--	1.2	--	1.3	--	0.39
Dairy cattle	--	0.81	--	1.2	--	2.0 <sup>a,b</sup>	--	0.65

\* Cattle only. Residues of IN-E8S72 and IN-SXS67 were not observed in the poultry metabolism studies and a separate study dosing with IN-SXS67 was not conducted for poultry.

- <sup>a</sup> Highest mean dietary burden for beef or dairy cattle; suitable for estimating STMRs for mammalian meat, fat, and offal.
- <sup>b</sup> Highest mean dietary burden for dairy cattle; suitable for estimating the STMR for milk.

### ***Animal commodity maximum residue levels***

Feeding studies were not provided in lactating cow or poultry. The Meeting notes that the dosing level for the oxathiapiprolin lactating goat metabolism study is 1.2× the cattle dietary burden. The Meeting was unable to estimate maximum residue levels based on the metabolism study. Therefore, the Meeting withdraws its previous recommended maximum residue levels of 0.01(\*) mg/kg for oxathiapiprolin in meat (from mammals other than marine mammals), edible offal (mammalian), mammalian fat, and milks and its previously recommended STMRs of 0 mg/kg for meat, 0 mg/kg for fat, 0 mg/kg for offal, and 0 mg/kg for milk.

Although the dietary burdens for poultry have increased, when considered with the previously reviewed poultry metabolism study, residues of oxathiapiprolin, IN-E8S72, and IN-SXS67 are not expected in poultry commodities. Therefore, the Meeting concluded that the previously recommended maximum residue levels adequately cover the estimated maximum residues and confirms its previous maximum residue level recommendations of 0.01(\*) mg/kg for oxathiapiprolin in poultry meat, poultry offal, poultry fat and eggs and STMRs for dietary assessment of 0 mg/kg for meat, 0 mg/kg for edible offal, 0 mg/kg for fat, and 0 mg/kg for eggs.

## **RECOMMENDATIONS**

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 dietary risk assessment.

Definition of the residue for compliance with the MRL: *oxathiapiprolin*.

Definition of the residue for dietary risk assessment for plant and animal commodities: *Sum of oxathiapiprolin, 5-(Trifluoromethyl)-1H-pyrazole-3-carboxylic acid and 1-β-D-Glucopyranosyl-3-(trifluoromethyl)-H-pyrazole-5-carboxylic acid, expressed as parent equivalents.*

The residue is not fat-soluble.

## **DIETARY RISK ASSESSMENT**

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

The International Estimated Daily Intakes (IEDIs) for oxathiapiprolin were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. Additionally, the IEDI calculations include residues from rotational crops that were previously calculated by the 2016 Meeting for rotational commodities. The results are shown in Annex 3 of the 2018 JMPR Report. The IEDIs were 0% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of oxathiapiprolin from uses considered by the JMPR is unlikely to present a public health concern.

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

The 2016 JMPR decided that an ARfD for oxathiapiprolin was unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of oxathiapiprolin from the uses considered is unlikely to present a public health concern.



## 5.22 PROFENOFOS (171)

### RESIDUE AND ANALYTICAL ASPECTS

Profenofos is an organophosphorus insecticide. The mode of action is via the inhibition of the acetylcholinesterase enzyme.

It was first evaluated by the JMPR in 1990 as a new compound. It was re-evaluated in the 2007 JMPR for toxicology and the 2008 JMPR for residues. The 2007 JMPR evaluated profenofos for toxicology under the Periodic Review Programme and recommended the current ADI of 0–0.03 mg/kg bw and ARfD of 1 mg/kg bw.

The 2008 JMPR evaluated profenofos for residue under the Periodic Review Programme and concluded that the definition of residue for compliance with MRL and for dietary risk assessment was profenofos.

Profenofos was re-evaluated by the 2011 and 2015 JMPR for additional uses.

Profenofos was scheduled at the Forty-ninth Session of the CCPR for the evaluation of additional uses in the 2018 JMPR. The current Meeting received residues data for green coffee beans.

#### ***Methods of analysis***

The Meeting received two new methods for the determination of profenofos in green coffee bean. The two data generation methods involved extraction with methanol followed by sample clean up by SPE. Final determination was achieved using either GC-NPD or LC-MS/MS; the LOQ for profenofos was either 0.01 mg/kg or 0.02 mg/kg respectively.

The Meeting concluded that suitable methods are available for the determination of profenofos in green coffee beans.

For enforcement, a review of the literature demonstrated that residues of profenofos in green coffee beans can be determined using the QuEChERS method with an LOQ of 0.01 mg/kg.

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

Data were previously evaluated by the 2008 JMPR for crops with high oil content. The Meeting concluded that the demonstrated storage stability for various cotton fractions was sufficient to support the maximum length of storage of the green coffee beans (445 days prior to analysis).

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

The Meeting received residue trials data for profenofos on green coffee beans.

##### ***Coffee beans***

The critical GAP in Brazil, is for two foliar applications of 400 g ai/ha, a re-treatment interval of 30 days and a PHI of 7 days.

A total of seven supervised residue trials, conducted in Brazil on green coffee beans following normal agricultural practices, supported the critical GAP.

Residues in green coffee beans in rank order (n = 7) were: < 0.01, < 0.01, < 0.01, < 0.02, < 0.02, < 0.02 and 0.02 mg/kg.

The Meeting estimated a maximum residue level of 0.04 mg/kg and a STMR of 0.02 mg/kg for green coffee beans.

### 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 an IEDI and IESTI assessment.

### DIETARY RISK ASSESSMENT

#### *Long-term dietary exposure*

The ADI for profenofos is 0–0.03 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for profenofos 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 2018 JMPR Report. The IEDIs ranged from 0–20% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of profenofos from uses considered by the JMPR is unlikely to present a public health concern.

#### *Acute dietary exposure*

The ARfD for profenofos is 1 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for profenofos 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 2018 JMPR Report. The IESTI was 0% of the ARfD.

The Meeting concluded that acute dietary exposure to residues of profenofos from the use considered by the present Meeting is unlikely to present a public health concern.



## 5.23 PROPAMOCARB (148)

### RESIDUE AND ANALYTICAL ASPECTS

Propamocarb is a systemic carbamate fungicide, which was first evaluated in 1984. It was evaluated under the periodic review program in 2005 for toxicology and 2006 for residues. It was last evaluated by the 2014 JMPR, which recommended maximum residue levels for additional uses. The ADI and ARfD are established as 0–0.4 mg/kg bw and 2 mg/kg bw, respectively. The residue definition for plant and animal commodities is propamocarb (free base) for both enforcement of MRLs and dietary exposure assessment. The residue is not fat-soluble.

At the Forty-ninth Session of the CCPR (2017), propamocarb was scheduled for the evaluation of a new livestock feeding study by the 2018 JMPR and consideration of maximum residue levels for mammalian commodities. The Meeting received a dairy cow feeding study, analytical method and storage stability study from the manufacturer.

#### *Methods of analysis*

The Meeting received a new analytical method for the determination of propamocarb and its metabolites (propamocarb N-oxide, 2-hydroxypropyl propamocarb, propamocarb oxazolidinone and propamocarb glucuronide) in animal matrices. For extraction of residues, either 0.1% 1 N acetic acid in methanol for propamocarb glucuronide or acetonitrile for all other analytes were used. LC-MS/MS was used for the determination of the analytes. This method was successfully validated and the LOQ levels achieved for all analytes were 0.010 mg/kg in milk and 0.020 mg/kg in tissues (muscle, fat, liver and kidney), as parent equivalents.

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

Analysis for propamocarb was completed within one month of sampling.

#### *Residues in animal commodities*

##### *Farm animal feeding studies*

The Meeting received information on the residue levels in milk and tissues of dairy cows administered propamocarb (as propamocarb-HCl) at doses equivalent to of 13.6, 26.3 and 138 ppm in the feed for 29 consecutive days.

In milk, parent compound was found only at the highest dose (138 ppm) at the level of 0.015 mg/kg (< 0.01 mg/kg at the medium dose, 26.3 ppm).

In tissues, mean (maximum) concentrations of parent were at the lowest, medium and the highest doses, respectively: for muscle, < 0.02 (< 0.02) mg/kg, 0.02 (0.020) mg/kg and 0.077 (0.088) mg/kg; for fat, < 0.02 (< 0.02) mg/kg, < 0.02 (< 0.02) mg/kg and 0.029 (0.042) mg/kg; for liver, 0.23 (0.28) mg/kg, 0.38 (0.50) mg/kg and 1.3 (1.3) mg/kg; for kidney, 0.49 (0.57) mg/kg, 0.92 (1.1) mg/kg and 3.4 (3.7) mg/kg.

During the depuration phase for cows dosed at 138 ppm, residue levels of parent declined rapidly. In milk (3 days) and tissues (7 days) after the cessation of dosing, the residue levels of parent were all below LOQs.

#### *Animal commodity maximum residue levels*

The 2014 JMPR estimated the propamocarb dietary burdens for the calculation of mammalian commodity maximum residue levels and STMRLs as 31.55 ppm and 10.7 ppm, respectively. The calculations used to

estimate maximum residue levels, STMR and HR values for cattle matrices (based on the dietary burdens and feeding study results described above) is shown below.

	Feed level (ppm) for milk residues	Residues (mg/kg) in milk	Feed level (ppm) for tissue residues	Propamocarb (mg/kg)			
				Muscle	Liver	Kidney	Fat
Maximum residue level (mg/kg), beef or dairy cattle							
Feeding study	26.3	< 0.01	26.3	0.020	0.50	1.1	0.02
	138	0.015	138	0.088	1.3	3.7	0.042
Dietary burden and high residue estimation	31.55	0.010	31.55	0.023	0.54	1.2	0.021
STMR (mg/kg), beef or dairy cattle							
Feeding study	13.6	< 0.01	13.6	0.020	0.28	0.57	0.02
Dietary burden and median residue estimation	10.7	< 0.01	10.7	0.016	0.22	0.45	0.016

The Meeting estimated a maximum residue level of 0.01(\*) mg/kg and a STMR of 0 mg/kg for milks. For tissues, the Meeting estimated maximum residue levels of 0.03 mg/kg for meat (from mammals other than marine mammals) and mammalian fat (except milk fats) and 1.5 mg/kg for edible offal (mammalian) based on residues in kidney. The Meeting estimated STMR and HR values of 0.016 mg/kg and 0.023 mg/kg for muscle, 0.016 mg/kg and 0.021 mg/kg for fat and 0.45 mg/kg and 1.2 mg/kg for edible offal, respectively.

## RECOMMENDATIONS

On the basis of the available data, 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 and dietary risk assessment for plant and animal commodities: *propamocarb*.

The residue is not fat-soluble.

## DIETARY RISK ASSESSMENT

### *Long-term dietary exposure*

The ADI for propamocarb is 0–0.4 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for propamocarb 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 2018 JMPR Report. The IEDIs ranged from 0–2% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of propamocarb from uses considered by the JMPR is unlikely to present a public health concern.

### *Acute dietary exposure*

The ARfD for propamocarb is 2 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for propamocarb 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 2018 JMPR Report. The IESTIs were 0% of the ARfD for children and varied from 0–1% for the general population.

The Meeting concluded that acute dietary exposure to residues of propamocarb from uses considered by the present Meeting is unlikely to present a public health concern.



## 5.24 PYDIFLUMETOFEN (309)

### TOXICOLOGY

Pydiflumetofen is the ISO-approved common name for the 50:50 enantiomer ratio of (*S*)-3-difluoromethyl-1-methyl-1*H*-pyrazole-4-carboxylic acid methoxy-[1-methyl-2-(2,4,6-trichloro-phenyl)-ethyl]-amide (SYN546968) and (*R*)-3-difluoromethyl-1-methyl-1*H*-pyrazole-4-carboxylic acid methoxy-[1-methyl-2-(2,4,6-trichloro-phenyl)-ethyl]-amide (SYN546969) (IUPAC), with the CAS number 1228284-64-7.

Both pydiflumetofen enantiomers are biologically active. Pydiflumetofen is a member of the *N*-methoxy-(phenyl-ethyl)-pyrazole-carboxamide group of fungicides. Its mode of action is respiration inhibition at complex II (succinate dehydrogenase) in mitochondria of phytopathogenic fungi.

Pydiflumetofen has not been previously 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 indicated. No additional information from a literature search was identified that complemented the toxicological information submitted for the current assessment.

#### **Biochemical aspects**

In rats administered radiolabelled pydiflumetofen by gavage, the oral absorption of total radioactivity was 85–90% at doses up to 30 mg/kg bw. Absorption became limited at 100 mg/kg bw (females) and 300 mg/kg bw (males). Pydiflumetofen was widely distributed, with highest concentrations of radioactivity observed in the liver and kidney. There was no evidence for accumulation. Following a single oral gavage dose of 5 mg/kg bw, excretion was rapid (91% within 48 hours). Excretion was predominantly in faeces via the bile. Systemic exposure ( $AUC_{(0-t)}$ ) of pydiflumetofen was non-linear from 300 mg/kg bw in males and from 100 mg/kg bw in females. Following a single oral administration of radiolabelled pydiflumetofen,  $C_{max}$  was observed at 0.5–2 hours at 5 mg/kg bw and at 8 hours at 100 mg/kg bw and above.

In rats, unchanged parent accounted for less than 4% of the 5 mg/kg bw dose by oral administration. The primary metabolic routes included demethoxylation, *N*-dealkylation, monohydroxylation and dihydroxylation, *O*-demethylation, and oxidative and reductive dechlorination. Numerous metabolites were detected, with only four metabolites each accounting for between 10% and 14% of the dose: 1) hydroxy pydiflumetofen glucuronide, 2) SYN547891 glucuronide, and the cleaved molecules 3) trichlorophenol (TCP) sulfate (phenyl label) and 4) SYN548263 (pyrazole label). The majority of these four metabolites were also monohydroxylated and dihydroxylated and in many cases were conjugated with glucuronic acid or sulfate.

Studies in mice demonstrated similar toxicokinetics and biotransformation as were found in rats. The toxicokinetics of pydiflumetofen in pregnant rabbits indicated a subproportional increase in systemic exposure with dose, with no increase in systemic exposure with doses of 750 mg/kg bw or higher.

#### **Toxicological data**

In rats, the acute oral  $LD_{50}$  of pydiflumetofen was greater than 5000 mg/kg bw, the acute dermal  $LD_{50}$  was greater than 5000 mg/kg bw and the 4-hour acute inhalation  $LC_{50}$  was greater than 5.11 mg/L. Pydiflumetofen showed no skin irritation in rabbits, showed mild irritation to rabbit eyes and was not sensitizing in mice.

The main toxic effects of pydiflumetofen in short- and long-term toxicity studies were reduced body weight and effects in the liver in mice, rats and dogs.

In a 3-month toxicity study in mice fed pydiflumetofen at a dietary concentration of 0, 100, 500, 4000 or 7000 ppm (equal to 0, 17.5, 81.6, 630 and 1158 mg/kg bw per day for males and 0, 20.4, 106, 846 and 1483 mg/kg bw per day for females, respectively), the NOAEL was 500 ppm (equal to 81.6 mg/kg bw per day), based on reduced body weight gain and increases in cholesterol and triglycerides at 4000 ppm (equal to 630 mg/kg bw per day).

In a 28-day toxicity study in rats administered pydiflumetofen at a dietary concentration of 0, 500, 4000, 8000 or 16 000 ppm (equal to 0, 43, 343, 677 and 1322 mg/kg bw per day for males and 0, 40, 322, 619 and 1174 mg/kg bw per day for females, respectively), the NOAEL was 8000 ppm (equal to 619 mg/kg bw per day), based on reduction of body weight gain at 16 000 ppm (equal to 1174 mg/kg bw per day).

In a 91-day toxicity study in rats administered pydiflumetofen in the diet at a concentration of 0, 250, 1500, 8000 or 16 000 ppm (equal to 0, 18.6, 111, 587 and 1187 mg/kg bw per day for males and 0, 21.6, 127, 727 and 1325 mg/kg bw per day for females, respectively), the NOAEL was 250 ppm (equal to 18.6 mg/kg bw per day), based on follicular cell hypertrophy in the thyroid at 1500 ppm (equal to 111 mg/kg bw per day). The Meeting noted that mode of action studies for the effect of pydiflumetofen on the thyroid indicated that the induction of follicular cell hypertrophy by pydiflumetofen at high doses was secondary to increased hepatic microsomal uridine diphosphate glucuronosyltransferase activity, not a direct effect on the thyroid. Therefore, the Meeting concluded that the follicular cell hypertrophy in the thyroid of rats would not be relevant to humans.

In a 90-day oral toxicity study in dogs treated with pydiflumetofen in capsules at 0, 30, 300 or 1000 mg/kg bw per day, the NOAEL was 300 mg/kg bw per day, based on reduced body weight gain at 1000 mg/kg bw per day.

In a 1-year oral toxicity study in dogs administered pydiflumetofen in capsules at a dose of 0, 30, 100 or 300 mg/kg bw per day, the NOAEL was 300 mg/kg bw per day, the highest dose tested.

The overall NOAEL for pydiflumetofen in dogs was 300 mg/kg bw per day, and the overall LOAEL was 1000 mg/kg bw per day.

In an 18-month carcinogenicity study in mice administered pydiflumetofen at a dietary concentration of 0, 75, 375 or 2250 ppm (equal to 0, 9.2, 45.4 and 287.9 mg/kg bw per day for males and 0, 9.7, 48.4 and 306.2 mg/kg bw per day for females, respectively), the NOAEL for systemic toxicity was 375 ppm (equal to 45.4 mg/kg bw per day), based on reduced body weight gain in males at 2250 ppm (equal to 287.9 mg/kg bw per day). The NOAEL for carcinogenicity was 75 ppm (equal to 9.2 mg/kg bw per day), based on increased incidence of liver tumours at 375 ppm (equal to 45.4 mg/kg bw per day).

The results of several mechanistic studies of the liver effects of pydiflumetofen in mice indicate that pydiflumetofen has a CAR-mediated mode of action in the induction of liver tumours. The mode of action for these tumours was assessed using the IPCS human relevance framework. It was concluded that these carcinogenic responses are not relevant to humans.

In a 2-year toxicity and carcinogenicity study in rats administered pydiflumetofen at a dietary concentration of 0, 200, 1000 or 6000 ppm for males (equal to 0, 9.9, 51.0 and 319 mg/kg bw per day, respectively) or 0, 150, 450 or 1500 ppm for females (equal to 0, 10.2, 31.0 and 102 mg/kg bw per day, respectively), the NOAEL for toxicity was 200 ppm (equal to 9.9 mg/kg bw per day), based on decreased body weights in males at 1000 ppm (equal to 51.0 mg/kg bw per day). No treatment-related increases in tumour incidence were observed.

The Meeting concluded that pydiflumetofen is carcinogenic in male mice, but not in female mice or rats.

Pydiflumetofen was tested for genotoxicity in an adequate range of in vitro and in vivo assays. It gave a positive/equivocal response in a chromosomal aberration mammalian test using human lymphocytes without S9, but a negative response in the micronucleus tests in vivo.

The Meeting concluded that pydiflumetofen is unlikely to be genotoxic in vivo.

In view of the lack of genotoxicity in vivo, the absence of carcinogenicity in rats and female mice and evidence that the tumours in male mice are not relevant to humans, the Meeting concluded that pydiflumetofen is unlikely to pose a carcinogenic risk to humans.

In a two-generation reproductive toxicity study, rats were given pydiflumetofen in the diet at a concentration of 0, 150, 750 or 4500 ppm (equal to 0, 9.1, 46.1 and 277 mg/kg bw per day, respectively) for males and 0, 150, 450 or 1500 ppm (equal to 0, 12.6, 33.7 and 115 mg/kg bw per day, respectively) for females. The NOAEL for parental toxicity was 750 ppm (equal to 46.1 mg/kg bw per day), based on reduced body weight and thyroidal effects (increased thyroid weight and minimal thyroid follicular cell hypertrophy) in males at 4500 ppm (equal to 277 mg/kg bw per day). The NOAEL for offspring toxicity was 450 ppm (equal to 33.7 mg/kg bw per day), based on reduced pup body weight before weaning in the F<sub>1</sub> generation at 1500 ppm (equal to 115 mg/kg bw per day). The NOAEL for reproductive toxicity was 1500 ppm (equal to 115 mg/kg bw per day), the highest dose tested.

In a developmental toxicity study, pregnant rats were administered pydiflumetofen by gavage at a dose of 0, 10, 30 or 100 mg/kg bw per day during gestation days 6–19. The NOAEL for maternal toxicity was 30 mg/kg bw per day, based on reductions in body weight gain and feed consumption at the beginning of dosing at 100 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 100 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in which rabbits were administered pydiflumetofen by gavage at a dose of 0, 10, 100 or 500 mg/kg bw per day during gestation days 6–27, the NOAEL for maternal and embryo/fetal toxicity was 500 mg/kg bw per day, the highest dose tested.

The Meeting concluded that pydiflumetofen is not teratogenic.

In an acute neurotoxicity study in female rats administered pydiflumetofen by gavage at a dose of 0, 100, 1000 or 2000 mg/kg bw, the NOAEL for systemic toxicity was 100 mg/kg bw, based on clinical signs, lower body temperature and decreased locomotor activity at 1000 mg/kg bw. There was no evidence of neuropathological changes. The NOAEL for neurotoxicity was 2000 mg/kg bw, the highest dose tested.

In an additional acute neurotoxicity study in female rats administered pydiflumetofen by gavage at a dose of 0, 100, 300 or 1000 mg/kg bw, the NOAEL for systemic toxicity was 100 mg/kg bw, based on clinical signs, lower body weight and decreased locomotor activity at 300 mg/kg bw. The NOAEL for neurotoxicity was 1000 mg/kg bw, the highest dose tested.

The overall NOAEL for systemic toxicity in the two acute neurotoxicity studies in rats was 100 mg/kg bw.

Although a subchronic neurotoxicity study was not submitted, the Meeting noted that FOB was performed in repeated-dose studies in mice, rats and dogs. No effects were observed.

The Meeting concluded that pydiflumetofen is not neurotoxic.

Although no immunotoxicity study was submitted, there was no indication of immunotoxicity in the submitted toxicity studies. The Meeting concluded that pydiflumetofen is not immunotoxic.

There was no information about the effect of pydiflumetofen on the microbiome of the human gastrointestinal tract based on a search of the literature.

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

#### ***2,4,6-Trichlorophenol (2,4,6-TCP)***

2,4,6-TCP was the major circulating metabolite of pydiflumetofen in rats (representing up to 5.3% in plasma) and is identified in animal commodities only. 2,4,6-TCP sulfate was identified in plasma at 32–44%.

WHO has established a drinking-water guideline value of 0.2 mg/L for 2,4,6-TCP, although it is generally found in drinking-water at concentrations below 0.001 mg/L. Like other chlorophenols (e.g. 2-chlorophenol and 2,4-dichlorophenol), 2,4,6-TCP is most likely to occur in drinking-water as a by-product of chlorination.

The Meeting noted that this metabolite was identified in animal commodities and concluded that the toxicity of 2,4,6-TCP and its conjugates would be covered by the parent compound.

#### ***SYN547897 (livestock and rat metabolite)***

SYN547897 is present at greater than 10% in rat faeces (from bile). Therefore, the Meeting concluded that this metabolite and its conjugates would be covered by the parent compound.

#### ***SYN508272 (Reg. No. 5621781)***

SYN508272 was found in rats. The precursor of this metabolite was SYN548263, a major metabolite in rats. The acute oral LD<sub>50</sub> of SYN508272 was greater than 500 mg/kg bw and lower than 2000 mg/kg bw.

In a 28-day toxicity study in which rats were administered diets containing SYN508272 at a concentration of 0, 100, 500 or 2000 ppm (males) / 4000 ppm (females) (equal to 0, 7.3, 37.4 and 143 mg/kg bw per day for males and 0, 7.8, 42.5 and 244 mg/kg bw per day for females, respectively), marginally lower body weights and lower feed consumption were observed in females only during the first part of the study at 4000 ppm (equal to 244 mg/kg bw per day). The Meeting noted that these effects on body weight and feed consumption may have been due to palatability issues. The NOAEL was 2000 ppm (equal to 143 mg/kg bw per day), the highest dose tested.

The toxicological profile of this metabolite was the same as that of pydiflumetofen. The NOAEL of the metabolite in the 28-day rat study (2000 ppm, equal to 143 mg/kg bw per day, the highest dose tested) was similar to that of the parent compound in a similar study (NOAEL 8000 ppm, equal to 619 mg/kg bw per day).

SYN508272 showed one positive result in an in vitro genotoxicity study and negative results in two other in vitro studies and an in vivo study.

### ***Human data***

In reports on manufacturing plant personnel, no adverse health effects were noted by the sponsor during the manufacture of pydiflumetofen or its product formulation.

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

### **Toxicological evaluation**

The Meeting established an ADI of 0–0.1 mg/kg bw on the basis of the NOAEL of 9.9 mg/kg bw per day in



a 2-year study in rats for decreased body weight in males observed at 51.0 mg/kg bw per day. A safety factor of 100 was applied.

The Meeting established an ARfD of 0.3 mg/kg bw on the basis of the NOAEL of 30 mg/kg bw per day in a rat developmental toxicity study for reduction in maternal body weight gain and feed consumption early during treatment, observed at 100 mg/kg bw per day. A safety factor of 100 was applied.

The ADI and the ARfD apply to the metabolites 2,4,6-TCP and SYN547897 and their conjugates, expressed as pydiflumetofen.

A toxicological monograph was prepared.

***Levels relevant to risk assessment of pydiflumetofen***

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of carcinogenicity <sup>a</sup>	Toxicity	375 ppm, equal to 45.4 mg/kg bw per day	2 250 ppm, equal to 287.9 mg/kg bw per day
		Carcinogenicity	75 ppm, equal to 9.2 mg/kg bw per day	375 ppm, equal to 45.4 mg/kg bw per day
Rat	Two-year study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	200 ppm, equal to 9.9 mg/kg bw per day	1 000 ppm, equal to 51.0 mg/kg bw per day
		Carcinogenicity	1 500 ppm, equal to 102 mg/kg bw per day <sup>b</sup>	–
	Two-generation study of reproductive toxicity <sup>a</sup>	Reproductive toxicity	1 500 ppm, equal to 115 mg/kg bw per day <sup>b</sup>	–
		Parental toxicity	750 ppm, equal to 46.1 mg/kg bw per day	4 500 ppm, equal to 277 mg/kg bw per day
		Offspring toxicity	450 ppm, equal to 33.7 mg/kg bw per day	1 500 ppm, equal to 115 mg/kg bw per day
	Developmental toxicity study <sup>c</sup>	Maternal toxicity	30 mg/kg bw per day	100 mg/kg bw per day
		Embryo and fetal toxicity	100 mg/kg bw per day <sup>b</sup>	–
Rabbit	Developmental toxicity study <sup>c</sup>	Maternal toxicity	500 mg/kg bw per day <sup>b</sup>	–
		Embryo and fetal toxicity	500 mg/kg bw per day <sup>b</sup>	–
Dog	Three-month and 1-year studies of toxicity <sup>d,e</sup>	Toxicity	300 mg/kg bw per day	1 000 mg/kg bw per day

<sup>a</sup> Dietary administration.

- <sup>b</sup> Highest dose tested.
- <sup>c</sup> Gavage administration.
- <sup>d</sup> Two or more studies combined.
- <sup>e</sup> Capsule administration.

*Acceptable daily intake (ADI) (applies to pydiflumetofen and the metabolites 2,4,6-TCP and SYN547897 and their conjugates, expressed as pydiflumetofen)*

0–0.1 mg/kg bw

*Acute reference dose (ARfD) (applies to pydiflumetofen and the metabolites 2,4,6-TCP and SYN547897 and their conjugates, expressed as pydiflumetofen)*

0.3 mg/kg bw

*Information that would be useful for the continued evaluation of pydiflumetofen*

Further characterization of the toxicity of metabolites found in plant and animal commodities; results from epidemiological, occupational health and other such observational studies of human exposure

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

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

Rate and extent of oral absorption	85–90% absorbed; T <sub>max</sub> within 2 hours at low dose
Distribution	Widely distributed; highest levels in liver and kidney
Potential for accumulation	No indication for accumulation in tissues
Rate and extent of excretion	Rapidly excreted (>90% within 48 hours)
Metabolism in animals	Demethoxylation, N-dealkylation, monohydroxylation and dihydroxylation, O-demethylation, oxidative and reductive dechlorination
Toxicologically significant compounds in animals and plants	Pydiflumetofen, 2,4,6-trichlorophenol (2,4,6-TCP)

##### *Acute toxicity*

Rat, LD <sub>50</sub> , oral	>5 000 mg/kg bw
Rat, LD <sub>50</sub> , dermal	>5 000 mg/kg bw
Rat, LC <sub>50</sub> , inhalation	>5.11 mg/L
Rabbit, dermal irritation	Not irritating to skin
Rabbit, ocular irritation	Slightly irritating to eye
Mouse, dermal sensitization	Not sensitizing (local lymph node assay)

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

Target/critical effect	Thyroid follicular cell hyperplasia (rat)
Lowest relevant oral NOAEL	18.6 mg/kg bw per day (rat)
Lowest relevant dermal NOAEL	1 000 mg/kg bw per day, highest dose tested (rat)
Lowest relevant inhalation NOAEC	No data

*Long-term studies of toxicity and carcinogenicity*

Target/critical effect	Reduced body weight gain (rat)
Lowest relevant NOAEL	9.9 mg/kg bw per day (rat)
Carcinogenicity	Carcinogenic in male mice, but not in female mice or rats <sup>a</sup>

*Genotoxicity*No evidence of genotoxicity in vivo<sup>a</sup>*Reproductive toxicity*

Target/critical effect	Thyroid follicular cell hyperplasia (rat)
Lowest relevant parental NOAEL	46.1 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	33.7 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	115 mg/kg bw per day, highest dose tested (rat)

*Developmental toxicity*

Target/critical effect	Reduced body weight gain and feed consumption (rat)
Lowest relevant maternal NOAEL	30 mg/kg bw per day (rat)
Lowest relevant embryo/foetal NOAEL	100 mg/kg bw per day, highest dose tested (rat)

*Neurotoxicity*

Acute neurotoxicity NOAEL	1 000 mg/kg bw, highest dose tested (rat)
Subchronic neurotoxicity NOAEL	No evidence for neurotoxicity in repeated-dose studies in mice, rats and dogs

*Other toxicological studies*

Immunotoxicity NOAEL	No evidence for immunotoxicity in repeated-dose toxicity studies
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*Studies on toxicologically relevant metabolites*

2,4,6-Trichlorophenol (2,4,6-TCP)	Major metabolite (rat) WHO drinking-water guideline value: 0.2 mg/L
SYN508272	500 mg/kg bw < LD <sub>50</sub> < 2 000 mg/kg bw 28-day study NOAEL 143 mg/kg bw per day, highest dose tested No evidence of genotoxicity in vivo

*Human data*

No adverse health effects on manufacturing plant personnel have been reported

<sup>a</sup> Unlikely to pose a carcinogenic risk to humans.**Summary**

	Value	Study	Safety factor
ADI	0–0.1 mg/kg bw <sup>a</sup>	Two-year study of toxicity and carcinogenicity in rats	100

ARfD

0.3 mg/kg bw<sup>a</sup>

Developmental toxicity study in rats

100

<sup>a</sup> Applies to pydiflumetofen and the metabolites 2,4,6-TCP and SYN547897 and their conjugates, expressed as pydiflumetofen.

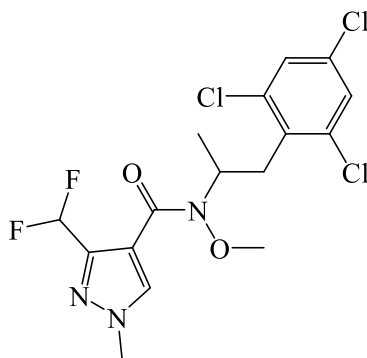
### RESIDUE AND ANALYTICAL ASPECTS

Pydiflumetofen was evaluated for the first time by the Meeting. At the Forty-ninth Session of the CCPR (2017), the compound was scheduled for evaluation as a new compound by the 2018 JMPR.

Pydiflumetofen is a broad-spectrum fungicide of the chemical group of N-methoxy-(phenyl-ethyl)-pyrazole-carboxamide and belongs to the SDHI (Succinate Dehydrogenase Inhibitors) fungicide group. It inhibits succinate dehydrogenase in complex II of fungal mitochondrial respiration.

The Meeting received information on physical and chemical properties, animal and plant metabolism, environment fate, rotational crop residues, analytical methods, storage stability, use pattern, supervised trials, and fate of residues in processing.

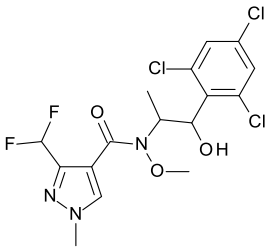
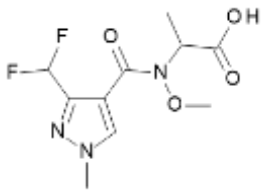
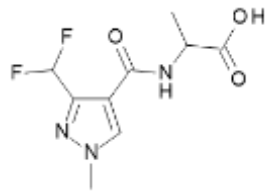
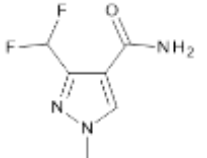
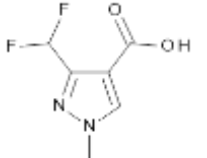
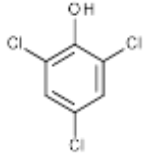
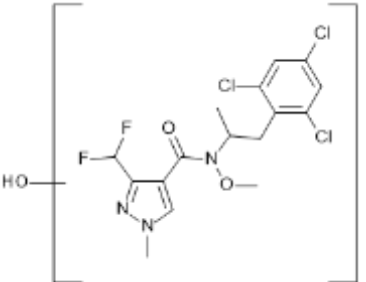
*N*-methoxy-*N*-[(*RS*)-1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide



Pydiflumetofen is a 1:1 mixture of the enantiomers.

In this appraisal, the following abbreviated names were used for metabolites.

SYN545547	SYN547891	SYN547897
3-(difluoromethyl)-1-ethyl-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]pyrazole-4-carboxamide	3-(difluoromethyl)-N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1H-pyrazole-4-carboxamide	MW = 442,7 3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-methyl-2-(2,4,6-trichloro-3-hydroxy-phenyl)ethyl]pyrazole-4-carboxamide

SYN547948 	SYN548263 	SYN548264 
3-(difluoromethyl)-N-[2-hydroxy-1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-N-methoxy-1-methylpyrazole-4-carboxamide	2-[[3-(difluoromethyl)-1-methylpyrazole-4-carbonyl]-methoxy-amino] propanoic acid	2-[[3-(difluoromethyl)-1-methylpyrazole-4-carbonyl]amino] propanoic acid
SYN508272 	NOA449410 	2,4,6-TCP  MW = 197.45
3-(difluoromethyl)-1-methylpyrazole-4-carboxamide	3-(difluoromethyl)-1-methylpyrazole-4-carboxylic acid	2,4,6-trichlorophenol
Hydroxylated pydiflumetofen 		
Hydroxylated N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide		

### Physical and chemical properties

Pydiflumetofen has a higher solubility in organic solvents in comparison to water and is not volatile. Pydiflumetofen was shown to be hydrolytically and photolytically stable.

### Plant metabolism

The Meeting received plant metabolism studies on tomato, wheat and oilseed rape with pydiflumetofen labelled with  $^{14}\text{C}$  at two different rings ([phenyl- $\text{U-}^{14}\text{C}$ ] and [pyrazole-5- $^{14}\text{C}$ ]).

In a tomato metabolism study, [ $^{14}\text{C}$ ]-pydiflumetofen was applied to tomato plants grown in a glasshouse with two foliar spray applications at total rate of 0.40 kg ai/ha. As a separate study, [ $^{14}\text{C}$ ]-pydiflumetofen was applied as a single application direct to soil containing tomato plants grown in a

glasshouse at a rate of 20 mg ai/plant. Residue levels (0.64 mg eq/kg) were highest in the foliar treated fruit harvested 14 DALA. Surface wash with acetonitrile extracted  $\geq 89\%$  TRR in the foliar experiment. Total extractability was  $\geq 98\%$  TRR in all commodities extracted with acetonitrile/water.

In the foliar spray experiment, the highest residues of pydiflumetofen were detected in 14 DALA fruit (0.59–0.61 mg/kg, 92–97% TRR). Metabolism was limited and metabolites identified were SYN545547 and SYN547891. Residues of SYN545547 and SYN547891 accounted for a maximum of 3.6% TRR and 1.6% TRR respectively.

In the soil treated experiment, total radioactive residues in the fruit were low ( $\leq 0.013$  mg eq/kg). The principal component detected in fruit harvested 103 days after treatment (DAT) was pydiflumetofen accounting for 4.1% TRR (0.001 mg/kg). Unidentified components in fruit accounted for 89% TRR (0.008 mg eq/kg) with no individual component  $> 12\%$  TRR (0.002 mg eq/kg).

In a wheat metabolism study, [ $^{14}\text{C}$ ]-pydiflumetofen was applied twice to spring wheat as spray applications at a total rate of 0.25 kg ai/ha. Residues increased from forage to straw to a maximum of 1.5 mg eq/kg; residues in grain were the lowest of all commodities with residues  $\leq 0.057$  mg eq/kg. Extractability was  $\geq 85\%$  TRR in all commodities extracted with acetonitrile/water (80:20).

The highest residues of pydiflumetofen were detected in straw (1.1–1.2 mg/kg,  $\geq 76\%$  TRR), and the lowest in grain (0.030–0.046 mg/kg,  $\geq 82\%$  TRR) at 50 days after last application (DALA). Metabolism was limited and metabolites identified were the de-alkylated molecules, SYN545547 and SYN547891. Residues of SYN545547 accounted for  $\leq 3.9\%$  TRR with the largest residue detected in straw (0.059 mg eq/kg, 3.9% TRR). Residues of SYN547891 accounted for  $\leq 8.3\%$  TRR with the highest residue in straw (0.065 mg eq/kg, 4.3% TRR).

In an oilseed rape metabolism study, [ $^{14}\text{C}$ ]-pydiflumetofen was applied to oilseed rape as a spray application at a rate of 0.15 kg ai/ha. Residues in trash were 0.061–0.062 mg eq/kg and residues in seed were 0.019–0.020 mg eq/kg at 62 DAT. Extractability was 72–75% TRR in seed extracted with acetonitrile/water (80:20) plus hexane and 76–81% TRR in trash extracted with acetonitrile /water (80:20).

The highest residues of pydiflumetofen were detected in trash (0.018–0.032 mg/kg,  $\geq 30\%$  TRR); lower residues were detected in seed (0.007–0.012 mg/kg,  $\geq 39\%$  TRR). Metabolism was limited. Low residues of SYN545547 ( $\leq 3.7\%$  TRR,  $\leq 0.002$  mg eq/kg) and SYN547891 ( $\leq 5.1\%$  TRR,  $\leq 0.003$  mg eq/kg) were detected in trash. Low residues of SYN545547 ( $\leq 6.1\%$  TRR,  $\leq 0.001$  mg eq/kg) and SYN547891 ( $\leq 2.7\%$  TRR,  $\leq 0.001$  mg eq/kg) were detected in seed. Unknown residues of the [pyrazole- $^{14}\text{C}$ ] label (35% TRR, 0.022 mg eq/kg) remained in trash, but they were comprised of 10 individual components and none individually exceeding 8.4% TRR (0.005 mg eq/kg).

In summary, pydiflumetofen was the major component of the residues found in wheat, tomato and oilseed rape. SYN545547 was formed by reduction of the parent molecule and SYN547891 was formed by demethylation of the pyrazole ring but they were not present as significant residues in plants.

### ***Animal metabolism***

The Meeting received farm animal metabolism studies with pydiflumetofen on lactating goat and laying hens. The metabolism and distribution of pydiflumetofen in farm animals were investigated using the [phenyl- $^{14}\text{C}$ ] and [pyrazole-5- $^{14}\text{C}$ ]-pydiflumetofen.

Metabolism in rats was summarised and evaluated by the WHO panel of the JMPR in 2018.

Lactating goats were orally dosed with radiolabelled pydiflumetofen daily for 7 consecutive days at a nominal rate of 100 ppm dietary dry matter intake. The radioactive balance for goats was greater than 94% with the majority of the radioactivity excreted in the urine (30–32% AR) and faeces (46–53% AR).

Following the administration of [ $^{14}\text{C}$ ]-pydiflumetofen, TRRs were 7.0–8.8 mg eq/kg in liver, 1.7–2.3 mg eq/kg in kidney, 0.10–0.14 mg eq/kg in muscle and 0.22–0.28 mg eq/kg in fat. Residues in milk achieved a plateau concentration of approximately 0.091–0.13 mg eq/kg after 2–6 days of dosing. Following solvent extraction with aqueous acetonitrile and hexane for milk and fat, and with aqueous acetonitrile for liver, kidney and muscle, residue extractabilities were generally high ( $\geq 83\%$  TRR) for milk, kidney, muscle and fat. Residue extractability was lower in liver (47–50% TRR). Where appropriate fractions were also subject to organic solvent/water partition and  $\beta$ -glucuronidase enzyme hydrolysis procedures prior to chromatographic analysis.

Pydiflumetofen %TRRs were greatest in fat (67–74% TRR, 0.15–0.21 mg/kg), muscle (13–24% TRR, 0.018–0.025 mg/kg), milk (8.7–16% TRR, 0.011–0.019 mg/kg) and liver (2.0–8.2% TRR, 0.18–0.57 mg/kg) with much smaller percentage TRRs being found in kidney (0.5–0.8% TRR, 0.011–0.014 mg/kg).

SYN548264 (N-desmethoxy carboxylic acid) occurred at its highest %TRR in milk (29% TRR, 0.038 mg eq/kg, found in its free form). Much lower %TRRs were detected in kidney (0.8% TRR, 0.019 mg eq/kg, conjugated form only) and in muscle (0.6% TRR, 0.001 mg eq/kg, found in its free form only). It was not detected in liver or fat.

SYN508272 (amide) occurred at its highest %TRRs in muscle (18% TRR, 0.024 mg eq/kg) and milk (11% TRR, 0.014 mg eq/kg) both were found in the free form only. Much lower %TRRs were detected in kidney (1.5% TRR, 0.036 mg eq/kg; found in both its free and conjugated forms) and in fat (1.0% TRR, 0.003 mg eq/kg, in its free form only). It was not detected in liver.

SYN548263 (carboxylic acid) occurred at its highest %TRRs in kidney (17% TRR, 0.39 mg eq/kg, in predominantly its conjugated form) and milk (14% TRR, 0.019 mg eq/kg, found in its free form only). Much lower %TRRs were detected in muscle (4.9% TRR, 0.007 mg eq/kg) and in fat (4.3% TRR, 0.012 mg eq/kg), where it was found in the free form only. It was not detected in liver.

NOA449410 (carboxylic acid) occurred at its highest %TRR in kidney (12% TRR, 0.28 mg eq/kg, in predominantly its conjugated form). Lower %TRRs were detected in liver (2.9% TRR, 0.25 mg eq/kg, found in both the free and conjugated forms) and in muscle and milk (3.6% TRR and 2.6% TRR respectively,  $\leq 0.005$  mg eq/kg) in only the free form. It was not detected in fat.

2,4,6-TCP occurred at its highest %TRRs in milk (43% TRR, 0.052 mg eq/kg) and muscle (9.0% TRR, 0.009 mg eq/kg). In both milk and muscle the residue was found predominantly in its sulphate ester conjugated form of the metabolite. Levels of this metabolite were much lower in kidney (1.2% TRR, 0.021 mg eq/kg) and liver (0.5% TRR, 0.037 mg eq/kg), where it was only found in the conjugated form in both tissues. It was not detected in fat.

Other identified metabolites, hydroxylated metabolite of pydiflumetofen, SYN545547, SYN547948, SYN547897 and SYN547891, were observed ( $\leq 11\%$  TRR).

Aliquots of liver and kidney PES were subject to protease enzyme hydrolysis which released significant proportions of the residues (liver: 40–46% TRR; kidney: 9.3–15% TRR) into the resulting hydrolysate.

Laying hens were orally dosed with radiolabelled pydiflumetofen daily for 14 days at a dose level of 30 ppm dietary dry matter intake. The radioactive balance for all hens was greater than 81% with the majority of the radioactivity recovered in excreta.

Samples were extracted with solvents (fat: hexane and aqueous acetonitrile, liver, egg yolk, egg white and muscle: aqueous acetonitrile). Good extractability was achieved for the eggs, muscle and fat ( $\geq$

81% TRR). Extractability of liver was lower ( $\geq 52\%$  TRR). Where appropriate, these fractions were subject to organic solvent/water partition and  $\beta$ -glucuronidase enzyme hydrolysis procedures prior to chromatographic analysis. Mean residues in egg whites achieved a plateau concentration of approximately 0.062–0.064 mg eq/kg after 6–7 days of dosing. Mean residues in egg yolks achieved a plateau concentration of approximately 0.34 mg eq/kg (phenyl) and 0.12 mg eq/kg (pyrazole) after 10 and 7 days of dosing, respectively.

Pydiflumetofen %TRRs were greatest in egg white (27–47% TRR, 0.014–0.025 mg/kg) and fat (17–31% TRR, 0.010–0.017 mg/kg) with much smaller %TRRs being found in muscle (4.7–8.7% TRR, 0.001–0.002 mg/kg), egg yolk (3.0–11% TRR, 0.011–0.012 mg/kg) and liver (0.5–5.3% TRR, 0.001–0.021 mg/kg).

2,4,6-TCP occurred at its highest %TRRs in egg yolk (68% TRR, 0.24 mg eq/kg), egg white (15% TRR, 0.008 mg eq/kg), muscle (48% TRR, 0.013 mg eq/kg) and fat (29% TRR, 0.030 mg eq/kg). In eggs and all tissues the residue of this metabolite was found predominantly in its sulphate ester conjugated form.

SYN508272 (amide) occurred at its highest %TRRs in muscle (46% TRR, 0.010 mg eq/kg, the free form), egg white (34% TRR, 0.018 mg eq/kg, the free form) and fat (9.6% TRR, 0.003 mg eq/kg, the free form). Much lower %TRRs were detected in egg yolk (7.2% TRR, 0.008 mg eq/kg, the free and conjugated forms) and liver (2.4% TRR, 0.005 mg eq/kg, the free and conjugated forms).

NOA449410 (carboxylic acid) occurred at its highest %TRR in egg white (15% TRR, 0.008 mg eq/kg, the free form). Lower %TRRs were detected in egg yolk (6.6% TRR, 0.007 mg eq/kg, the free and conjugated forms), in fat (3.1% TRR, 0.001 mg eq/kg, the free form) and was not detected in liver and muscle.

Other identified metabolites, SYN545547, SYN547948, SYN547897 and SYN547891, were observed ( $\leq 6.7\%$  TRR).

Separate aliquots of liver and egg yolk PES were subject to protease enzyme hydrolysis which released significant proportions of the residues (liver: 32–46% TRR; egg yolk: 6.1–11% TRR) into the resulting hydrolysate.

In summary, pydiflumetofen was detected in all goat and hen commodities. The most abundant metabolite detected in milk, egg yolk and hen muscle was 2,4,6-TCP. In the goat, SYN548263 and SYN548264 occurred in milk, kidney and muscle. SYN548264 was further metabolised to form SYN508272 and NOA449410. In the hen, the intermediate metabolites SYN548263 and SYN548264 were not observed but SYN508272 and NOA449410 were identified. Protease hydrolysates of PES comprised a complex mixture of unknown and highly polar metabolites in liver (goat and hen) and kidney (goat).

### ***Environmental fate in water and soil***

The Meeting received information on hydrolysis, soil photolysis and soil degradation.

In the hydrolytic degradation study, pydiflumetofen was hydrolytically stable at pH 4, 7 and 9 after incubation at 50 °C for 5 days ( $> 92\%$  of applied radioactivity was recovered as unchanged pydiflumetofen).

In the aqueous photolysis study, pydiflumetofen degraded slowly in sterile buffer (pH 7) with 73–79% of applied radioactivity recovered after incubation at 25 °C for 30 days.

In the soil photolysis study, the  $DT_{50}$  of pydiflumetofen was 77 days in dry soils and 197 days in moist soils.

Hydrolysis and photolysis are not considered significant routes of degradation for pydiflumetofen.

In the soil degradation studies, pydiflumetofen was found to remain mostly in the top soil layer (0–10 cm) during soil dissipation field trials (6 different soils) of duration up to 24 months. The  $DT_{50}$  of



pydiflumetofen was 398–2380 days and the  $DT_{90}$  could not be reached within one year after application to bare soil (> 40 months in all trials). Pydiflumetofen is persistent in soil.

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

The Meeting received a confined rotational crop study with  $^{14}\text{C}$ -labeled pydiflumetofen ([phenyl- $^{14}\text{C}$ ] and [pyrazole-5- $^{14}\text{C}$ ]) and field rotational crop studies.

In a confined rotational crop study, rotational crops (lettuce, wheat and turnip) were sown at 30, 120 and 270 days after a single spray treatment (DAT) of [ $^{14}\text{C}$ ]-pydiflumetofen at a rate of 0.40 kg ai/ha to a sandy loam soil.

Extractability was 83–97% TRR for all analysed commodities. Pydiflumetofen represented the major portion of the residue taken up into rotated wheat, lettuce and turnip commodities up to a maximum of 78% TRR. Maximum residues of pydiflumetofen were detected in 120 DAT wheat straw (29% TRR, 0.063 mg/kg). Uptake of radioactive residues into grain and turnip tubers was low accounting for  $\leq 0.008$  mg eq/kg.

Metabolites identified were SYN5457891 ( $\leq 0.012$  mg eq/kg) and SYN545547 ( $\leq 0.005$  mg eq/kg) detected in all commodities.

The results show that the metabolism of pydiflumetofen in rotated crops was similar for all crop types. Comparison with primary crop metabolism studies shows that the pathway in rotational crops is consistent with that in primary crops, though the magnitude of residues in rotational crops is lower.

In field rotational crop studies in Europe and the USA, pydiflumetofen SC formulation was applied to bare ground at 0.40–0.50 kg ai/ha (Europe:  $0.50 \times 1$  kg ai/ha, USA:  $0.20 \times 2$  kg ai/ha). The trials were established for each of three rotational crop types (Europe: spinach, carrot and spring barley, USA: spinach or lettuce, radish, and wheat) at several rotational crop plantback intervals (Europe: 30, 60 and 365 days, USA: 30, 60, 90, and 150 days).

Residues of pydiflumetofen were all below 0.02 mg/kg in spinach, lettuce, carrot, radish, cereal whole plant and grains.

Residues of pydiflumetofen were found in spring barley straw, wheat hay and wheat straw. For spring barley straw in the European studies, residues of pydiflumetofen were 0.02–0.06 mg/kg at a 30 day PBI and 0.02–0.09 mg/kg at a 60 day PBI. For wheat straw and hay in the USA study, a peak in residues is apparent at 90 day PBI (0.011–0.12 mg/kg) with a subsequent decline in residues at 150 day PBI ( $< 0.01$ –0.067 mg/kg).

The Meeting noted that residues of pydiflumetofen may be taken up by rotational crops. The active substance is very persistent in soil (up to 2380 days  $DT_{50}$ ) and accumulation following subsequent years of treatment is expected. The submitted field rotational crop study only approximates the annual application rates of the uses evaluated. The Meeting concluded that the information available does not allow estimation of pydiflumetofen residues in rotational crops, especially in view of expected plateau soil concentrations being significantly higher than the rate applied in the field rotational crop study available.

### ***Methods of analysis***

The Meeting received descriptions and validation data for analytical methods for residue of pydiflumetofen in plant commodities and for residues of pydiflumetofen, 2,4,6-TCP, SYN548264, SYN548263, SYN508272 and SYN547897 in animal commodities.

In the method for determination of pydiflumetofen in plant, homogenised samples were extracted with acetonitrile: water (80:20 v/v), with clean up via a solid phase extraction. Residues were determined by LC-MS/MS. The method of analysis was validated at various fortification levels with an LOQ of 0.01 mg/kg for pydiflumetofen. A QuEChERS method was also validated for pydiflumetofen residues in plant matrices with an LOQ of 0.01 mg/kg.

In the methods for determination of pydiflumetofen and 2,4,6-TCP in animal commodities, samples were homogenized with acetonitrile: water (80:20 v/v). The fat samples were dissolved into hexane and partitioned into acetonitrile: water (80:20 v/v). An aliquot for the analysis of pydiflumetofen was directly diluted with 0.1% ultra-pure water. A separate aliquot for the analysis of 2,4,6-TCP was hydrolysed by  $\beta$ -glucuronidase and cleaned up with a solid phase extraction. Residues of both compounds were determined by LC-MS/MS. The method of analysis was validated with LOQs of 0.01 mg/kg for pydiflumetofen and 2,4,6-TCP. QuEChERS method was also validated for pydiflumetofen residue in animal commodities with an LOQ of 0.01 mg/kg.

In the method for determination of SYN548264 and SYN508272 in milk, samples were shaken with acetonitrile and diluted with aqueous acetonitrile. Residues of both compounds were determined by LC-MS/MS. The method of analysis was validated with LOQs of 0.01 mg/kg for SYN548264 and SYN508272.

In the method for determination of SYN547897 and SYN548263 in kidney and liver, homogenised samples were extracted with acetonitrile: water (80:20 v/v) and filtered through a C18 cartridge. An aliquot was hydrolysed by  $\beta$ -glucuronidase and cleaned up with a solid phase extraction. Residues of both compounds were determined by LC-MS/MS. The method of analysis was validated with LOQs of 0.01 mg/kg for SYN547897 and SYN548263.

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

The Meeting received information on the freezer storage stability of pydiflumetofen in plant (lettuce, orange, oilseed rape seed, potato, beans without pods, wheat grain and straw), processed commodities of plants (corn, soya bean, grape and apple fractions) and animal commodities (bovine muscle, liver, fat, milk and eggs).

Storage stability results indicate that pydiflumetofen residues were stable at approximately -18 °C for at least 23 months in lettuce (high water), orange (high acid), oilseed rape seed (high oil), potato (high starch), beans without pods (high protein), wheat grain (high starch) and straw, at approximately -20 °C for at least 12 months in maize (flour, meal and oil), soya bean (flour, milk, oil), grape (raisin) and apple fractions (dried fruit and juice), and at approximately -20 °C for at least 24 months in bovine muscle, liver, fat, milk and eggs.

The Meeting also received information on the freezer storage stability of SYN508272 and SYN548264 in milk, SYN547897 in liver, SYN547897 and SYN548263 in kidney, and 2,4,6-TCP in bovine muscle, liver, kidney, fat, whole milk and egg. The residues of SYN508272, SYN548264, SYN547897, SYN548263 and 2,4,6-TCP were stable at approximately -18 °C for at least 12 months in animal commodities except SYN547897 in liver (up to 9 months).

The demonstrated periods of storage stability cover the sample storage intervals in the residue trials.

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

In plant metabolism studies, parent pydiflumetofen was a major component (30–97% TRR) for foliar treatment in wheat, tomato and oilseed rape. SYN545547 and SYN547891 were identified at 0.001–0.049 mg eq/kg (< 10% TRR) in wheat, tomato and oilseed rape. No other individual metabolite was present in the

edible plant parts at a level greater than 10% TRR.

The residue profile was similar in rotational crops, for which the only identified compounds were pydiflumetofen, SYN545547, and SYN547891. SYN547891 occurred at > 10%TRR in some commodities; however, in such cases, the concentration levels were < 0.005 mg eq/kg.

The Meeting decided that the suitable analyte for enforcement purposes is parent pydiflumetofen in plant commodities.

Although SYN545547 and SYN547891 share a high degree of structural similarity to parent pydiflumetofen and may be toxicologically relevant, the Meeting concluded that dietary exposure to these compounds is likely to be insignificant in comparison to that of the parent residue. Therefore, the Meeting decided that the suitable analyte for dietary risk assessment is pydiflumetofen in plant commodities.

In animal metabolism studies, pydiflumetofen was the principal component of the residue in fat (goat: 67–74% TRR, 0.15–0.21 mg/kg, hen: 17–31% TRR, 0.010–0.017 mg/kg) and egg white (27–47% TRR, 0.014–0.025 mg/kg), a major residue in goat muscle (13–24% TRR, 0.018–0.025 mg/kg), milk (8.7–16% TRR, 0.011–0.019 mg/kg) and goat liver (2.0–8.2% TRR, 0.18–0.57 mg/kg).

The Meeting decided that pydiflumetofen is a suitable analyte for enforcement purposes. Analytical methods are available to determine residues of pydiflumetofen in animal commodities.

In deciding if additional 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 those compounds.

2,4,6-TCP (free + conjugated form) was the principal component of the residue in egg yolk (68% TRR, 0.24 mg eq/kg), milk (43% TRR, 0.052 mg eq/kg) and fat (29% TRR, 0.030 mg eq/kg), a major residue in muscle (goat: 9.0% TRR, 0.009 mg/kg, hen: 48% TRR, 0.013 mg eq/kg) and egg white (15% TRR, 0.008 mg eq/kg).

SYN508272 (free form) was a major residue in milk (11% TRR, 0.014 mg eq/kg), muscle (goat: 18% TRR, 0.024 mg eq/kg, hen: 46% TRR, 0.010 mg eq/kg) and egg white (34% TRR, 0.018 mg eq/kg).

SYN548263 was a major component of the residue in milk (free form: 14% TRR, 0.019 mg eq/kg) and goat kidney (free + conjugated form: 17% TRR, 0.39 mg eq/kg).

SYN548264 (free form) was a major residue in milk (29% TRR, 0.038 mg eq/kg).

The other major residue was NOA449410 (free + conjugated form, goat kidney: 12% TRR, 0.28 mg eq/kg, egg white: 15% TRR, 0.008 mg eq/kg).

In the lactating dairy cow feeding studies, SYN548264 and SYN508272 residues (free form) in milk were < 0.01 mg/kg except for one cow (0.01 mg/kg) at the 150 ppm dose rate. SYN548263 residue (free + conjugated form) were found in kidney (0.02 mg/kg at 45 ppm and 0.08 mg/kg at 150 ppm) but < 0.01 mg/kg in liver. SYN547897 residue (free + conjugated form) were found in liver (0.06 mg/kg at 15 ppm and 0.60 mg/kg at 150 ppm) and kidney (0.08 mg/kg at 15 ppm and 0.44 mg/kg at 150 ppm).

The Meeting concluded that the metabolites 2,4,6-TCP, SYN547897, SYN548263, SYN548264, SYN508272 and NOA449410 may potentially contribute to the dietary exposure. All compounds are covered by the toxicological reference values for parent pydiflumetofen.

2,4,6-TCP (incl. conjugates) was found in all animal commodities. Therefore, the Meeting decided to include 2,4,6-TCP (including conjugates) in the residue definition for dietary exposure, and noted that this compound is not specific to the use of pydiflumetofen and can be formed in animal commodities from other sources.

SYN547897 was identified only in minor proportions in liver and kidney in the goat metabolism study. However, in the dairy cattle feeding study, it represented the major residue in liver and kidney, found at levels 4 to 10 times higher than parent. The Meeting concluded that SYN547897 (including conjugates) should be included in the residue definition for dietary exposure purposes specifically for mammalian liver and kidney.

SYN548263 was identified as a major metabolite in milk and kidney in the lactating goat metabolism study. In milk, its proportion was major (14% TRR), however absolute levels were low (0.019 mg eq/kg), following administration of 100 ppm in the diet. In view of the estimated dietary burden for dairy cattle of 1.2 ppm, the contribution of SYN548263 to the dietary exposure via milk was considered insignificant.

In kidney, the dairy cattle feeding study showed quantifiable residues of SYN548263 (incl. conjugates) at feeding levels of 45 ppm or higher. However, the Meeting noted that the metabolite SYN547897 was present at amounts approximately 10 times higher and concluded, that SYN548263 does not contribute significantly to the total residue and toxicological burden in kidney.

SYN548264 was a major residue in milk (up to 29% TRR). However, its presence in milk was not observed in the dairy cattle feeding study following the administration of parent pydiflumetofen up to 150 ppm. The Meeting concluded that SYN548264 does not contribute significantly to the dietary exposure via milk.

SYN508272 was a major residue in milk but found at < 0.01–0.01 mg/kg in the dairy cattle feeding study. SYN508272 was also found as the major residue in muscle (18% TRR in goat and 46% TRR in hen) and egg white (34% TRR), however the levels were low (0.01–0.02 mg eq/kg). The toxicity of SYN508272 is considered to be less than that of parent pydiflumetofen. The Meeting concluded that SYN508272 does not contribute significantly to the total residue and toxicological burden in muscle and egg.

NOA44910 (incl. conjugates) was a major residue in goat kidney (12% TRR) and egg white (15% TRR) but the level in egg white was < 0.01 mg/kg. In view of the dietary burden for dairy cattle as above, the expected contribution of NOA44910 to the dietary exposure was not significant.

The Meeting decided that for animal commodities, except mammalian liver and kidney, the definition for the estimation of the dietary exposure is the sum of pydiflumetofen and 2,4,6-TCP (incl. conjugates), expressed as pydiflumetofen. For mammalian liver and kidney, the definition for the estimation of the dietary exposure is the sum of pydiflumetofen, SYN547897 (incl. conjugates) and 2,4,6-TCP (incl. conjugates), expressed as pydiflumetofen.

The octanol/water coefficient (log Pow) of pydiflumetofen is 3.8. Pydiflumetofen in fat is 10 times higher than in muscle, and, in cream, more than 10 times higher than in skimmed milk. The Meeting considered the residue of pydiflumetofen to be fat-soluble.

The Meeting recommended the following residue definition:

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

Definition of the residue for animal commodities other than mammalian liver and kidney for dietary risk assessment: *sum of pydiflumetofen and 2,4,6-trichlorophenol (2,4,6-TCP) and its conjugates, expressed as pydiflumetofen*

Definition of the residue for mammalian liver and kidney for dietary risk assessment: *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

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

The Meeting received supervised residue trial data for foliar application of pydiflumetofen on grapes, cucumber, summer squash, cantaloupe, tomato, pepper, head lettuces, leaf lettuce, spinach, dry beans, soya bean, dry peas, potato, celery, wheat, barley, oats, maize, sweet corn, oilseed rape and peanut. Residue trials were conducted in Canada and the USA.

Labels from Argentina, Canada and the USA were available.

The Meeting concluded that accumulation of pydiflumetofen in soil and uptake of residues into rotational crops may significantly contribute to the terminal residue in food and feed commodities. The Meeting decided that residues found in annual crops following treatment as a primary crop (cucumber, summer squash, melon, tomato, pepper, head lettuces, leaf lettuce, spinach, dry beans, soya bean (dry), dry peas, potato, celery, wheat, barley, oats, maize, sweet corn, oilseed rape, peanut and pea vines) may substantially underestimate the potential residues and thus impact the estimation of maximum residue levels, STMRs and HRs.

For these crops, maximum residue levels, STMRs and HRs will be estimated by a future Meeting when additional information addressing the contribution of the additional uptake from soil become available.

### ***Berries and other small fruits***

#### ***Small fruit vine climbing***

#### ***Grapes***

Data were available from supervised trials on grapes in the USA.

The GAP of the USA for grape and small fruits vine climbing (Crop Subgroup 13–07F), except fuzzy kiwifruit allows foliar applications of up to 0.20 kg ai/ha at a maximum annual rate of 0.40 kg ai/ha with a PHI of 14 days.

Pydiflumetofen residues in grapes from independent trials in the USA matching USA GAP were (n = 11): < 0.01, 0.053, 0.16 (2), 0.20, 0.29, 0.37, 0.39, 0.50, 0.61 and 0.77 mg/kg.

The Meeting noted that the GAP of the USA is for grape and small fruits vine climbing except fuzzy kiwifruit and grape is the representative commodity for subgroup of small fruit vine climbing in the Codex classification.

Based on the residues in grapes from trials in the USA, the Meeting estimated a maximum residue level of 1.5 mg/kg, a STMR value of 0.29 mg/kg and a HR value of 0.85 mg/kg (based on the highest residue of replicate samples) for pydiflumetofen in the subgroup of small fruit vine climbing.

### ***Fruiting vegetables, Cucurbits***

The GAP for cucurbit vegetables, crop group 9 of the USA is two foliar applications of up to 0.13 kg ai/ha at a maximum annual rate of 0.25 kg ai/ha with a PHI of 0 days.

*Fruiting vegetables, Cucurbits – Cucumbers and Summer squashes**Cucumber*

Data were available from supervised trials on cucumber in the USA.

Pydiflumetofen residues in cucumber from independent trials in the USA matching USA GAP were (n = 10): 0.11 (3), 0.12, 0.14, 0.16 and 0.19 mg/kg (outdoor) and 0.11, 0.23 and 0.26 mg/kg (indoor).

*Squash, summer*

Data were available from supervised trials on summer squash in the USA.

Pydiflumetofen residues in summer squash from independent outdoor trials in the USA matching GAP were (n = 5): 0.056, 0.061, 0.10, 0.16 and 0.18 mg/kg.

*Fruiting vegetables, Cucurbits – Melons, Pumpkins and Winter Squashes**Melon*

Data were available from supervised trials on cantaloupe in the USA.

Pydiflumetofen residues in cantaloupe from independent outdoor trials in the USA matching GAP were (n = 6): 0.067, 0.078, 0.11, 0.15, 0.16 and 0.17 mg/kg.

To consider a maximum residue level for a group, residues in individual crops should be similar (e.g. medians should not differ by more than 5×). The Meeting agreed to estimate a maximum residue level for the group of fruiting vegetables, cucurbits. In considering whether to combine data to estimate a maximum residue level, the Meeting recognized that the residue populations from trials on cucumber, summer squash and cantaloupe were not different according to statistical test (Kruskal-Wallis H-test). Therefore the Meeting decided to combine the data from cucumber, summer squash and cantaloupe 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.

As indicated no recommendation could be made for fruiting vegetables, cucurbits.

*Fruiting vegetables, other than Cucurbits*

The GAP for fruiting vegetables, crop group 8–10 of the USA is two foliar applications of up to 0.13 kg ai/ha at a maximum annual rate of 0.25 kg ai/ha with a PHI of 0 days.

*Tomato*

Data were available from supervised trials on tomatoes in the USA.

Pydiflumetofen residues in tomato and cherry tomato from independent outdoor trials in the USA matching USA GAP were (n = 10+2): 0.030, 0.043, 0.075, 0.077, 0.082, 0.083, 0.11, 0.13, 0.16 and 0.23 mg/kg for tomato and 0.20 and 0.27 mg/kg for cherry tomato.

*Peppers*

Data were available from supervised trials on peppers in the USA.

Pydiflumetofen residues in bell pepper and non-bell pepper from independent outdoor trials in the USA matching USA GAP were (n = 6+3): 0.062, 0.076, 0.081, 0.17, 0.26 and 0.37 mg/kg for bell pepper and 0.088, 0.14 and 0.26 mg/kg for non-bell pepper.

To consider a maximum residue level for a group, residues in individual crops should be similar (e.g. medians should not differ by more than 5×). The Meeting agreed to estimate a maximum residue level for the group of fruiting vegetables, other than cucurbits. In considering whether to combine data to estimate a maximum residue level, the Meeting recognized that the residue populations from trials on tomatoes and peppers were not different according to statistical test (Mann-Whitney U-test). Therefore the Meeting decided to combine the data from tomatoes and peppers to estimate a maximum residue level for fruiting vegetables, other than cucurbits.

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.

As indicated no recommendation could be made for fruiting vegetables, other than cucurbits.

#### *Leafy vegetables (including Brassica leafy vegetables)*

##### *Leafy greens*

The GAP for leafy greens, crop subgroup 4-16A of the USA is two foliar applications of up to 0.20 kg ai/ha at a maximum annual rate of 0.40 kg ai/ha with a PHI of 0 days.

##### *Lettuce, Head*

Data were available from supervised trials on head lettuce in the USA.

Pydiflumetofen residues in head lettuce with wrapper leaves from independent trials in the USA matching GAP were (n = 8): 0.51, 0.78, 1.2, 2.3, 2.4, 2.6, 3.0 and 4.5 mg/kg.

##### *Lettuce, Leaf*

Data were available from supervised trials on leaf lettuce in the USA.

Pydiflumetofen residues in leaf lettuce from independent trials in the USA matching GAP were (n = 8): 1.7, 3.5, 4.4, 5.5, 7.7, 9.7, 11 and 12 mg/kg.

##### *Spinach*

Data were available from supervised trials on spinach in the USA.

Pydiflumetofen residues in spinach from independent trials in the USA matching GAP were (n = 8): 7.5, 9.2, 9.7, 12, 13 (2), 14 and 16 mg/kg.

To consider a maximum residue level for a group, residues in individual crops should be similar (e.g. medians should not differ by more than 5×). The Meeting agreed to estimate a maximum residue level for the subgroup of leafy greens. In considering whether to combine data to estimate a maximum residue level, the Meeting recognized that the residue populations from trials on head lettuce, leaf lettuce and spinach were significantly different according to statistical test (Kruskal-Wallis H-test). Therefore the Meeting decided to use the dataset from spinach leading to the highest maximum residue level for leafy greens.

As indicated no recommendation could be made for leafy greens.

*Pulses*

The GAP for dried shelled peas and beans (except soya bean) of Canada and the USA is two foliar applications of up to 0.20 kg ai/ha with an application interval of 14 days, at a maximum annual rate of 0.40 kg ai/ha with a PHI of 14 days.

The GAP for soya bean of Canada and the USA is two foliar applications of up to 0.20 kg ai/ha with an application interval of 7–14 days, at a maximum annual rate of 0.40 kg ai/ha with a PHI of 14 days.

*Dry beans**Beans (dry)*

Data were available from supervised trials on dry beans in Canada and the USA.

Pydiflumetofen residues in dry beans from independent trials in Canada and the USA matching GAP were (n = 10): < 0.01 (5), 0.014, 0.018, 0.060, 0.10 and 0.24 mg/kg.

*Soya bean (dry)*

Data were available from supervised trials on soya bean in the USA.

Pydiflumetofen residues in soya bean from independent trials in the USA matching GAP were (n = 21): < 0.01 (4), 0.011, 0.012, 0.013, 0.016 (2), 0.027, 0.028, 0.029, 0.031, 0.032, 0.036, 0.039, 0.041, 0.060, 0.088, 0.29 and 0.37 mg/kg.

*Dry peas**Peas (dry)*

Data were available from supervised trials on dry peas in Canada and the USA.

Pydiflumetofen residues in dry peas from independent trials in Canada and the USA matching GAP were (n = 10): 0.023 (2), 0.028, 0.035, 0.053, 0.057, 0.059, 0.063, 0.064 and 0.096 mg/kg.

To consider a maximum residue level for a group, residues in individual crops should be similar (e.g. medians should not differ by more than 5×). The Meeting agreed to estimate a maximum residue level for the subgroup of dry beans and the subgroup of dry peas. In considering whether to combine data to estimate a maximum residue level, the Meeting recognized that the residue populations from trials on dry beans, soya bean and dry peas were not different according to statistical test (Kruskal-Wallis H-test). Therefore the Meeting decided to combine the data from dry beans, soya bean and dry peas to estimate a maximum residue level for the subgroup of dry beans and the 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.

As indicated no recommendation could be made for the subgroup of dry beans and the subgroup of dry peas.



*Root and tuber vegetables**Tuberous and corm vegetables**Potato*

Data were available from supervised trials on potato in Canada and the USA.

The GAP for tuberous and corm vegetables crop subgroup 1C of the USA is three foliar applications of up to 0.13 kg ai/ha at a maximum annual rate of 0.38 kg ai/ha with a PHI of 7 days.

Pydiflumetofen residues in potatoes from independent trials in Canada and the USA matching GAP were (n = 22): < 0.01 (21) and 0.014 mg/kg.

No recommendation can be made for tuberous and corm vegetables.

*Stalk and stem vegetables**Stalk and stem vegetables - Stems and Petioles**Celery*

Data were available from supervised trials on celery in the USA.

The GAP for leaf petioles vegetables, crop subgroup 22B of the USA is two foliar applications of 0.073–0.20 kg ai/ha at a maximum annual rate of 0.40 kg ai/ha with a PHI of 0 day.

Pydiflumetofen residues in celery from independent trials in the USA matching GAP were (n = 8): 2.6, 2.7, 3.9, 4.3, 4.5, 4.8, 5.4 and 8.1 mg/kg.

As indicated no recommendation could be made for stems and petioles.

*Cereal grains*

The GAP for cereal grains in the USA is a foliar application of up to 0.20 kg ai/ha at a maximum annual rate of 0.35 kg ai/ha, do not apply after full head emergence (Feekes 10.54 = BBCH 71).

*Wheat, similar grains, and Pseudocereals without husks**Wheat*

Data were available from supervised trials on wheat in Canada and the USA.

Pydiflumetofen residues in wheat grains from independent trials in Canada and the USA matching 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.

As indicated no recommendation could be made for wheat, similar grains, and pseudocereals without husks.

*Barley, similar grains, and pseudocereals with husks**Barley*

Data were available from supervised trials on barley in Canada and the USA.

Pydiflumetofen residues in barley grains from independent trials in Canada and the USA matching GAP were (n = 14): 0.068, 0.081 (2), 0.11, 0.15, 0.19, 0.20, 0.23, 0.31, 0.55, 0.57, 0.66, 0.82 and 3.0 mg/kg.

*Oats*

Data were available from supervised trials on oats in Canada and the USA.

Pydiflumetofen residues in oats from independent trials in Canada and the USA matching GAP were (n = 24): 0.056, 0.079, 0.11, 0.12, 0.14, 0.15 (2), 0.19, 0.20, 0.21, 0.22, 0.23, 0.24, 0.27, 0.32, 0.36, 0.41, 0.44, 0.48, 0.51, 0.54, 0.66, 0.94 and 2.1 mg/kg.

The combined pydiflumetofen residues in barley 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.

As indicated no recommendation could be made for barley, similar grains, pseudocereals with husks.

*Maize Cereals**Maize*

Data were available from supervised trials on field corn and popcorn in Canada and the USA.

The GAP for corn (field corn and popcorn) of the USA is a foliar application of up to 0.20 kg ai/ha at a maximum annual rate of 0.25 kg ai/ha with a PHI of 30 days.

Pydiflumetofen residues in field corn and popcorn from independent trials in Canada and the USA matching GAP were (n = 22): < 0.01 (21) and 0.012 mg/kg.

No recommendation can be made for maize cereals.

*Sweet Corns**Sweet corn (Corn-on-the-cob) (kernels plus cob with husk removed)*

Data were available from supervised trials on sweet corn in the USA.

The GAP for sweet corn in the USA is two foliar application of up to 0.13 kg ai/ha at a maximum annual rate of 0.25 kg ai/ha with a PHI of 7 days.

Pydiflumetofen residues in sweet corn from independent trials in the USA matching GAP were (n = 12): < 0.01 (12) mg/kg.

As indicated no recommendation could be made for sweet corn.

*Oilseeds and oilfruits**Small seed oilseeds**Rape seed*

Data were available from supervised trials on oilseed rape in Canada and the USA.

The GAP for canola (rapeseed, crop subgroup 20A) of Canada and the USA is a foliar application of up to 0.20 kg ai/ha at a maximum annual rate of 0.33 kg ai/ha with a PHI of 30 days.

Pydiflumetofen residues in rape seed from independent trials in Canada and the USA matching 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.

No recommendation can be made for small seed oilseeds.

*Other oilseeds*

*Peanut*

Data were available from supervised trials on peanut in the USA.

The GAP for peanut in the USA is four foliar application of 0.025–0.050 kg ai/ha at a maximum annual rate of 0.20 kg ai/ha with a PHI of 14 day.

Pydiflumetofen residues in peanut nutmeat from independent trials in the USA matching GAP were (n = 12): < 0.01 (9), 0.012 and 0.018 (2) mg/kg.

No recommendation can be made for peanut.

***Animal feedstuffs***

*Legume animal feeds*

*Pea vines and hay*

Data were available from supervised trials on pea in the USA.

The GAP for vine and hay of dried shelled peas and beans (except soya bean) in Canada is two foliar applications of up to 0.20 kg ai/ha at a maximum annual rate of 0.40 kg ai/ha with a PHI of 14 days.

Pydiflumetofen residues in pea vines (as received basis) from independent trials in the USA matching GAP were (n = 5): 0.36, 0.42, 0.88, 0.90 and 2.8 mg/kg.

As indicated no recommendation could be made for pea vines.

Pydiflumetofen residues in pea hay (dry weight basis) from independent trials in the USA matching GAP were (n = 5): 1.8, 3.0, 3.4, 5.9 and 17 mg/kg.

As indicated no recommendation could be made for pea hay until the contribution of residues in dry peas from direct application as well as uptake through the soil can be assessed.

*Peanut hay*

Data were available from supervised trials on peanut in the USA.

The GAP for peanut in the USA is four foliar application of up to 0.050 kg ai/ha at a maximum annual rate of 0.20 kg ai/ha with a PHI of 14 days.

Pydiflumetofen residues in peanut hay (dry weight basis) from independent trials in the USA matching GAP were (n = 11): 2.0, 3.1, 4.3, 4.5, 4.7, 9.2, 12 (3), 13 and 15 mg/kg.

As indicated no recommendation could be made for peanut fodder until the contribution of residues in peanut from direct application as well as uptake through the soil can be assessed.

*Soya bean forage and hay*

Data were available from supervised trials on soya bean in the USA.

The GAP for soya bean in Canada and the USA does not allow the feeding of treated forage, hay and silage to livestock. The GAP for soya bean of Argentina is two foliar application of up to 0.045 kg ai/ha with a PHI of 30 day.

The trials conducted in the USA do not match the GAP for soya bean in Argentina.

The Meeting agreed that no recommendation could be made for soya bean forage and fodder.

#### *Straw and fodder (dry) of cereal grains*

The GAP for cereal grains in the USA is a foliar application of up to 0.20 kg ai/ha at a maximum annual rate of 0.35 kg ai/ha, do not apply after full head emergence (Feekes 10.54 = BBCH 71). The GAP for cereal hay in the USA is a foliar application of up to 0.20 kg ai/ha with a PHI of 7 days.

#### *Barley straw and fodder, dry*

Data were available from supervised trials on barley in Canada and the USA.

Pydiflumetofen residues in barley straw (correction for an average 89% dry matter content) and hay (dry weight basis) from independent trials in Canada and the USA matching GAP were (n = 21): 1.4, 3.7, 4.0, 4.2, 5.1, 5.7, 6.0, 6.5, 6.8, 8.0, 8.4, 9.2 (2), 10, 11, 13, 14, 17, 18, 20 and 26 mg/kg on a dry weight basis.

#### *Oat straw and fodder, dry*

Data were available from supervised trials on oats in Canada and the USA.

Pydiflumetofen residues in oats straw (correction for an average 90% dry matter content) and hay (dry weight basis) from independent trials in Canada and the USA matching GAP were (n = 29): 1.4, 1.9, 2.0, 2.2, 3.0, 3.1, 3.7, 3.8, 3.9, 4.7, 5.3, 5.5, 5.7, 5.9, 6.6, 7.5, 7.7, 8.2, 8.3, 10, 11 (2), 14, 15, 19, 21, 23 (2) and 25 mg/kg on a dry weight basis.

#### *Wheat straw and fodder, dry*

Data were available from supervised trials on wheat in Canada and the USA.

Pydiflumetofen residues in wheat straw (correction for an average 88% dry matter content) and hay (dry weight basis) from independent trials in Canada and the USA matching GAP were (n = 31): 1.8, 2.5, 3.6, 4.0, 4.5, 5.7, 6.5, 6.8, 7.2, 8.0, 9.5, 9.9, 10, 11, 12 (2), 13, 16, 17 (2), 18, 19, 20 (4), 24, 29, 33, 34 and 40 mg/kg on a dry weight basis.

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.

As indicated no recommendation could be made for straw and fodder (dry) of cereal grains until the contribution of residues in cereal grains from direct application as well as uptake through the soil can be assessed.

#### *Oat forage*

Data were available from supervised trials on oats in Canada and the USA.

The GAP for cereal forage in the USA is a foliar application of up to 0.20 kg ai/ha with a PHI of 7 days.

Pydiflumetofen residues in oats forage (as received basis) from independent trials in Canada and the USA matching 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 and 7.0 mg/kg.

As indicated no recommendation could be made for oat forage until the contribution of residues in cereal grains from direct application as well as uptake through the soil can be assessed.

#### *Wheat forage*

Data were available from supervised trials on wheat in Canada and the USA.

The GAP for cereal forage of the USA is a foliar application of up to 0.20 kg ai/ha with a PHI of 7 days.

Pydiflumetofen residues in wheat forage (as received basis) from independent trials in Canada and the USA matching 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.

As indicated no recommendation could be made for wheat forage until the contribution of residues in cereal grains from direct application as well as uptake through the soil can be assessed.

#### *Maize forage*

Data were available from supervised trials on field corn in the USA.

The GAP for corn (field corn and popcorn) forage in the USA is a foliar application of up to 0.20 kg ai/ha with a PHI of 7 days.

Pydiflumetofen residues in corn forage (as received basis) from independent trials in the USA matching 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.

As indicated no recommendation could be made for maize forage until the contribution of residues in maize from direct application as well as uptake through the soil can be assessed.

#### *Sweet corn forage*

Data were available from supervised trials on sweet corn in the USA.

The GAP for sweet corn in the USA is two foliar application of up to 0.13 kg ai/ha at a maximum annual rate of 0.25 kg ai/ha with a PHI of 7 days.

Pydiflumetofen residues in sweet corn forage (as received basis) from independent trials in the USA matching 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.

As indicated no recommendation could be made for sweet corn forage until the contribution of residues in sweet corn from direct application as well as uptake through the soil can be assessed.

#### *Maize fodder*

Data were available from supervised trials on field corn and popcorn in the USA.

The GAP for corn (field corn and popcorn) of Canada is two foliar application of 0.10 kg ai/ha at a maximum annual rate of 0.20 kg ai/ha with a 30-day PHI.

Pydiflumetofen residues in corn stover (as received basis) from independent trials in the USA matching 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.

As indicated no recommendation could be made for maize fodder until the contribution of residues in maize from direct application as well as uptake through the soil can be assessed.

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

#### ***High temperature hydrolysis***

The hydrolytic stability of [pyrazole-5-<sup>14</sup>C]-pydiflumetofen was studied under conditions of high temperature in sterile aqueous buffers at pH 4, 5 and 6 for periods of up to 60 minutes so as to simulate common processing practices (pasteurization, baking/brewing/boiling, and sterilization). Pydiflumetofen recoveries ranged from 95.5 to 97.5% of the applied radioactivity at the investigated pH and temperature ranges. Pydiflumetofen is considered stable under hydrolytic conditions at high temperatures.

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

The fate of pydiflumetofen residues has been examined in grape processing studies. Estimated processing factors and the derived STMR-Ps are summarised in the Table below.

Processing factors, STMR-P and HR-P for food and feed

Crop	Commodity	Calculated processing factors* [best estimate]	maximum residue level (mg/kg)	STMR-P (mg/kg)	HR-P (mg/kg)
		Pydiflumetofen			
Grape	RAC (fruit)	-	1.5	0.29	0.85
	Must	0.13, 0.32, 0.44, 0.62, 1.5, 1.7, 2.1, 3.0 [1.06]	-	0.31	-
	Juice	0.02, 0.02, 0.05, 0.07, 0.49, 0.57 [0.06]	-	0.017	-
	Red wine	< 0.20, 0.10, 0.17, 0.24 [0.135]	-	0.039	-
	White wine	0.08, 0.11, 0.52, 0.60 [0.315]	-	0.091	-
	Dried grapes	1.7, 2.0, 2.4, 2.5, 2.8, 4.8 [2.45]	4	0.71	2.1
	Refined seed oil	0.71, 1.0, 1.1, 1.1 [1.05]	-	0.30	-
	Wet pomace	0.39, 1.0, 1.6, 2.3, 2.4, 3.0, 4.3, 4.4, 6.3, 8.0, 8.3 [3.0]	-	0.87	-

\* Each value represents a separate study. The factor is the ratio of the residue in processed commodity divided by the residue in the RAC.

### ***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 pydiflumetofen residues in the animal diet.

#### ***Lactating dairy cows***

Holstein/Friesian dairy cows were dosed with pydiflumetofen for 28 days at the equivalent of 15, 45 and 150 ppm in the diet. Residues of pydiflumetofen were below the LOQ (0.01 mg/kg) in muscle at all feeding levels. Whole milk and kidney contained no residue (< 0.01 mg/kg) of pydiflumetofen at the 15 and 45 ppm feeding level. Liver and fat contained pydiflumetofen residues of < 0.01–0.01 mg/kg at the 15 ppm feeding level, 0.02–0.05 mg/kg at the 45 ppm level and 0.05–0.10 mg/kg at the 150 ppm level.

For estimation of dietary exposure, residues of pydiflumetofen and 2,4,6-TCP (free + conjugated forms; total 2,4,6-TCP), expressed as pydiflumetofen were below the LOQ in muscle at all feeding levels. Whole milk contained no residue (<LOQ) of pydiflumetofen and total 2,4,6-TCP, expressed as pydiflumetofen at the 15 ppm feeding level. Residues of pydiflumetofen and total 2,4,6-TCP, expressed as

pydiflumetofen in whole milk achieved a plateau concentration of 0.03–0.05 mg/kg at the 45 feeding ppm level and 0.18–0.20 mg/kg at the 150 ppm level.

Residues of pydiflumetofen, total 2,4,6-TCP and SYN547897 (free + conjugated form), expressed as pydiflumetofen in liver and kidney were 0.07–0.08 mg/kg at the 15 ppm feeding level, 0.28–0.31 mg/kg at the 45 ppm level and 0.78 mg/kg at the 150 ppm level.

#### *Laying hens*

Laying hens were dosed with pydiflumetofen for 28 days at the equivalent of 3, 9 and 30 ppm in the diet. Residues of pydiflumetofen were below the LOQ (0.01 mg/kg) in muscle, liver, kidney and fat at all feeding levels, and in eggs at the 3 ppm feeding level. At the 30 ppm level, pydiflumetofen residues in eggs were 0.02–0.03 mg/kg from day 3 to day 24.

For estimation of dietary exposure, residues of pydiflumetofen and total 2,4,6-TCP, expressed as pydiflumetofen were below the LOQ in muscle, liver and fat at all feeding levels. Eggs contained no residue (<LOQ) of pydiflumetofen and total 2,4,6-TCP, expressed pydiflumetofen at the 3 ppm feeding level. Residues of pydiflumetofen and total 2,4,6-TCP, expressed as pydiflumetofen in eggs achieved a plateau concentration of 0.03 mg/kg at the 9 ppm feeding level and 0.09 mg/kg at the 30 ppm level. Kidney contained pydiflumetofen and total 2,4,6-TCP, expressed as pydiflumetofen of 0.05 mg/kg at the 9 ppm feeding level and 0.12 mg/kg at the 30 ppm level.

#### *Farm animal dietary burden*

The Meeting concluded that the contribution of the additional uptake from soil to residues in feed commodities following treatment as a primary crop may significantly increase the terminal residue. However, the information available for rotational crops was not considered sufficient to estimate median and highest residues in feed commodities. Therefore, the current Meeting did not estimate the farm animal dietary burden and consequently did not estimate residues in animal commodities.

At a future Meeting, the farm animal dietary burden will be estimated when additional information addressing the contribution of soil uptake into feed commodities becomes available.

### **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.

The Meeting recommended the following residue definitions for pydiflumetofen.

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

Definition of the residue for animal commodities other than mammalian liver and kidney for dietary risk assessment: *sum of pydiflumetofen and 2,4,6-trichlorophenol (2,4,6-TCP) and its conjugates, expressed as pydiflumetofen*

Definition of the residue for mammalian liver and kidney for dietary risk assessment: *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 2018 JMPR Report. The IEDIs were 0% 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 2018 JMPR Report. The IESTIs varied from 0–20% of the ARfD for children and 0–9% for the general population.

The Meeting concluded that acute dietary exposure to residues of pydiflumetofen from uses considered by the present Meeting is unlikely to present a public health concern.



## 5.25 PYRACLOSTROBIN (210)

### TOXICOLOGY

Pyraclostrobin was evaluated previously by JMPR in 2003, when an ADI of 0–0.03 mg/kg bw was established based on a NOAEL of 3.4 mg/kg bw per day in two 2-year studies in rats and application of a safety factor of 100. An ARfD of 0.05 mg/kg bw was established based on a NOAEL of 5 mg/kg bw per day for embryo and fetal toxicity in a developmental toxicity study in rabbits and application of a safety factor of 100. The 2003 Meeting noted that further information on the relationship between local irritation of the gastrointestinal tract and reduced body weight gains in pregnant rabbits and the effect of maternal nutritional deficit on fetal resorptions might allow the ARfD to be refined.

Following a request by CCPR for additional maximum residue levels and an evaluation of metabolites possibly relevant to these new uses, pyraclostrobin was placed on the agenda of the present Meeting, which assessed additional toxicological information available since the last review.

Additional studies on pyraclostrobin (inhalation toxicity in rats, carcinogenicity in rats and the mechanism of mucosal hyperplasia in the duodenum) and its metabolites (toxicity and genotoxicity studies) were evaluated by the present Meeting. In particular, the present Meeting reviewed the new studies on pyraclostrobin to determine whether they would allow its ARfD to be refined.

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***

Based on in vivo studies or in vitro incubations with rat serum or plasma, six biotransformation reactions were observed: 1) desmethoxylation of the side-chain, 2) hydroxylation of the chlorophenyl pyrazole ring system, 3) hydroxylation of the tolyl ring system, 4) cleavage of the ether bond, resulting in chlorophenyl pyrazole or anthranilic acid derivatives, 5) desmethylation of the side-chain and 6) cleavage of the amide bond in the side-chain. The combination of these reactions with subsequent conjugation resulted in a large number of metabolites.

An in vitro comparison of metabolic profiles among rats, rabbits, dogs and humans shows the same key degradation steps in all species. The metabolites 500M04, 500M73, 500M108, 500M103, 500M104 and 500M88 were common to all test species. 500M02, 500M106 and 500M107, identified as the metabolites in humans, were also identified in other species used for toxicological testing.

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

Additional data were made available on the histopathology of the 2-year toxicity and carcinogenicity studies in rats that had been evaluated by the 2003 Meeting, and two 2-year toxicity and carcinogenicity studies not available to the 2003 Meeting were submitted. The two new studies were conducted at concentrations (400 and 600 ppm, respectively) higher than those used in the first study. As these concentrations were above the maximum tolerable dose because of toxicity resulting in early termination, these studies provided no additional information relevant to the risk assessment.

Three new immunotoxicity studies were conducted, one of which was uninterpretable due to the inconsistent results in negative and positive controls.

In an immunotoxicity study, female mice were administered pyraclostrobin in the diet at 0, 50, 200 or 750 ppm (equal to 0, 13, 50 and 165 mg/kg bw per day, respectively) for 28 days. The NOAEL for immunotoxicity was 750 ppm (equal to 165 mg/kg bw per day), the highest dose tested. The NOAEL for systemic toxicity was 200 ppm (equal to 50 mg/kg bw per day), based on reduced body weight gain and feed consumption and reduced thymus and spleen weights at 750 ppm (equal to 165 mg/kg bw per day). The reduced spleen and thymus weights were considered to be secondary to the extreme reductions in body weight gain in mice receiving 750 ppm.

Another immunotoxicity study was conducted in female mice administered pyraclostrobin in the diet at 0, 50, 200 or 750 ppm (equal to 0, 14, 55 and 191 mg/kg bw per day, respectively) for 28 days. The NOAEL for immunotoxicity was 750 ppm (equal to 191 mg/kg bw per day), the highest dose tested. The NOAEL for systemic toxicity was 200 ppm (equal to 55 mg/kg bw per day), based on reduced body weight gain and feed consumption, decreased thymus and spleen weights, and low numbers of spleen cells at 750 ppm (equal to 191 mg/kg bw per day). The reduced spleen and thymus weights were considered secondary to the extreme reductions in body weight gain in mice receiving 750 ppm.

The Meeting concluded that pyraclostrobin is not immunotoxic.

A study of phototoxicity in vitro indicated that pyraclostrobin was not phototoxic.

Two repeated-dose inhalation studies in rats were submitted. In the first study, rats were exposed to an aerosol of pyraclostrobin, nose only, at 0, 1, 30 or 300 mg/m<sup>3</sup> for 6 hours per day, 5 days per week, for 4 weeks. In the second study, rats were exposed to an aerosol of pyraclostrobin, nose only, at 0, 3, 10 or 30 mg/m<sup>3</sup> for 6 hours per day, 5 days per week, for 4 weeks. In both studies, there were local irritant effects leading to inflammation of the nasal tract at 30 mg/m<sup>3</sup>. In addition, mucosal hyperplasia in the duodenum was observed at 30 mg/m<sup>3</sup> in the first study (no-observed-adverse-effect concentration [NOAEC] of 1 mg/m<sup>3</sup>) and not seen in the second study (NOAEC of 30 mg/m<sup>3</sup>, the highest dose tested).

Additional studies indicated that the mucosal hyperplasia observed in mice, rats and dogs following repeated dietary exposure could be induced by reduced uptake of iron in the duodenum, resulting in lower serum iron levels, but not by local irritation. It is unlikely that this mode of action would be applicable to effects seen after a single dose.

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

#### ***500M04***

500M04 (pyrazolon) is a metabolite in rats, rabbits and humans. Its acute oral LD<sub>50</sub> is greater than 2000 mg/kg bw. 500M04 was not irritating to the eyes of rabbits, slightly irritating to the skin of rabbits and not sensitizing in guinea-pigs.

500M04 was tested for genotoxicity in an adequate range of in vitro and in vivo assays. No evidence of genotoxicity was found.

In a 3-month toxicity study in which rats were administered 500M04 by gavage at a dose of 0, 100, 300 or 1000 mg/kg bw per day, the NOAEL was 100 mg/kg bw per day, based on kidney effects at 300 mg/kg bw per day. Effects on the kidney were also identified with the parent compound, with a NOAEL of 10.7 mg/kg bw per day in a short-term toxicity study in rats.

The Meeting concluded that the toxicity of 500M04 was similar to or lower than that of pyraclostrobin.

**500M106**

500M106 is a metabolite in rats, rabbits and humans. In a 28-day study in which rats were administered 500M106 by gavage at a dose of 0, 100, 300 or 1000 mg/kg bw per day, the NOAEL was 300 mg/kg bw per day, based on effects on the duodenum, liver, spleen and haematological system at 1000 mg/kg bw per day. These effects were also observed for pyraclostrobin, but at much higher doses.

500M106 was tested for genotoxicity in an adequate range of in vitro and in vivo assays. Negative results were seen in an Ames test and a chromosomal aberration assay. In a forward mutation test, 500M106 was positive with S9. In two genotoxicity studies in vivo (micronucleus assay in mice and Muta™Mouse transgenic mouse model), 500M106 showed no genotoxicity.

The Meeting concluded that the toxicity of 500M106 was similar to or lower than that of pyraclostrobin.

**500M02**

500M02 was tested for genotoxicity in an adequate range of in vitro assays. No evidence of genotoxicity was found.

The subchronic toxicity of 500M02 was considered to be tested in the 28-day rat study with 500M106, as 500M02 is metabolically formed from 500M106 to a substantial extent (~11.5% of the dose).

The Meeting concluded that, on the basis of its formation from 500M106 and the absence of genotoxicity, the toxicity of 500M02 was similar to or lower than that of pyraclostrobin.

**500M24**

500M24 was tested for genotoxicity in an adequate range of in vitro and in vivo assays. It gave negative results for gene mutation and a positive response in an in vitro chromosomal aberration assay, but it was negative in an in vivo micronucleus test.

**500M49**

500M49 was tested for genotoxicity in an adequate range of in vitro assays. No evidence of genotoxicity was found.

**500M51**

500M51 was tested for genotoxicity in an adequate range of in vitro assays. No evidence of genotoxicity was found.

**500M76**

500M76 was tested for genotoxicity in an adequate range of in vitro and in vivo assays, producing mainly negative results. It gave a positive response in an in vitro chromosomal aberration assay, but it was negative in an in vivo micronucleus test.

**500M07 (plant metabolite)**

No toxicological information on 500M07 was submitted to the present Meeting; however, 500M07 is a rat metabolite found in serum and is formed early in the metabolic pathway.

**Human data**

Information on 33 cases of accidental exposure to pyraclostrobin was submitted. In almost all incidents,

the exposure was to spray drift from aerial application. The most severe incident involved 27 subjects. Skin, eye and upper respiratory irritation were frequently reported.

### Toxicological evaluation

The Meeting concluded that no revision of the ADI established by the 2003 Meeting was necessary.

The Meeting established a new ARfD of 0.7 mg/kg bw, based on the overall NOAEL of 5.8 mg/kg bw per day in 90-day and 1-year dog feeding studies (evaluated by the 2003 Meeting). A safety factor of 8 (2.5 for interspecies toxicodynamic differences, 3.2 for interindividual toxicodynamic differences) was applied. The previous ARfD was withdrawn.

Vomiting and diarrhoea seen during the first week of dosing of dogs with feed at 11 mg/kg bw per day were identified as the critical effects. These critical effects are considered to be secondary to a direct, local effect of pyraclostrobin on the gastrointestinal tract, which is local concentration related and independent of absorption and metabolism. Therefore, the default 100-fold safety factor was modified based on the scheme outlined by IPCS on chemical-specific adjustment factors by removing the interindividual and interspecies toxicokinetic factors of 3.2 and 4, respectively.

The Meeting concluded that the effects secondary to local irritation following gavage dosing with pyraclostrobin were not relevant to human dietary risk assessment, and therefore the basis for the previously established ARfD was no longer applicable, as this was a gavage study in rabbits.

#### Acute reference dose (ARfD)

0.7 mg/kg bw

#### Critical end-points for setting guidance values for exposure to pyraclostrobin

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

Metabolism	Desmethoxylation of the side-chain Hydroxylation of the chlorophenyl pyrazole ring system Hydroxylation of the tolyl ring system Cleavage of the ether bond, resulting in chlorophenyl pyrazole or anthranilic acid derivatives Desmethylation of the side-chain Cleavage of the amide bond in the side-chain
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Toxicologically significant compounds in animals and plants	Pyraclostrobin
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##### *Other toxicological studies*

Immunotoxicity	No immunotoxicity
Phototoxicity	No phototoxicity

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##### *Studies on toxicologically relevant metabolites*

500M04 (pyrazolon)	Oral LD <sub>50</sub> > 2 000 mg/kg bw (rats) Three-month oral toxicity study NOAEL 100 mg/kg bw per day (rats) No evidence of genotoxicity
500M24	No evidence of genotoxicity in vivo

500M49	No evidence of genotoxicity in vitro
500M51	No evidence of genotoxicity in vitro
500M76	No evidence of genotoxicity in vivo
500M02	No evidence of genotoxicity in vitro
500M106	Four-week oral toxicity study NOAEL 300 mg/kg bw per day (rats)
	No evidence of genotoxicity in vivo

#### Human data

Skin, eye or upper respiratory irritation

### Summary

	Value	Study	Safety factor
ARfD	0.7 mg/kg bw	Ninety-day and 1-year feeding studies in dogs	8

### RESIDUE AND ANALYTICAL ASPECTS

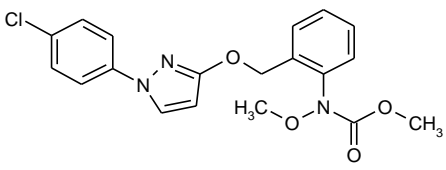
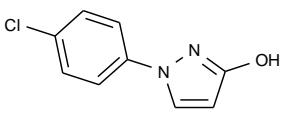
Pyraclostrobin was first evaluated for toxicology by the 2003 JMPR when an ADI of 0–0.03 mg/kg bw and an ARfD of 0.05 mg/kg bw were established. The current Meeting established a new ARfD of 0.7 mg/kg bw. The compound was evaluated for residues by the JMPR in 2006, 2011 and 2014, and was listed by the Forty-ninth Session of the CCPR for the evaluation of additional uses by the 2018 JMPR. The Meeting received information on the animal and plant metabolism, analytical methods, use patterns, supervised trials, and processing.

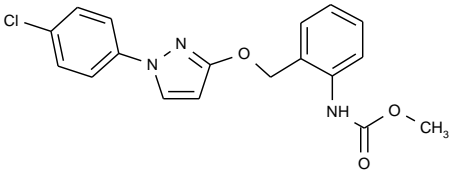
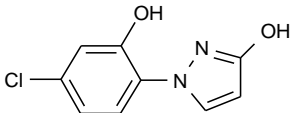
The 2004 JMPR recommended the following residue definition for pyraclostrobin:

Definition of the residue for compliance with the MRL and for dietary risk assessment: *pyraclostrobin*.

The residue is fat-soluble.

The following metabolites of pyraclostrobin are discussed in this document

Code Name	Chemical Name	Structure
Pyraclostrobin	methyl N-(2-([1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxymethyl)phenyl)-(N-methoxy)carbamate	
500M04	1-(4-chlorophenyl)-1H-pyrazol-3-ol	

Code Name	Chemical Name	Structure
500M07	methyl N-(2-([1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxymethyl)phenyl) carbamate	
500M85	1-(4 chloro2-hydroxy phenyl) 1H-pyrazol-3-yl	

### Plant metabolism

The Meeting received four new metabolism studies, three for foliar treatment (grape, Chinese cabbage, rice) and for one seed treatment (wheat).

#### Grape

Grape vines received six foliar applications of chlorophenyl- or tolyl- [ $^{14}\text{C}$ ] pyraclostrobin at a rate of 250 g ai/ha (total 1500 g ai/ha). The first application was performed at growth stage BBCH 53–55 (inflorescences visible to fully developed), and the application was repeated 5 times approximately every 16 to 19 days thereafter. The last application was done at BBCH 81 (beginning of ripening), 40 days before harvest.

TRR levels ranged from 0.95 to 1.56 mg eq/kg in grape berries and from 40 to 41 mg eq/kg in grape leaves. In grape berries, the extraction of radioactivity with methanol was high (84 to 88% TRR). Parent compound (56–62% TRR) and its main metabolite 500M07 (11–17% TRR) were shown to be present in grape methanol extracts. Three minor metabolites were shown to be present in grape berries,  $\leq 4\%$  TRR.

In leaves, around 70% of the TRR could be extracted with methanol for both labels. Most of the radioactivity (54% TRR) was found to be organo-soluble. Pyraclostrobin and its desmethoxy metabolite 500M07 formed the major part of the radioactivity in the MeOH extracts.

#### Chinese cabbage

The metabolism of pyraclostrobin in Chinese cabbage (head, *Shin-Kyoto No. 3*) was investigated following three foliar treatments of chlorophenyl- or tolyl- [ $^{14}\text{C}$ ] pyraclostrobin at a rate of 130 g ai/ha (total 390 g ai/ha) and applied at a 7 day interval. Three days after the final application, the treated plants were harvested and separated into a leaf-ball (as edible portion) and outer leaves.

TRR levels ranged from 2.8 to 3.7 mg eq/kg in outer leaves and from 1.1 to 1.2 mg eq/kg in leaf ball. The extraction of radioactivity with benzene and methanol ranged from 89 to 109% of the TRR. Most of the residues were unchanged pyraclostrobin, representing 83% (2.3 mg eq/kg)–82.5% (3.03 mg eq/kg) of the TRR in the outer leaves and 74.2% (0.83 mg eq/kg) - 85.1% (1.01 mg eq/kg) of the TRR in leaf-ball. The major metabolite identified was desmethoxylated 500M07, representing 8.5% (0.23 mg eq/kg) to 12% (0.44 mg eq/kg) of the TRR in the outer leaves and 5.6% (0.06 mg eq/kg) to 11% (0.13 mg eq/kg) of the TRR in leaf-ball.

#### Rice

Pyraclostrobin metabolism in rice was investigated following two foliar application of chlorophenyl- or tolyl- [ $^{14}\text{C}$ ] pyraclostrobin, at a rate of 101 g ai/ha. The first application was carried out at growth stage BBCH 39

(Flag leaf stage) with the second at BBCH 69 (End of flowering). Forage samples of both labels were taken one day before the second application. Straw, grain and husks were sampled from mature rice plants at BBCH 89. The husks were combined with straw.

The TRR levels in forage ranged from 1.6 to 1.9 mg eq/kg, in rice straw from 8.6 to 10 mg eq/kg and in rice grain from 2.0 to 2.1 mg eq/kg. The extractability of the radioactivity with methanol and water was 84–86% of the TRR in forage, 65–68% of the TRR in rice straw and 71–76% of the TRR in rice grain.

Most of the residues were unchanged pyraclostrobin, representing 42–73% of the TRR in rice forage, straw and grain. The major metabolite identified was 500M07, representing 8–17% of the TRR. Some further polar and medium polar components were found at levels below 10% TRR.

#### *Wheat (seed treatment)*

The metabolism of pyraclostrobin in wheat was investigated following seed treatment with chlorophenyl- or tolyl- [<sup>14</sup>C] pyraclostrobin, at a rate of 5 g ai/100 kg seeds. Samples of forage were collected at growth stage BBCH59 (end of heading), of hay at BBCH 73–75 (early milk) and of grain and straw at BBCH 89 (fully ripe).

Total radioactive residue levels were below 0.01 mg eq/kg in all matrices. The extraction rates of the radioactive residues from straw with methanol and water was moderate (46–63% TRR). In straw, the only significant peak detected in the chromatogram was probably the parent pyraclostrobin and/or its metabolite 500M07. Since the amount of radioactive residues was below 0.01 mg eq/kg in all matrices, no further investigations were performed for forage, hay and grain.

#### *Residues in succeeding crops*

A confined rotational crop study was conducted to examine the nature and level of residues of pyraclostrobin in succeeding crops. [<sup>14</sup>C] - pyrazole labelled pyraclostrobin was applied to the bare soil of a planting container by spray application at a nominal rates of 500 g ai/ha. Rotational crops (radish, wheat and lettuce) were sown at a plant back interval of 32 days after application.

In all rotational crop matrices (radish, wheat, lettuce), low levels of radioactive residues were found. TRRs in radish leaf accounted for 0.01 mg eq/kg, for radish root 0.003 mg eq/kg, for wheat forage 0.014 mg eq/kg and for lettuce plant 0.016 mg eq/kg.

The major portions of the radioactive residues were extracted with methanol (47–63% TRR). Subsequent extractions with water contained ≤ 8.5% TRR.

The results indicate that there was no significant translocation of pyraclostrobin and/or its degradation products from the soil to crops and confirm the conclusions of 2004 JMPR

#### *Methods of analysis*

The current Meeting received description and validation data for analytical methods of pyraclostrobin and its metabolites in plant and animal commodities.

Methods for the determination of pyraclostrobin and its metabolite 500M07 in plant matrices and 500M04 and 500M85 in animal matrices are based on HPLC-MS/MS detection. Plant matrices can be extracted with methanol:water:hydrochloric acid or methanol:water and purified on a C18-column or by partitioning with cyclohexane.

Animal matrices are extracted by partitioning into acetonitrile/iso-hexane. The common moiety method hydrolysed residues with aqueous sodium hydroxide to yield hydroxypyrazole(s), which can be extracted using ethyl acetate.

The LOQ for pyraclostrobin is 0.02 mg/kg in plant matrices, and 0.01 mg/kg in animal matrices. The LOQ for pyraclostrobin metabolite 500M07 is 0.02–0.05 mg/kg in plant matrices, while it is 0.01 mg/kg for metabolites 500M04 and 500M85 in animal matrices.

The methods are suitable for the analysis of pyraclostrobin and related metabolites in plants and animal matrices.

### **Definition of the residue**

The 2004 JMPR meeting concluded that for plants, pyraclostrobin was the major component of the <sup>14</sup>C residue in grape, potato and wheat. For the desmethoxy metabolite 500M07, the 2004 JMPR concluded that, as it was present in much smaller amounts than parent pyraclostrobin, the metabolite did not need to be included in the residue definition. The Meeting recommended the residue definition for compliance with the MRL and for dietary risk assessment for plant commodities should be pyraclostrobin. The additional plant metabolism studies on grape, Chinese cabbage, rice and wheat, showed that unchanged pyraclostrobin was the major residue in all samples examined.

The current Meeting confirmed the following residue definitions for pyraclostrobin:

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

The residue is fat-soluble.

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

The Meeting received data from supervised trials on apple, pear, table olives, litchi, avocado, mango, papaya, banana, passion fruit, spinach, lettuce, witloof chicory, green bean, broad bean, common bean, soya bean, pea, garden pea, dry beans, field pea, lentil, radish, carrot, celeriac, sugar beet, potato, celery, asparagus, rice, sugar cane, oilseeds, cacao beans, and tea.

The Meeting noted that some GAPs included both a latest growth stage for application and a PHI in the use instructions. In interpreting these use instructions, the Meeting decided that trial data reflecting application at the prescribed growth stage and with harvest no earlier than the PHI was considered for the estimation of residue levels.

#### **Pome fruits**

The critical GAP in Germany for the use of pyraclostrobin in pome fruits consists of 4 foliar applications of 0.1 kg ai/ha, a re-treatment interval (RTI) of 8 days and a PHI of 7 days.

The 2006 JMPR reported 25 European trials conducted in apples according to the cGAP in Germany. The residues were 0.03 (2), 0.04, 0.05, 0.06 (3), 0.07 (2), 0.08, 0.01 (3), 0.12 (2), 0.13, 0.14 (3), 0.16, 0.17, 0.18, 0.28 and 0.29 (2) mg/kg.

The current Meeting received eight field trials in pears conducted in Europe that matched cGAP in Germany. Residues were 0.058, 0.068, 0.069, 0.12, 0.23, 0.27, 0.29 and 0.69 mg/kg.

The Kruskal-Wallis test was used. The data sets from apple and pear are not significantly different, and can be combined as (n = 33) 0.03(2), 0.04, 0.05, 0.06 (4), 0.07 (4), 0.08, 0.1 (3), 0.12 (3), 0.13, 0.14 (3), 0.16, 0.17, 0.18, 0.23, 0.27, 0.28, 0.29 (3) and 0.69 mg/kg

The Meeting estimated a maximum residue level of 0.7 mg/kg, a STMR of 0.12 mg/kg and a HR of 0.69 mg/kg for pome fruits. The Meeting withdrew its previous recommendation of 0.5 mg/kg for apple.



*Assorted tropical and sub-tropical fruits – edible peel**Table olives*

The critical GAP for the use of pyraclostrobin in olives was from Greece and consists of 2 foliar applications of 0.1 kg ai/ha, with the last application no later than BBCH 71. The PHI is determined by the growth stage. Eight field trials were conducted in Europe matching the cGAP with residues of < 0.01(8) mg/kg.

The Meeting estimated a maximum residue level of 0.01 mg/kg, a STMR of 0.01 mg/kg and a HR of 0.01 mg/kg for pyraclostrobin on table olives. The Meeting agreed to extrapolate this estimation for olives for oil production.

*Assorted tropical and sub-tropical fruits – inedible peel - small**Litchi*

The critical GAP in Australia is three foliar applications at 0.01 kg ai/hL at a RTI of 10 days with a PHI of 3 days. Two field trials were conducted in litchi in Australia matching the Australian GAP. The meeting agreed that the number of trials is not sufficient for the estimation of a maximum residue level.

*Assorted tropical and sub-tropical fruits – inedible smooth peel – large**Avocado*

The critical GAP for pyraclostrobin on avocado in the USA consists of 2 foliar applications of 0.166 kg ai/ha with a RTI of 7 days and a 0-day PHI.

In four field trials on avocado in the USA matching cGAP residues were (n = 4): 0.028, 0.04, 0.065 and 0.104 mg/kg.

The Meeting recommended a maximum residue level of 0.2 mg/kg, a STMR of 0.053 mg/kg and a HR of 0.104 mg/kg for pyraclostrobin in avocado.

*Mango*

The critical GAP in Brazil consists of four foliar applications of 0.133 kg ai/ha with a RTI of 7 days and a 7-day PHI. In field trials conducted in mango in Brazil according to the Brazilian GAP residues were (n = 6): 0.04, 0.08 (2), 0.14, 0.16 and 0.35 mg/kg. The Meeting recommended a maximum residue level, STMR and HR of 0.6, 0.11 and 0.35 mg/kg respectively for mango to replace its previous recommendation of 0.05(\*) mg/kg.

*Papaya*

Pyraclostrobin is registered in Brazil with a cGAP of four foliar applications at 0.13 kg ai/ha with a 7-day RTI, and a PHI of 7 days.

In four field trials matching cGAP and conducted in Brazil, residues were (n = 4): 0.02, 0.1, 0.2 and 0.22 mg/kg.

The Meeting agreed that the number of trials is not sufficient for the estimation of a maximum residue level for pyraclostrobin in papaya.

*Assorted tropical and sub-tropical fruits – inedible rough or hairy peel – large**Pineapple*

The critical GAP for pyraclostrobin in pineapple in Brazil consists of 4 × 0.15 kg ai/ha foliar applications and a PHI of 3 days.

In eight field trials conducted in pineapple in Brazil according to the Brazilian GAP, residues were 0.02(2), 0.03, 0.04, 0.05, 0.07, 0.09 and 0.19 mg/kg. Residues in pulp, were < 0.002 (4) mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, a STMR of 0.002 mg/kg and a HR of 0.002 mg/kg for pyraclostrobin in pineapples.

*Passion fruit*

The critical GAP in Brazil for pyraclostrobin in passion fruit is 4 × 0.15 kg ai/ha foliar applications at a RTI of 10 days (total maximum seasonal application of 0.6 kg ai/ha), with a 7-day PHI. In trials in Brazil according to the Brazilian GAP residues were (n = 4): 0.03, 0.04, 0.05 and 0.1 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 0.1 mg/kg for pyraclostrobin in passion fruit.

*Leafy vegetables (including Brassica leafy vegetables)**Lettuce, head*

The 2006 JMPR estimated a HR of 19.7 mg/kg for pyraclostrobin in lettuce based on six trials conducted in the USA according to GAP (0.23 kg ai/ha and 0 days PHI). This resulted in an IESTI estimation that was 390% of the ARfD of 0.05 mg/kg bw. As a consequence of this exceedance, the 2006 Meeting considered an alternative GAP in Europe.

At the present Meeting, a new ARfD of 0.7 mg/kg was established for pyraclostrobin. The Meeting decided to reconsider the trials submitted to the 2006 JMPR conducted according to the USA GAP for the estimation of a maximum residue level. Residues were (n = 6): 1.95, 3.69, 4.96, 13.7, 14.9, and 19.7 mg/kg.

The Meeting estimated a maximum residue level of 40 mg/kg, a STMR of 9.33 mg/kg and a HR of 19.7 mg/kg for pyraclostrobin in lettuce head.

The meeting withdrew its previous maximum residue level recommendation of 2 mg/kg for pyraclostrobin in lettuce head.

*Spinach*

The critical GAPs for pyraclostrobin on spinach in European countries is characterised by the GAP in Germany (2 × 0.1 kg ai/ha, a RTI of 8 days and a 14-day PHI) and Italy (2 × 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), 0.13 (2), 0.28, 0.31 and 0.91 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg, a STMR of 0.09 mg/kg and a HR of 0.91 mg/kg for pyraclostrobin in spinach.

*Witloof chicory (sprouts)*

The critical GAP for pyraclostrobin in witloof chicory sprouts in France consists of one application to roots

after their transfer to forcing trays, at 0.42 g ai/m<sup>2</sup> tray area. The PHI is 21 days.

Four trials conducted in Europe according to matching France GAP were 0.02, 0.027, 0.03 and 0.04 mg/kg.

The Meeting estimated a maximum residue level of 0.09 mg/kg, a STMR of 0.029 mg/kg and a HR of 0.04 mg/kg for pyraclostrobin in witloof chicory (sprouts).

### *Legume vegetables*

#### *Common bean (poroto)*

Critical GAP in France for green beans (common beans) is 2 × 0.1 kg ai/ha, a RTI 10 days and a 7-day PHI. Data were available from residue trials on common beans in Belgium, France, Germany, Greece, Italy, Netherlands, Spain and the United Kingdom approximating the GAP of France.

Residues trials conducted in Europe according to the French GAP gave residues of 0.03(4), 0.04, 0.06(2), 0.12, 0.13(2), 0.14, 0.21, 0.24(2), 0.26, 0.28 and 0.37 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg, a STMR of 0.13 mg/kg and a HR of 0.37 mg/kg for pyraclostrobin in common beans.

#### *Subgroup Beans with pods, except common beans (poroto)*

The GAP for pyraclostrobin in the USA for edible podded legume vegetables (including the whole subgroup of beans with pods) is 3 × 0.16 kg ai/ha, a RTI of 7 days and a 7-day PHI.

The 2004 JMPR reported seven trials conducted in the USA in snap beans at 2×0.23 kg ai/ha, PHI of 7 days. Residues were 0.04, 0.08, 0.1(2), 0.11, 0.13 and 0.16 mg/kg.

Residue decline trials show that an additional spray 21 days prior to harvest would not contribute significantly to the final residue and these trials can be evaluated against the USA GAP. The Meeting agreed that the proportionality approach could be applied to the data reported in by the 2004 JMPR (scaling factor of 0.7) giving residues of 0.028, 0.056, 0.07 (2), 0.077, 0.091 and 0.11 mg/kg

The Meeting noted that the GAP from France is for green beans (common beans), is more critical and results in a higher maximum residue level estimation than the USA GAP for the whole subgroup of beans with pods, and decided to exclude it from the subgroup recommendation.

The Meeting estimated a maximum residue level, a STMR and a HR of 0.3, 0.07 and 0.11 mg/kg for pyraclostrobin in the subgroup of beans with pods [014A], except common beans (poroto).

#### *Broad beans and common beans without pods (succulent seeds)*

The GAP for pyraclostrobin in France for broad beans and common beans is 2 × 0.1 kg ai/ha, with a 7-day PHI. In eight trials conducted in Europe in broad bean according to this GAP residues in broad beans without pods were < 0.01 (8) mg/kg.

The Meeting estimated a maximum residue level of 0.01 mg/kg, a STMR of 0.01 mg/kg and a HR of 0.01 mg/kg for pyraclostrobin in broad bean without pods (succulent seeds).

Eleven trials conducting with common bean according to GAP gave residues of < 0.01 (6), 0.01(2), 0.018, 0.02 and 0.27 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, a STMR of 0.01 mg/kg and a HR of 0.27 mg/kg for pyraclostrobin in common beans without pods (succulent seeds).

*Peas with pods*

Critical GAP in Spain is  $2 \times 0.1$  kg ai/ha, RTI of 10 days and a PHI of 7 days. In five trials conducted in Europe, pea vines were sprayed at  $2 \times 0.067$  kg ai/ha, residues were 0.03, 0.05, 0.05, 0.06 and 0.08 mg/kg at 6–7 DALA. The Meeting agreed to use proportionality to scale the residues (scaling factor of 1.5) giving residues of 0.045, 0.075, 0.075, 0.09 and 0.12 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, STMR of 0.075 mg/kg and HR of 0.12 mg/kg for the subgroup of peas with pods and agreed to withdraw its previous recommendation of 0.02(\*) mg/kg for peas (pods and succulent=immature seeds).

*Succulent peas without pods*

Critical GAP in Spain is  $2 \times 0.1$  kg ai/ha, RTI of 10 days and a PHI of 7 days. Sixteen trials were conducted in Europe according to this GAP giving residues in peas without pods of < 0.01(9), 0.01, 0.011, 0.013, 0.014 (2), 0.02 and 0.07 mg/kg.

The Meeting estimated a maximum residue level, a STMR and a HR of 0.08, 0.01 and 0.07 mg/kg for pyraclostrobin, respectively, in the subgroup of succulent peas without pods.

*Pulses**Dry peas*

The critical GAP for dried and succulent shelled peas and beans (including soya bean) in Canada comprises of two foliar applications at 0.15 kg ai/ha and a 30-day PHI. Data were available from supervised residue trials on field pea and lentil from USA and Canada at  $2 \times 0.224$  kg ai/ha with harvest 30 DALA.

Residues found in nine trials on field peas were: < 0.02(2), 0.04, 0.05, 0.09(2), 0.13, 0.14 and 0.2 mg/kg. The Meeting agreed to apply the proportionality approach (scaling factor of 0.67) giving residues of < 0.02 (2), 0.027, 0.034, 0.06 (2), 0.087, 0.094 and 0.134 mg/kg.

Residues in lentils were (n = 5): 0.03, 0.08, 0.085, 0.165 and 0.25 mg/kg. Scaled residues were (n = 5): 0.0201, 0.0536, 0.057, 0.111 and 0.168 mg/kg.

The Meeting noted that GAP in Canada includes the subgroup dried peas. The Kruskal-Wallis test showed that the data sets from field peas and lentils are not significantly different and they can be combined as (n = 14) < 0.02 (2), 0.201, 0.027, 0.034, 0.054, 0.057, 0.06 (2), 0.087, 0.094, 0.111, 0.134 and 0.168 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and a STMR of 0.059 mg/kg for pyraclostrobin on the subgroup dry peas.

*Root and tuber vegetables**Root vegetables*

The critical GAP for root vegetables in the USA is for three foliar applications at 0.234 kg ai/ha with a 7 day RTI and a 0-day PHI. In five trials conducted in the USA matching cGAP residues in radishes were: 0.05, 0.07, 0.08, 0.23 and 0.30 mg/kg.

In six trials on carrots conducted in the USA and matching cGAP residues were 0.03, 0.04, 0.12 (2), 0.15 and 0.24 mg/kg/kg.

The Kruskal-Wallis test showed that the data sets from radish and carrots are not significantly different and can be combined as (n = 11): 0.03, 0.04, 0.05, 0.07, 0.08, 0.12(2), 0.15, 0.23, 0.24 and 0.3 mg/kg

The Meeting estimated a maximum residue level of 0.5 mg/kg, a STMR of 0.12 mg/kg and a HR of 0.3 mg/kg for pyraclostrobin in root vegetables

The Meeting withdrew its previous maximum residue recommendations for carrot (0.5 mg/kg) and radish (0.5 mg/kg).

#### *Tuberous and corm vegetables*

The critical GAP for tuberous and corm vegetables in the USA is for six foliar applications at 0.22 kg ai/ha with a 7 day RTI and a 3-day PHI. Nineteen trials conducted in the USA according to GAP gave residues of < 0.02 (19) mg/kg. The Meeting noted that, pyraclostrobin was not detected in the potato metabolism study reported by the 2004 JMPR.

The Meeting estimate a maximum residue level of 0.02(\*) mg/kg, a STMR and a highest residue level of 0 mg/kg, for pyraclostrobin in subgroup of tuberous and corm vegetables.

The Meeting withdrew its previous maximum residue recommendation of 0.02(\*) mg/kg for potato.

#### *Stalk and stem vegetables – Stems and petioles*

##### *Celery*

In Poland the cGAP for celery is for two foliar applications at 0.1 kg ai/ha with a 14-day RTI and a 14-day PHI. Nine trials were conducted in Europe matching this GAP, giving residues of 0.05, 0.09, 0.1, 0.11, 0.15, 0.21, 0.213, 0.59 and 0.61 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg, a STMR of 0.15 mg/kg and a HR of 0.61 mg/kg for pyraclostrobin in celery.

##### *Asparagus*

The cGAP for asparagus in Germany is two foliar applications to the ferns (not before BBCH 69 after asparagus spears have been harvested) at 0.1 kg ai/ha with a 14-day RTI and a PHI not required. In seven trials from France, Germany, Italy and Spain approximating cGAP in Germany residues were < 0.01 mg/kg (7).

The Meeting estimated a maximum residue level of 0.01(\*) mg/kg, a STMR and a HR of 0.01 mg/kg for pyraclostrobin in asparagus.

#### *Cereals*

##### *Rice*

The cGAP for rice in Indonesia is for two foliar applications at 0.1 kg ai/ha with a 10 day RTI and a PHI not specified (last application at mid-flowering BBCH 65).

Sixteen trials in paddy rice from China, Greece, India, Indonesia, Italy, Philippines, Spain, Taiwan Province of China, Thailand and Vietnam matching the Indonesia GAP gave residues in grain (with hulls) of < 0.01(3), 0.06, 0.07(2), 0.084, 0.17, 0.22, 0.26, 0.33, 0.38, 0.45, 0.49, 0.53 and 0.60 mg/kg.

Residues in brown rice (grain without hulls) were < 0.01(6), 0.02(2), 0.03(3), 0.04(4) and 0.06 mg/kg. Residues in polished rice were < 0.01(11), 0.015, 0.016 (2), 0.017 and 0.02 mg/kg.

The Meeting estimated a maximum residue levels of 1.5 mg/kg and a STMR of 0.195 mg/kg for pyraclostrobin in rice grain.

The Meeting estimated a maximum residue levels of 0.09 mg/kg and a STMR of 0.02 mg/kg for pyraclostrobin in husked rice (brown rice).

The Meeting estimated a maximum residue levels of 0.03 mg/kg and a STMR of 0.01 mg/kg for pyraclostrobin in polished rice

#### *Grasses for sugar or syrup production*

##### *Sugar cane*

The cGAP for sugar cane in Brazil consists of a single in-furrow application at 0.133 kg ai/ha followed by 5 foliar applications of 0.13 kg ai/ha at intervals of 21 days. The PHI is 30 days.

In four field trials were conducted in sugar cane in Brazil according to the Brazilian GAP the residues were < 0.01(2), 0.02 and 0.03 mg/kg.

In eight additional trials conducted in Brazil using 2.4× cGAP in Brazil, residues were: 0.011, 0.012, 0.056, 0.062, 0.066, 0.079, 0.093 and 0.11 mg/kg. Residues scaled to the cGAP are: 0.0045, 0.005, 0.023, 0.026, 0.027, 0.032, 0.038 and 0.045 mg/kg.

The Meeting estimated a maximum residue level of 0.08 mg/kg, a STMR of 0.0265 mg/kg and a HR of 0.045 mg/kg for pyraclostrobin in sugarcane.

#### *Seed for beverages and sweets*

##### *Cacao beans*

The GAP for cacao in Brazil consists of maximum 3 foliar applications of 0.2 kg ai/ha at intervals of 30 days. The PHI is 14 days. In three trials conducted in Brazil matching this GAP residues were: < 0.01(3) mg/kg.

The Meeting estimated a maximum residue level of 0.01 mg/kg, and a STMR of 0.01 mg/kg for pyraclostrobin in cacao beans.

##### *Tea*

The cGAP in Japan is 2 × 0.003 kg ai/hL with a PHI of 7 days. In six trials in China, India, Japan and Taiwan Province of China conducted at a higher rate than the Japanese GAP, residues in dried green tea leaves were: 0.64, 1.0, 1.4, 2.5, 5.3 and 5.8 mg/kg.

The Meeting agreed to apply proportionality to scale the residues (scaling factors of 0.68, 0.65, 0.5, 0.49, 0.46 and 0.57 respectively) to give scaled residues: 0.44, 0.65, 0.7, 1.23, 2.4 and 3.3 mg/kg.

The Meeting estimated a maximum residue level of 6 mg/kg and a STMR of 0.965 mg/kg for pyraclostrobin in tea (green, black).

#### ***Animal feedstuffs***

##### *Bean (vines)*

Critical GAP in France for green beans is 2×0.1 kg ai/ha, a 10-day RTI and a 7-day PHI. Sixteen trials conducted in Europe according to this GAP gave pyraclostrobin residue in vines of common bean of 0.21, 0.28, 0.43, 0.44, 0.85, 0.92, 1.6, 1.63, 2.5, 2.65, 2.8, 3.54, 3.9, 3.9, 6.34 and 8.45 mg/kg.

The Meeting estimated a median residue of 2.065 mg/kg and a highest residue level of 8.45 mg/kg for pyraclostrobin on bean forage (vines), as received.

#### *Rice straw and fodder, dry*

The critical GAP for rice in Indonesia is two foliar applications at 0.1 kg ai/ha with a 10-day RTI and a PHI not required (last application at mid-flowering BBCH 65). Residues found in straw from trials matching Indonesian GAP were (n = 16): < 0.01, 0.013, 0.349, 0.402, 0.506, 0.73, 0.75, 0.821, 0.89, 0.93, 1.2, 1.5, 2.19, 2.22, 2.24 and 2.69 mg/kg, as received basis.

The Meeting estimated a maximum residue level of 5 mg/kg for pyraclostrobin in rice straw and fodder, dry. The Meeting estimated median and highest residues of 0.856 mg/kg and 2.69 mg/kg, respectively, for pyraclostrobin in rice straw and fodder (as received).

#### *Rice hulls*

Residues in rice hulls from trials matching Indonesian GAP were (n = 16): < 0.01, 0.031, 0.031, 0.138, 0.264, 0.282, 0.32, 0.532, 0.739, 0.99, 1.2, 1.25, 1.46, 1.5, 2.35 and 2.65 mg/kg.

The Meeting estimated a median residue for rice hulls of 0.636 mg/kg.

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

#### *High temperature hydrolysis*

The degradation of [<sup>14</sup>C] pyraclostrobin was studied in an olive oil / water mixture to simulate the process of olive oil raffination (deodorisation step from raw oil to refined oil). A mixture of olive oil and aqueous NaCl were heated at 190 or 240 °C for 30 minutes. Most of the radioactivity was retained in the olive oil phase. Pyraclostrobin was degraded by loss of an acetyl to 500M07 (32–50% AR 190 °C; 6.0–23% AR at 240 °C) which undergoes cleavage to produce 500M04 (13–25% AR at 190 °C; 70–82% AR at 240 °C) and 500M049 (5.7–10% AR at 190 °C; 0–4.6 at 240 °C).

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

The Meeting received data on the effects of processing and preparation of apple, olives, spinach, rice, sugarcane and tea on residue levels of pyraclostrobin. Residue information, processing factors, and recommendations for STMR-P, HR-P, and maximum residue level recommendations relevant to the current evaluation are shown in the table, below.

Summary of pyraclostrobin residues in processed commodities.

Crop	Residue value (mg/kg) in raw commodity			Processed Commodity	Calculated PF	PF (Mean or best estimated)*	Residue value (mg/kg) in processed commodity		
	MRL	STMR	HR				MRL**	STMR-P	HR-P
Sugar cane		0.0265		Molasses		0.2		0.005	0
				Refined sugar		0.1		0.0025	
Apple	0.7	0.12	0.69	fresh pomace	14.82, 6.39, 16.01, 9.88	11.77		1.41	
				juice	0.12, 0.04, 0.08, 0.15	0.1		0.012	
				apple sauce	0.38, 0.41, 0.67, 0.65	0.53		0.0697	
Olives				Wash cater (olives)	0.02, 0.1, 0.03, 0.04	0.05		0.0005	

Crop	Residue value (mg/kg) in raw commodity			Processed Commodity	Calculated PF	PF	Residue value (mg/kg) in processed commodity		
	MRL	STMR	HR			(Mean or best estimated)*	MRL**	STMR-P	HR-P
Spinach	0.01	0.01	0.01	Virgin oil	7.36, 5.91, 5.18, 6.5	6.24	0.07	0.0624	
				Fermented olives	1.09, 1.02, 1.45, 1.17	1.18		0.0118	0.0118
	1.5	0.09	0.91	Washed spinach	0.96, 0.63, 0.9, 1.17	0.92		0.082	0.84
				Blanched spinach	0.81, 0.66, 1.31, 0.83	0.91		0.092	0.83
Rice				Cooked spinach	0.78, 0.45, 1.31, 0.62	0.79		0.07	0.72
	1.5	0.195	0.604	Bran	0.59, 0.36, 0.69	0.55	a	a	
				Parboiled white milled rice	0.09, 0.08, 0.11	0.09		0.018	
				Flour	0.01, 0.03, 0.02	0.02		0.004	
				Brown rice	0.1, 0.07, 0.14	0.1	a	a	
				Polished rice	0.02, 0.03, 0.02	0.02	a	a	
				Hulls	4.28, 4.47, 4.54	4.43		a	
Tea		0.965	3.3	Sake	0.01, 0.03, 0.02	0.02		0.004	
	6			Infusion solution	0.175, 0.007, 0.0010.001	0.001		0.0009	
				Instant tea	0.0020.175, 0.007, 0.002	0.002		0.0019	
				Steeped leaves (infusion)	0.270.246, 0.313, 0.272	0.27		0.26	

\*The factor is the ratio of the total residue in processed commodity divided by the total residue in the RAC.

\*\* maximum residue levels in processed commodities are only proposed where they are higher than the maximum residue level in the RAC.

<sup>a</sup> Estimated on a basis of supervised residue trials.

In the supervised trials on rice, residues of pyraclostrobin in bran were analysed. Residues in bran from trials matching the Indonesian GAP were (n = 16): < 0.01(3), 0.027, 0.036, 0.08, 0.089, 0.13, 0.15, 0.17, 0.18, 0.21, 0.23, 0.24, 0.29 and 0.38 mg/kg. The Meeting estimated a STMR-P of 0.14 mg/kg for rice bran (unprocessed).

### **Residue in animal commodities**

#### ***Farm animal dietary burden***

The Meeting estimated the dietary burden of pyraclostrobin in farm animals on the basis of the diets listed in Appendix IX of the FAO Manual 2016. Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides levels in feed suitable for estimating maximum residue levels, while



calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities. The percentage dry matter is taken as 88–89% when the highest residue levels and STMRs are already expressed on a dry weight basis. The Meeting was informed by an official communication of the government of Australia that no bean fodder is imported. Therefore, the animal burden due to treated bean fodder was not taken into account for that region.

#### *Estimated maximum and mean dietary burdens of farm animals*

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 OECD diets listed in Appendix IX of the 2016 edition of the FAO manual, are presented in Annex 6 and summarised below.

Region	Livestock dietary burden, pyraclostrobin, ppm of dry matter diet							
	US - Canada		EU		Australia		Japan	
	Maximum	Mean	Maximum	Mean	Maximum	Mean	Maximum	Mean
Beef cattle	7.92	1.83	27.82	10.18 <sup>b,d</sup>	22.53	7.715	4.009	1.55
Dairy cattle	19.8	5.79	29.41 <sup>a,c</sup>	9.22	22.53	5.921	9.347	3.35
Broiler poultry	0.319	0.319	0.59	0.41	0.108	0.108	0.995	0.304
Laying poultry	0.319	0.319	9.996 <sup>e</sup>	3.179 <sup>f</sup>	0.108	0.108	0.049	0.049

<sup>a</sup> suitable for estimating maximum residue levels for meat, fat and edible offal of cattle.

<sup>b</sup> suitable for estimating STMR for meat, fat and edible offal of cattle.

<sup>c</sup> suitable for estimating maximum residue levels for Milk.

<sup>d</sup> suitable for estimating STMR for Milk.

<sup>e</sup> suitable for estimating maximum residue levels for poultry meat, offal and eggs.

<sup>f</sup> suitable for estimating STMRs for poultry meat, offal and eggs.

The resulting maximum dietary burdens for beef and dairy cattle, including the additional feed stuffs considered by the current Meeting, were slightly higher than those previously estimated.

#### *Cattle-STMR, HR and maximum residue levels*

The current Meeting received no additional animal feeding studies. The resulting maximum dietary burdens calculated for beef and dairy cattle were slightly higher than those previously estimated.

The Meeting used TRR levels from the lactating goat metabolism study. In the metabolism study, C<sup>14</sup>-pyraclostrobin, equivalent to 12–50 ppm in the diet, was orally administered to lactating goats for 5 consecutive days, the highest residues (0.82 mg/kg) were found in fat, 0.047 mg/kg in milk, 0.089 mg/kg in muscle, 0.07 mg/kg in liver and 0.074 mg/kg in kidney.

When scaled to the dietary burden of 29.41 ppm, the anticipated residues are 0.0276 mg/kg in milk, 0.0523 mg/kg in muscle, 0.482 mg/kg in fat, 0.0411 mg/kg in liver, and 0.0435 mg/kg in kidney.

On the basis of the anticipated residues, the Meeting estimated a maximum residue level of 0.03 mg/kg and a STMR of 0.0095 mg/kg for milk.

The meeting recommended maximum residue levels of 0.5, 0.5 and 0.05 mg/kg for meat (fat) (from mammals other than marine mammals), mammalian fats (except milk fats) and for edible offal, respectively. The meeting estimated STMRs and HRs of 0.015 and 0.044 mg/kg for edible offal, 0.0181 and 0.052 mg/kg for muscle, and 0.166 and 0.48 mg/kg for fat. The meeting agreed to withdraw its previous recommendations for mammalian tissues and milk

The Meeting confirms the previous recommendations for poultry commodities.

## RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed in Annex 1 are appropriate for establishing a maximum residue level and for an IEDI and IESTI assessment.

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

## DIETARY RISK ASSESSMENT

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

The ADI for pyraclostrobin is 0–0.03 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for pyraclostrobin 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 2018 JMPR Report. The IEDIs ranged from 1–7% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of pyraclostrobin from uses considered by the JMPR is unlikely to present a public health concern.

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

The ARfD for pyraclostrobin is 0.7 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for pyraclostrobin 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 2018 JMPR Report. The IESTIs varied from 0–60% of the ARfD for children and 0–30% for the general population.

The Meeting concluded that acute dietary exposure to residues of pyraclostrobin from uses considered by the present Meeting is unlikely to present a public health concern.

## 5.26 PYRIOFENONE (310)

### TOXICOLOGY

Pyriofenone is the ISO-proposed common name for (5-chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-*o*-tolyl) methanone, with the CAS number 688046-61-9.

Pyriofenone is an aryl phenyl ketone fungicide used to control powdery mildew on grapevines.

Pyriofenone has not been previously 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*

Following oral administration of [<sup>14</sup>C-phenyl]pyriofenone or [<sup>14</sup>C-pyridyl]pyriofenone to bile duct cannulated rats at 5 or 200 mg/kg bw, the compound was rapidly absorbed; absorption 48 hours after dosing ranged from 76% to 89% of the dose at 5 mg/kg bw and from 36% to 53% of the dose at 200 mg/kg bw for the two radiolabels. The compound was largely excreted into bile (at the low dose, 64–81%; at the high dose, 33–49%) and urine (<13%, regardless of dose, sex or label) within 48 hours. In intact animals, most of the radiolabel was excreted in the faeces, probably via the bile, within 120 hours. Based on half-life considerations, there was some evidence of accumulation of radioactivity in plasma and whole blood. Pharmacokinetic parameters after single oral doses indicated that the rate and extent of exposure were higher in males than in females and that this difference was greater at 200 mg/kg bw than at 5 mg/kg bw.

In a metabolic study, unchanged pyriofenone represented maxima of 29% of the low dose and 63% of the high dose (faeces). Other components identified in faeces were 2MDPM (maximum 21% of the low dose), 3HDPM (maximum 16% of the low dose) and 4HDPM (maximum 11% of the low dose). In bile, two major metabolites were identified as glucuronide conjugates of 3HDPM and 4HDPM, each accounting for a maximum of 39% of the low dose. All other metabolites in bile accounted for 5% of the dose or less. In the urine of female rats at the low dose, there was one major metabolite at a maximum of 9.5% of the dose, which was identified as an unstable conjugate of 2MDPM. In male and female rats, no other metabolites accounted for more than 3% of the dose in urine.

At the  $T_{max}$ , the major metabolite in plasma was identified as a glucuronide conjugate of 2MDPM. Parent pyriofenone, 3HDPM and/or 4HDPM were present in extracts of livers from treated rats. Parent pyriofenone was the major component in extracts of kidney at the high dose.

#### *Toxicological data*

The acute toxicity of pyriofenone was studied by oral ( $LD_{50} > 2000$  mg/kg bw), inhalation ( $LC_{50} > 5.18$  mg/L) and dermal ( $LD_{50} > 2000$  mg/kg bw) administration in rats. Pyriofenone was not irritating to the skin of rabbits, but it induced slight ocular irritation in rabbits. Pyriofenone was not sensitizing in mice.

In a 13-week study in mice using dietary concentrations of pyriofenone of 0, 300, 1000, 3000 and 7000 ppm (equal to 0, 53, 176, 514 and 1318 mg/kg bw per day for males and 0, 61, 214, 695 and 1504 mg/kg bw per day for females, respectively), the NOAEL was 7000 ppm (equal to 1318 mg/kg bw per day), the highest dose tested.

In a 28-day dose range finding study in rats using dietary concentrations of pyriofenone of 0, 300, 3000, 10 000 and 20 000 ppm (equal to 0, 24.2, 251, 823 and 1657 mg/kg bw per day for males and 0, 26.1, 261, 841 and 1660 mg/kg bw per day for females, respectively), the NOAEL was 300 ppm (equal to 24.2 mg/kg bw per day), based on increased serum ALP, total protein and albumin (males), distended caeca (both sexes), increased liver weights (both sexes) and increased kidney weights (females) at 3000 ppm (equal to 251 mg/kg bw per day).

In a 93-day study in which rats were administered a dietary concentration of pyriofenone of 0, 300, 1000, 2500 or 5000 ppm (equal to 0, 17.9, 60.5, 150 and 305 mg/kg bw per day for males and 0, 20.6, 69.0, 171 and 350 mg/kg bw per day for females, respectively), the NOAEL was 1000 ppm (equal to 60.5 mg/kg bw per day), based on increased liver weights in both sexes, increased kidney weights in males, increased caecum weights in females, altered clinical chemistry in both sexes and prolonged activated partial thromboplastin time (APTT) in females at 2500 ppm (equal to 150 mg/kg bw per day).

In a 90-day study in dogs administered a dietary concentration of pyriofenone of 0, 500, 3000 or 25 000 ppm (equal to 0, 15.0, 90.3 and 776 mg/kg bw per day, respectively) for males and 0, 500, 3000 or 15 000 ppm (equal to 0, 15.3, 89.8 and 475 mg/kg bw per day, respectively) for females, the NOAEL was 3000 ppm (equal to 89.8 mg/kg bw per day), based on a marked increase in ALP in females at 15 000 ppm (equal to 475 mg/kg bw per day).

In a 1-year study in dogs administered a dietary concentration of pyriofenone of 0, 500, 3000 or 25 000 ppm (equal to 0, 13.7, 83.5 and 701 mg/kg bw per day, respectively) for males and 0, 500, 3000 or 15 000 ppm (equal to 0, 14.1, 86.2 and 448 mg/kg bw per day, respectively) for females, the NOAEL was 3000 ppm (equal to 86.2 mg/kg bw per day), based on a marked increase in ALP in females at 15 000 ppm (equal to 448 mg/kg bw per day).

The overall NOAEL for pyriofenone in dogs was 3000 ppm (equal to 89.8 mg/kg bw per day), and the overall LOAEL was 15 000 ppm (equal to 448 mg/kg bw per day).

In a 78-week carcinogenicity study in mice administered a dietary concentration of pyriofenone of 0, 600, 1800 or 5400 ppm (equal to 0, 77.6, 237 and 716 mg/kg bw per day, respectively) for males and 0, 300, 1000 or 3000 ppm (equal to 0, 49.4, 167 and 486 mg/kg bw per day, respectively) for females, the NOAEL for systemic toxicity was 600 ppm (equal to 77.6 mg/kg bw per day), based on liver and kidney histopathology (hepatocellular hypertrophy and single-cell necrosis and renal cortical tubular basophilia) in males at 1800 ppm (equal to 237 mg/kg bw per day). The NOAEL for carcinogenicity was 1800 ppm (equal to 237 mg/kg bw per day), based on an increase in the incidence of combined hepatocellular adenomas and adenocarcinomas in males at 5400 ppm (equal to 716 mg/kg bw per day). The Meeting noted that the incidence, while significant in comparison with concurrent controls, was within the historical control range.

In a 52-week study in rats using dietary administration of pyriofenone at 0, 200, 1000 or 5000 ppm (equal to 0, 8.51, 42.9 and 226 mg/kg bw per day for males and 0, 10.6, 53.5 and 275 mg/kg bw per day for females, respectively), the NOAEL was 1000 ppm (equal to 42.9 mg/kg bw per day), based on increased liver weight and centrilobular hypertrophy, increased APTT, decreased haemoglobin and red blood cell parameters (haematocrit, haemoglobin concentration, haemoglobin width, red blood cell count), increased GGT, ALP, aspartate aminotransferase (AST) and alanine aminotransferase (ALT) and increased total cholesterol in rats of both sexes at 5000 ppm (equal to 226 mg/kg bw per day). Additionally, at 5000 ppm, nephrotoxicity was observed in rats of both sexes, including increased kidney weights, altered clinical chemistry suggestive of renal dysfunction, and renal histopathology (tubular basophilic change in 10/20 males and increased brown pigment deposition in renal tubular cells in 20/20 females).

In a 2-year carcinogenicity study in rats administered a dietary concentration of pyriofenone of 0, 200, 1000 or 5000 ppm (equal to 0, 7.25, 36.4 and 197 mg/kg bw per day for males and 0, 9.13, 46.5 and

254 mg/kg bw per day for females, respectively), the NOAEL was 200 ppm (equal to 9.13 mg/kg bw per day), based on chronic nephropathy in female rats at 1000 ppm (equal to 46.5 mg/kg bw per day). The nephropathy in female rats at 1000 ppm and in both sexes at 5000 ppm was considered related to the nephrotoxicity observed in the 52-week rat study in both sexes at 5000 ppm. There was no evidence of increased neoplasia or tumour incidence after exposure to pyriofenone.

The Meeting concluded that there was limited evidence of carcinogenicity in the livers of male mice and that pyriofenone was not carcinogenic in female mice or rats.

Pyriofenone 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 pyriofenone is unlikely to be genotoxic.

In view of the lack of genotoxicity, the absence of carcinogenicity in rats and the fact that hepatocellular adenomas and adenocarcinomas were increased only in male mice at the highest dose tested, the Meeting concluded that pyriofenone is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation study of reproductive toxicity in rats, pyriofenone was administered in the diet to rats at 0, 150, 1000 or 5000 ppm (equal to 0, 7.29, 47.8 and 257 mg/kg bw per day for F<sub>0</sub> males and 0, 9.5, 58.1 and 301 mg/kg bw per day for F<sub>0</sub> females, respectively). The NOAEL for parental toxicity was 1000 ppm (equal to 47.8 mg/kg bw per day), based on altered haematological parameters and changes in liver, kidney, thyroid and caecum weights in F<sub>0</sub> and F<sub>1</sub> rats at 5000 ppm (equal to 257 mg/kg bw per day). The NOAEL for reproductive toxicity and offspring toxicity was 5000 ppm (equal to 257 mg/kg bw per day), the highest dose tested.

In a study of developmental toxicity, rats were dosed with pyriofenone by oral gavage from gestation days 6 to 19 at 0, 30, 300 or 1000 mg/kg bw per day. The NOAEL for maternal toxicity was 30 mg/kg bw per day, based on increased liver and caecum weights in dams at 300 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 1000 mg/kg bw per day, the highest dose tested.

In a study of developmental toxicity, rabbits were dosed with pyriofenone from gestation days 6 to 27 at 0, 30, 300 or 1000 mg/kg bw per day. The NOAEL for maternal and embryo/fetal toxicity was 1000 mg/kg bw per day, the highest dose tested.

The Meeting concluded that pyriofenone is not teratogenic in rats or rabbits.

Pyriofenone did not produce neurotoxicity in acute studies in rats at doses up to 2000 mg/kg bw or in subchronic studies in rats at doses up to 927 mg/kg bw per day.

The Meeting concluded that pyriofenone is not neurotoxic.

Pyriofenone did not produce immunotoxicity in 4-week studies in female mice at doses up to 1270 mg/kg bw per day or in female rats at doses up to 1690 mg/kg bw per day.

The Meeting concluded that pyriofenone is not immunotoxic.

No information on the potential effects of pyriofenone on the microbiome of the human gastrointestinal tract is available.

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

The main metabolites of pyriofenone were tested in acute toxicity studies and genotoxicity studies. The acute oral toxicity of 2MDPM, 3HDPM and 4HDPM was studied by the acute toxic class method in rats (all LD<sub>50</sub>s > 2000 mg/kg bw). All three metabolites tested negative for mutagenicity in bacterial reverse

mutation assays.

### **Human data**

In reports on manufacturing plant personnel, no adverse health effects were noted. No information on accidental or intentional poisonings in humans was identified.

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

### **Toxicological evaluation**

The Meeting established an ADI of 0–0.09 mg/kg bw on the basis of the NOAEL of 9.13 mg/kg bw per day from the 2-year carcinogenicity study in rats for chronic nephropathy in females at 46.5 mg/kg bw per day. A safety factor of 100 was applied. The upper bound of the ADI provides a margin of about 8000 relative to the LOAEL for carcinogenicity in male mice.

The Meeting concluded that it was not necessary to establish an ARfD for pyriofenone in view of its low acute oral toxicity and the absence of any other toxicological effects, including developmental toxicity, that would be likely to be elicited by a single dose.

A toxicological monograph was prepared.

### **Levels relevant to risk assessment of pyriofenone**

Species	Study	Effect	NOAEL	LOAEL
Mouse	Seventy-eight-week study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	600 ppm, equal to 77.6 mg/kg bw per day	1 800 ppm, equal to 237 mg/kg bw per day
		Carcinogenicity	1 800 ppm, equal to 237 mg/kg bw per day	5 400 ppm, equal to 716 mg/kg bw per day
Rat	Two-year studies of toxicity and carcinogenicity <sup>a</sup>	Toxicity	200 ppm, equal to 9.13 mg/kg bw per day	1 000 ppm, equal to 46.5 mg/kg bw per day
		Carcinogenicity	5 000 ppm, equal to 197 mg/kg bw per day <sup>b</sup>	–
	Two-generation study of reproductive toxicity <sup>a</sup>	Reproductive toxicity	5 000 ppm, equal to 257 mg/kg bw per day <sup>b</sup>	–
		Parental toxicity	1 000 ppm, equal to 47.8 mg/kg bw per day	5 000 ppm, equal to 257 mg/kg bw per day
		Offspring toxicity	5 000 ppm, equal to 257 mg/kg bw per day <sup>b</sup>	–
	Developmental toxicity study <sup>c</sup>	Maternal toxicity	30 mg/kg bw per day	300 mg/kg bw per day
		Embryo and fetal toxicity	1 000 mg/kg bw per day <sup>b</sup>	–
Rabbit	Developmental toxicity study <sup>c</sup>	Maternal toxicity	1 000 mg/kg bw per day <sup>b</sup>	–
		Embryo and fetal toxicity	1 000 mg/kg bw per day <sup>b</sup>	–

Species	Study	Effect	NOAEL	LOAEL
Dog	Three-month and one-year studies of toxicity <sup>a,d</sup>	Toxicity	3 000 ppm, equal to 89.8 mg/kg bw per day	15 000 ppm, equal to 448 mg/kg bw per day

<sup>a</sup> Dietary administration.

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

<sup>c</sup> Gavage administration.

<sup>d</sup> Two or more studies combined.

#### *Acceptable daily intake (ADI)*

0–0.09 mg/kg bw per day

#### *Acute reference dose (ARfD)*

Unnecessary

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

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

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

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

Rate and extent of oral absorption	Rapid; 76–89% of the dose at 5 mg/kg bw and 36–53% of the dose at 200 mg/kg bw in bile duct cannulated rats
Dermal absorption	No data
Distribution	Widespread: highest concentrations in liver, kidney, plasma, whole blood and blood cells
Potential for accumulation	Some evidence of accumulation in plasma and whole blood
Rate and extent of excretion	Rapid: Largely excreted into bile and urine by 48 hours
Metabolism in animals	Converted to 2MDPM, 3HDPM and 4HDPM
Toxicologically significant compounds in animals and plants	Pyriofenone

##### *Acute toxicity*

Rat, LD <sub>50</sub> , oral	>2 000 mg/kg
Rat, LD <sub>50</sub> , dermal	>2 000 mg/kg
Rat, LC <sub>50</sub> , inhalation	>5.18 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Slightly irritating
Mouse, dermal sensitization	Not sensitizing

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

Target/critical effect	Liver, kidney and blood / histopathological changes in liver and kidney, anaemia, increased APTT, decreased ALP
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Lowest relevant oral NOAEL	60.5 mg/kg bw per day (rat) <sup>a</sup>
Lowest relevant dermal NOAEL	1 000 mg/kg bw per day, highest dose tested (rat)
Lowest relevant inhalation NOAEC	No data
<i>Long-term studies of toxicity and carcinogenicity</i>	
Target/critical effect	Liver, kidney and blood / histopathological changes in liver and kidney, anaemia, increased APTT
Lowest relevant NOAEL	9.13 mg/kg bw per day (rat)
Carcinogenicity	Limited evidence of carcinogenicity in the liver of mice, not carcinogenic in rats <sup>b</sup>
<i>Genotoxicity</i>	
	No evidence of genotoxicity <sup>b</sup>
<i>Reproductive toxicity</i>	
Target/critical effect	No reproductive effect / increased liver and caecum weights, anaemia in parental animals
Lowest relevant reproductive NOAEL	257 mg/kg bw per day, highest dose tested (rat)
Lowest relevant parental NOAEL	47.8 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	257 mg/kg bw per day, highest dose tested (rat)
<i>Developmental toxicity</i>	
Target/critical effect	No embryo/fetal effects / increased liver and caecum weights in maternal rats
Lowest relevant maternal NOAEL	30 mg/kg bw per day (rat)
Lowest relevant developmental NOAEL	1 000 mg/kg bw per day, highest dose tested (rat and rabbit)
<i>Neurotoxicity/delayed neurotoxicity</i>	
Acute neurotoxicity	2 000 mg/kg bw, highest dose tested (rat)
Subchronic neurotoxicity	927 mg/kg bw, highest dose tested (rat)
<i>Other toxicological studies</i>	
Immunotoxicity	Negative
Studies with metabolites 2MDPM, 3HDPM and 4HDPM	Oral LD <sub>50</sub> > 2 000 mg/kg bw (rats) Negative in bacterial mutagenesis assays
<i>Human data</i>	
	None identified

<sup>a</sup> A NOAEL of 24.2 mg/kg bw per day was noted in a 28-day dose range finding study in rats.

<sup>b</sup> Unlikely to pose a carcinogenic risk to humans via exposure from the diet.

### Summary

	Value	Study	Safety factor
ADI	0–0.09 mg/kg bw per day	Two-year carcinogenicity study in rats	100
ARfD	Unnecessary	–	–

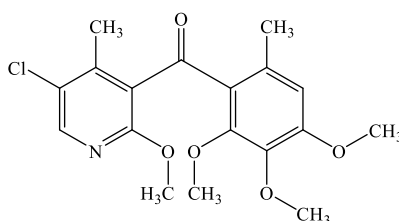


## RESIDUE AND ANALYTICAL ASPECTS

Pyriofenone, (5-chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-*o*-tolyl)-methanone (IUPAC name), is a member of aryl-phenyl ketone fungicides with the structure of benzoylpyridine. It can be used for control of powdery mildew on various crops with local systemic properties. It has been registered in many countries for use on berries and other small fruits, cucurbits, fruiting vegetables other than cucurbits, and cereal grains.

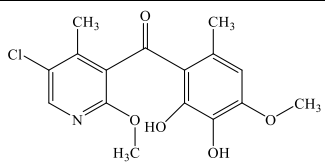
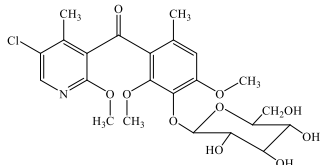
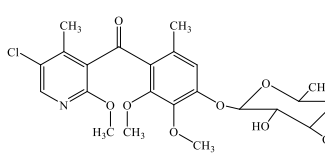
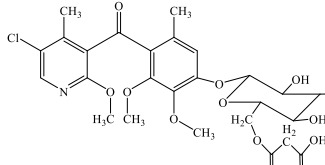
Pyriofenone was listed in the Codex Priority List by the Forty-seventh Session of CCPR in 2015 for toxicological and residue evaluation by the current Meeting as a new compound.

The Meeting received information on identity, chemical and physical properties, metabolism and environmental fate, residue analysis, use pattern, supervised trials on berries and other small fruits, kiwi fruit and cucurbits, and processing studies on wine grape.



The following abbreviated names were used for the metabolites referred to in this Appraisal.

Compound Name/Code	IUPAC name	Structure	Found in study on:
Pyriofenone IKF 309	(5-chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy- <i>o</i> -tolyl)methanone		Tomato, Grape, wheat, Rotational crops (wheat, lettuce, carrot) Goat liver & kidney Rat Soil
4HDPM	(5-chloro-2-methoxy-4-methyl-3-pyridinyl)(4-hydroxy-2,3-dimethoxy-6-methylphenyl) methanone		Grape, Wheat, Goat liver & kidney Rat
3HDPM	(5-chloro-2-methoxy-4-methyl-3-pyridinyl)(3-hydroxy-2,4-dimethoxy-6-methylphenyl) methanone		Grape, Wheat, Goat liver & kidney Rat
2MDPM	(5-chloro-2-methoxy-4-methyl-3-pyridinyl)(3,4-dihydroxy-2-methoxy-6-methylphenyl) methanone		Tomato, Grape, Wheat, Goat liver & kidney, Rat

Compound Name/Code	IUPAC name	Structure	Found in study on:
4MDPM	(5-chloro-2-methoxy-4-methyl-3-pyridinyl)(2,3-dihydroxy-4-methoxy-6-methylphenyl) methanone		Wheat, Rat
3GDPM	(5-chloro-2-methoxy-4-methyl-3-pyridinyl)(3-β-D-glucopyranosyloxy-2,4-dimethoxy-6-methylphenyl) Methanone		Grape, Wheat,
4GDPM	(5-chloro-2-methoxy-4-methyl-3-pyridinyl)(4-β-D-glucopyranosyloxy-2,3-dimethoxy-6-methylphenyl) methanone		Grape, Wheat, Rotational crops (wheat, carrot)
4MGDPM	(5-chloro-2-methoxy-4-methyl-3-pyridinyl)(4-(6-O-malonyl-β-D-glucopyranosyloxy)-2,3-dimethoxy-6-methylphenyl) methanone		Grape, Rotational crop (wheat)

### Plant metabolism

The Meeting received information on the fate of pyriofenone in tomato, grapevine and wheat after foliar spray applications. For the studies, pyriofenone labelled with  $^{14}\text{C}$  at the phenyl ring ([U-phenyl- $^{14}\text{C}$ ]-pyriofenone) and at position 2 and 6 of the pyridine ring ([pyridyl-2,6- $^{14}\text{C}$ ]-pyriofenone) were used. In metabolism studies, total radioactive residues (TRR) are expressed in mg pyriofenone equivalents/kg.

Phenyl labelled or pyridyl labelled pyriofenone was applied to potted tomato plants, grown in a multi-purpose compost under a plastic tunnel, as a foliar spray at a rate equivalent to 100 g ai/ha three times with a re-treatment interval (RTI) of 12 days with harvest 7 days after the last application (DALA).

Three applications of either of  $^{14}\text{C}$ -labelled pyriofenone resulted in similar total radioactive residues (TRR) in fruits or foliage: 0.17–0.19 mg eq/kg in fruits and 16–17 mg eq/kg in foliage harvested 7 days after the last application.

Distribution of radioactivity in fruits and foliage was similar between the two  $^{14}\text{C}$ -labelled pyriofenone treatments. Most of the radioactivity was recovered in the acetonitrile surface wash of fruits and foliage, accounting for 92–93% TRR and 84–90% TRR, respectively. Acetonitrile/water (4:1, v/v) further extracted 5.2–5.3% TRR of fruits and acetonitrile/water (1:1, v/v) extracted 9.0–14% TRR of foliage. The unextracted radioactivity was 1.9–2.5% TRR in fruit samples and 1.1–2.2% TRR in foliage samples.

The predominant radioactive residue in the surface wash and extracts was the parent pyriofenone accounting for 95% TRR (0.16–0.18 mg/kg) in fruit and 94–96% TRR in foliage. In the surface wash, no other radioactive residues other than the parent were found.

Some minor metabolites were found in the extracts, but none exceeded 2% of TRR (in fruits up to 0.01 mg eq/kg and in foliage up to 0.18 mg eq/kg).

Phenyl labelled or pyridyl labelled pyriofenone was applied to outdoor grown grape vines, as a foliar spray at a rate equivalent to 100 g ai/ha three times with a RTI of 14 days between applications, up to 29 days prior to harvest.

The TRR at 29 DALA to grape vines with either of the two  $^{14}\text{C}$ -labelled pyriofenone were 0.10–0.11 mg eq/kg in berries and 2.8–3.7 mg eq/kg in foliage. The majority of radioactivity was recovered in acetonitrile surface wash: 43–62% TRR for berries, and 65–76% TRR for foliage. Acetonitrile/water mixture (4:1 for fruit and 1:1 for foliage, v/v) extracted 33–51% TRR in fruit and 14–22% TRR in foliage. A small proportion of radioactivity remained unextracted in fruit (4.5–6.5% TRR) and foliage (10–13% TRR).

Most of the radioactivity in the surface wash, acetonitrile/water extracts and the ethyl acetate phase of acid hydrolysates was the parent pyriofenone (52–72% TRR for berries, and 56–68% TRR for foliage) with many small radioactive metabolites/components (up to a total of 34 peaks). In berry samples, none other than the parent was more than 7.1% TRR or 0.01 mg eq/kg. In foliage samples, a number of metabolites/components were found at higher than 0.01 mg eq/kg (up to 0.13 mg eq/kg) but only accounted for a maximum of 3.5% TRR.

Wheat, grown outdoor in a sandy loam soil, received two foliar applications of either a phenyl labelled or pyridyl labelled pyriofenone at a rate equivalent to 100 g ai/ha at BBCH 31 (first node detectable) and BBCH 71 (grain water ripe) (interval of 73 days between the two applications). Forage samples were obtained 7 days after the first application, hay samples 6 days after the last application, and grain, straw and chaff 40 days after the last application.

Low TRR in grain (0.042–0.059 mg eq/kg) indicated limited translocation within the plant. TRR were higher in forage (1.7–1.9 mg eq/kg), hay (0.83–1.2 mg eq/kg), straw (0.88–1.2 mg eq/kg) and chaff (2.1–3.9 mg eq/kg).

Grain samples were not surface-washed. A majority (59–71% TRR) of radioactivity in grain samples was extracted by acetonitrile/water mixture.

Significant proportions of radioactivity in forage, hay, straw and chaff were recovered in acetonitrile surface wash: 77–82% TRR, 50–55% TRR, 7.6–12% TRR, and 32–28% TRR, respectively.

Acetonitrile/water mixture extracted a further 16–20% TRR of forage, 36–42% TRR of hay, 61–64% TRR of straw, and 57–59% TRR of chaff. Surface wash and acetonitrile/water extracts accounted for > 69% of TRR.

The base treatment released 19–21% TRR of grain and 3.8–22% TRR of foliage fractions.

Radioactive residues remaining unextracted were 10–20% TRR of grain, 3.0–3.1% TRR of forage, 3.0–4.4% TRR of hay, 4.4–9.4% TRR of straw and 2.7–3.1% TRR of chaff.

Parent pyriofenone was the main component in all samples at harvest (40DALA) representing 13–29% TRR in grain, 35–49% TRR in straw, and 51–55% in chaff. Pyriofenone was metabolised to a large number of more polar known and unknown metabolites/components. None of these metabolites/components individually exceeded 8.4% TRR in the foliage fraction. 4HDPM and its conjugates were found at 12% TRR (0.10 mg/kg) in the straw sample from the pyridyl-label treatment. 4HDPM, 3-HDPM, 2MDPM were found at concentrations higher than 0.1 mg/kg in chaff samples but accounted for less than 8% TRR. A number of more polar metabolites were also formed in grain but none of which accounted for greater than 8.6% TRR (0.006 mg eq/kg) in wheat grain.

#### *Summary of plant metabolism*

When pyriofenone was applied to tomato, grape and wheat plants, residues were at lower concentrations

in edible parts of the plants than inedible parts. In all of the plants tested, the majority of the pyriofenone remained unmetabolised. The major radioactive residue in the surface wash and extracts was pyriofenone. Numerous metabolites/components were detected. However, none accounted for >10% TRR, except 4HDPM and its conjugates (12% TRR at 0.10 mg/kg) in wheat straw.

Pyriofenone, when sprayed onto plants, would follow demethylation at various positions of the molecule and then metabolites would produce conjugates.

Free forms of identified metabolites were also reported in the rat metabolism study.

### ***Animal metabolism***

The metabolism of pyriofenone in laboratory animals was reviewed within the framework of the toxicological evaluation by the current Meeting.

Following daily oral administration of phenyl- or pyridyl-labelled pyriofenone for 5 days to lactating goats at a nominal rate of 10 ppm in the diet, 80–84% of the cumulative administered dose was recovered at sacrifice 23 hours after the last dose. Excretion in urine, faeces and cage wash accounted for 75–79% of the administered dose. Radioactivity remaining in the tissues at sacrifice (excluding gastrointestinal tract and its contents) accounted for 0.22–1.5% of the administered dose. TRR in milk reached plateau concentrations of 0.001–0.004 mg eq/kg after day 3. TRR in muscle and fat were also very low at < 0.001 mg eq/kg and 0.003–0.004 mg eq/kg, respectively while TRR in liver and kidney were 0.135–0.156 mg eq/kg and 0.028–0.051 mg eq/kg, respectively. Therefore, identification/characterisation of radioactive residues were attempted for liver and kidney samples only.

Extraction using organic solvent, acid, base, reflux in 6M HCl and then 2M NaOH recovered 90–100% TRR in liver and kidney. Solvent extracts accounted for 53–61% TRR in liver and 90–95% TRR in kidney. In the extracts (from various steps), pyriofenone accounted for 2.8–5.6% TRR and free 2MDPM, 1.0–5.6% TRR in liver and kidney.

After the enzymatic hydrolysis using glucuronidase/sulfatase, the sum of free and conjugated 2MDPM and 3- or 4HDPM in liver was 8.1% TRR (0.011 mg eq/kg) and 24% TRR (0.032 mg eq/kg), respectively; and in kidney 16%TRR (0.004 mg eq/kg) and 24% TRR (0.007 mg eq/kg), respectively. 3- and 4-HDPM could not be resolved by HPLC. A number of minor components were found none of which were more than 10% TRR and 0.01 mg eq/kg.

### ***Summary of animal metabolism***

Pyriofenone was extensively metabolised to numerous metabolites/components, including glucuronized 2MDPM and 3- and/or 4-HDPM, through demethylation and glucuronization. In the extracts of liver and kidney, pyriofenone accounted for 2.8–5.6% TRR (0.005–0.007 mg/kg). Free forms of 2MDPM and 3- or 4HDPM accounted for 1.0–5.6% TRR and < 0.4–4.4% TRR, respectively. Pyriofenone and these metabolites were also found in rats.

### ***Environmental fate***

Pyriofenone is hydrolytically stable in aqueous solutions at 50 °C at the pH range of 4 to 9. Pyriofenone is also stable to aqueous photolysis.

### ***Residues in succeeding or rotational crops***

#### ***Confined rotational crop study***

In a confined rotational crop study, phenyl-labelled pyriofenone was applied to sandy loam soil at a rate

equivalent to 284 g ai/ha. Seeds of wheat, lettuce and carrot were sown 31, 122 and 364 days after the treatment.

TRR in crop samples sown at 31-, 122- and 364-day PBI were up to 0.23 mg eq/kg. Radioactive residues in crops showed a tendency to decrease with time over the three PBIs. TRR in lettuce from 31-day and 122-day PBI were less than 0.01 mg eq/kg. The highest total radioactive residues were detected in wheat hay (0.12 mg eq/kg) and straw (0.23 mg eq/kg). Residues in wheat forage, carrot tops and root were lower representing no more than 0.057 mg eq/kg. Residues in wheat grain were very low at no more than 0.008 mg eq/kg.

Pyriofenone (>15% TRR in wheat foliage fractions, >70% TRR in carrot root and >24% TRR in carrot foliage) was one of the main components identified along with 4GDPM (up to 17% TRR and 0.010 mg eq/kg in wheat straw) and 4MGDPM (up to 24% TRR and 0.011 mg eq/kg in wheat hay) and a number of minor polar metabolites. Similar metabolic profiles were present in each of the crop matrices analysed, and were comparable to the metabolism of pyriofenone observed in the grape and wheat metabolism studies.

The probability of detecting pyriofenone residues above 0.01 mg/kg could not be excluded for root crops or forage/fodder crops in rotation. Due to the lack of a soil degradation study or field rotational crop study, the Meeting considered that it was not possible to reach a conclusion on the residue situation in rotational crops.

### ***Methods of analysis***

Analytical methods for determination of residues of pyriofenone were provided to the current Meeting for a wide range of matrices of plant origin including crops on which supervised trials were conducted.

In general, the methods employ extraction by homogenisation with an aqueous hydrochloric acid/acetonitrile solution (acetonitrile/ultrapure water/ concentrated HCl, 50:50:1, v/v), clean-up with solid phase extraction cartridge, and determination of analyte using LC-MS/MS. Specific methods for the determination of pyriofenone in wheat grain and straw employ a treatment of homogenised sample in 2% HCl for 2 hours at room temperature before extraction with acetonitrile.

A number of methods were found suitable for analysis of pyriofenone in plant matrices of high water, high starch, high acid and high oil content with a LOQ of 0.01 mg/kg.

Radio-validation was conducted using the wheat straw, tomato foliage and grape berry samples obtained from applications with <sup>14</sup>C-labelled pyriofenone in metabolism studies and the results indicated that the extraction efficiency of acetonitrile/ultrapure water/concentrated HCl (50:50:1, v/v) was sufficient.

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 pyriofenone, 3HDPM and 4HDPM during frozen storage at -33 °C to -14 °C was investigated in a range of plant matrices (high water, high acid and high starch matrices).

The results showed that pyriofenone was stable in wheat matrices and grapes for at least 18 months and in summer squash for at least 9 months under frozen conditions. One of the pyriofenone metabolite, 3HDPM, was shown to be stable in wheat grain for a maximum of 3 months and in wheat straw and grapes for at least 18 months, and another metabolite, 4HDPM was shown to be stable in wheat matrices and grapes for at least 18 months under the same frozen conditions.

**Definition of the residue**

In the plant metabolism studies on tomato, grape vine and wheat, the predominant residue was parent pyriofenone (>90% TRR in tomato fruit, 52–72% TRR grape berries, and 13–29% TRR in wheat grain). Numerous metabolites were identified but none of them exceeded 10% TRR and 0.01 mg/kg.

The confined rotational crop studies indicate similar metabolic patterns to the primary crops. The major residue was the parent, pyriofenone (33–79% TRR in wheat forage, 15–26% TRR in wheat hay, 15–20% TRR in wheat straw, 72–81% TRR in mature carrot root and >24–40% TRR in mature carrot tops).

Suitable analytical methods are available to analyse pyriofenone in plant commodities.

The Meeting considered that pyriofenone, the predominant residue, was a suitable marker for enforcement of MRLs and for dietary risk assessment.

In an animal metabolism study on lactating goats (dose: 10 ppm in the diet), pyriofenone was excreted efficiently. Pyriofenone was extensively metabolised into numerous compounds including glucuronides. In liver and kidney, pyriofenone accounted for 2.8–5.6% TRR, free 2MDPM 1.0–5.3% TRR and free 3- or 4HDPM up to 4.4% TRR. Glucuronides of 2MDPM and 3- and/or 4-HDPM released by glucuronidase treatment, together with free forms, accounted for 1.1–16% TRR and 24% TRR respectively. The calculated maximum dietary burden using grape pomace was 0.61 ppm in the diet, much lower than the dose of 10 ppm in the diet used in the goat metabolism study. No other commodities for which trials were submitted are fed to cattle or hens according to the OECD Feed Table. Therefore, no residues of pyriofenone or metabolites were expected to occur above 0.01 mg/kg and the contribution of foods of animal origin in the human dietary exposure would be negligible.

No information was available on analytical methods for commodities of animal origin.

The Meeting considered that pyriofenone was a suitable marker for enforcement of MRLs and for dietary risk assessment for commodities of animal origin. When information on analytical method(s) for animal commodities became available, the Meeting may revisit the definition of residue.

The Meeting considered that information was insufficient for determining fat solubility of pyriofenone in commodities of animal origin.

Based on the above, the Meeting recommended the following residue definition.

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

**Results of supervised residue trials on crops**

The Meeting received supervised trial data for pyriofenone on grapes, strawberry, blueberries, blackberries, kiwifruit, cucumber, summer squash and cantaloupe.

**Berries and other small fruits***Cane berries: Blackberries*

Critical GAP in the USA for the cane berry crop sub-group allows applications at a maximum rate of 0.11 kg ai/ha up to the seasonal maximum rate of 0.35 kg ai/ha with an interval of 7 days, and PHI of 0 days.

Six supervised trials were conducted on blackberries in North America (one in Canada and five in the USA) in 2012. Pyriofenone was applied four times as a foliar spray at rates ranging from 0.085–0.093 kg ai/ha with a RTI of 7 days. Seasonal application rate ranged from 0.35–0.37 kg ai/ha. Samples were collected at 0 day after the last application.

The Meeting considered that the contribution of the first application to the residues in berries at harvest would be insignificant; and decided to use these supervised trials with four applications for estimating a maximum residue level and STMR.

Pyriofenone residues from trials approximating the above GAP were in rank order (n = 6): 0.07, 0.24, 0.25, 0.28, 0.41 and 0.47 mg/kg.

Noting that USA GAP is for the Cane berry crop sub-group including blackberry and that blackberry is a representative commodity for the cane berries sub-group in the Codex classification, the Meeting estimated a maximum residue level of 0.9 mg/kg and STMR of 0.265 mg/kg for the cane berries sub-group.

*Bush berries: Blueberries*

Critical GAP in the USA for the bush berry crop sub-group allows applications at a maximum rate of 0.11 kg ai/ha up to the seasonal maximum rate of 0.35 kg ai/ha with an interval of 7 days, and PHI of 0 day.

Ten supervised trials were conducted on blueberries in North America (two in Canada and eight in the USA) in 2012. Pyriofenone was applied four times as a foliar spray at rate ranging from 0.082–0.10 kg ai/ha with a RTI of 7 days. The seasonal application rate ranged from 0.35–0.38 kg ai/ha. Samples were collected at 0 day after the last application.

The Meeting considered that contribution of the first application to the residues in berries at harvest would be insignificant; and decided to use these supervised trials with four applications for estimating a maximum residue level and STMR.

Pyriofenone residues from trials approximating the above GAP were in rank order (n = 10): 0.10, 0.16, 0.26, 0.32, 0.33, 0.35, 0.44, 0.52, 0.55 and 0.64 mg/kg.

Noting that GAP in the USA is for the Bush berry crop sub-group, which includes blueberry, and that blueberry is the representative commodity for the Bush berry sub-group in the Codex classification, the Meeting estimated a maximum residue level of 1.5 mg/kg and STMR of 0.34 mg/kg for the Bush berry sub-group.

*Small fruit vine climbing: Grapes (table and wine grapes)*

Critical GAP for table grapes in Europe is that of Portugal which allows three application at 0.09 kg ai/ha with PHI of 14 days.

Twenty supervised trials were conducted on grapes in Europe (France, Germany, Italy and Spain) in 2007–2011: 15 on wine grapes and five on table grapes. In each trial, pyriofenone was applied three times as a foliar spray at a nominal rate of 0.09 kg ai/ha.

Residues of pyriofenone in table and wine grapes from trials matching GAP for table grapes in Portugal were in rank order (n = 10): 0.03, 0.06, 0.06, 0.09, 0.10, 0.13, 0.15, 0.19, 0.31 and 0.54 mg/kg.

Critical GAP for wine grapes in Europe is that of Portugal which allows three application at 0.09 kg ai/ha with a PHI of 28 days.

Fifteen supervised trials were conducted on wine grapes in Europe (France, Germany, Italy and Spain) in 2007–2009 as described above.

Pyriofenone residues in wine grapes from trials matching the GAP for wine grapes in Portugal were in rank order (n = 15): 0.02, 0.03, 0.03, 0.04, 0.04, 0.05, 0.06, 0.07, 0.08, 0.08, 0.10, 0.10, 0.10, 0.11 and 0.14 mg/kg.

Critical GAP for the Small fruit vine climbing crop sub-group in the USA allows applications at a maximum rate of 0.11 kg ai/ha up to the seasonal maximum of 0.35 kg ai/ha, with an interval of 14 days, and PHI of 0 days.

Twelve supervised trials were conducted on grapes in North America (one in Canada and 11 in the USA) in 2012. In each trial pyriofenone was applied four times as a foliar spray at rate ranging from 0.085–0.094 kg ai/ha with a RTI of 7 days. The seasonal application rate ranged from 0.35–0.37 kg ai/ha. Samples were collected at 0 days after the last application.

The first application in the North American trials took place, at the earliest, BBCH 81 (beginning of ripening) after which no significant dilution of residues by growth of berries is expected to occur. The Meeting utilised the prediction tool developed by the 2017 JMPR to determine if it was appropriate to use these trials (7 day RTI) on a basis of three decline trials (one conducted in the USA and another two in Europe, in which the first application was, at the earliest, at BBCH 81). An anticipated residue level at DALA of 0 days with four times application at the nominal rate of 0.09 kg ai/ha with a 7-day RTI would be about 20% higher than the residue level arising from applications according to critical GAP (14 day RTI) in the USA. Therefore, the Meeting decided to use these Canadian and USA trials.

Pyriofenone residues from trials in Canada and the USA approximating GAP in the USA were in rank order (n = 12): 0.06, 0.16, 0.18, 0.20, 0.20, 0.21, 0.25, 0.27, 0.29, 0.36, 0.42 and 0.46 mg/kg.

The residues in grapes from trials in Canada and the USA covers the residues in table and wine grapes from trials in Europe. Noting that USA GAP is for small fruit vine climbing crop sub-group including grapes and that grapes are the representative commodity for the Small fruit vine climbing sub-group in the Codex classification, the Meeting estimated, on the basis of the dataset from the Canadian/USA trials, a maximum residue level of 0.8 mg/kg and STMR of 0.23 mg/kg for the Small fruit vine climbing sub-group.

#### *Low growing berries: Strawberry*

Critical GAP for the Low growing berry crop sub-group in the USA allows applications at a maximum rate of 0.11 kg ai/ha up to the seasonal maximum rate of 0.35 kg ai/ha with a RTI of 7 days, and PHI of 0 days.

Nine supervised trials were conducted on strawberry in North America (one in Canada and eight in the USA) in 2012. Except for one trial conducted in the USA with a lower application rate, pyriofenone was applied four times as a foliar spray at rates ranging from 0.084–0.093 kg ai/ha with a RTI of 7 days. The seasonal application rate ranged from 0.35–0.37 kg ai/ha. Samples were collected at 0 days after the last application.

The Meeting considered that the contribution of the first application to the residues in berries at harvest would be insignificant; and decided to use these supervised trials with four applications for estimating a maximum residue level and STMR.

Pyriofenone residues from trials approximating the above GAP were in rank order (n = 8): 0.03, 0.08, 0.15, 0.16, 0.18, 0.21, 0.21 and 0.27 mg/kg.

Noting that GAP in the USA is for the Low growing berry crop sub-group, including strawberry, and that strawberry is the representative commodity for the Low growing berries sub-group in the Codex classification, the Meeting estimated a maximum residue level of 0.5 mg/kg and STMR of 0.17 mg/kg for the low growing berries sub-group.



*Assorted tropical and sub-tropical fruits-inedible peel**Inedible peel-vines: kiwifruit*

Critical GAP for the Small fruit vine climbing crop sub-group in the USA (in the USA, kiwifruit is classified within this sub-group) allows applications at a maximum rate of 0.11 kg ai/ha up to the seasonal maximum rate of 0.35 kg ai/ha with a RTI of 7 days, and PHI of 0 days.

Three supervised trials were conducted on kiwifruit in the USA in 2012. Pyriofenone was applied four times as a foliar spray at 0.088–0.093 kg ai/ha with an interval of 7 days. Seasonal application rates ranged from 0.34–0.37 kg ai/ha. Samples were collected at 0 days after the last application. The Meeting considered that contribution of the first application to the residues in berries at harvest would be insignificant; and decided to use these supervised trials with four applications for estimating a maximum residue level and STMR.

Pyriofenone residues from trials approximating the above GAP were in rank order (n = 3): 0.05, 0.13 and 0.61 mg/kg.

As the 2015 JMPR agreed that five trials were necessary for estimating a maximum residue level for kiwifruits (Category 3 minor crop), the Meeting concluded that the data were insufficient to estimate a maximum residue level or STMR for kiwifruit.

*Fruiting vegetables, Cucurbits: cucumber, summer squash and cantaloupe (melon)*

Critical GAP in the USA for cucurbit crop sub-group including cucumber, summer squash and cantaloupe allows applications at a rate of 0.11 kg ai/ha up to the seasonal maximum of 0.35 kg ai/ha with an interval of 7 days, and PHI of 0 day.

Nine supervised trials were conducted on each of cucumber and summer squash in North America (one in Canada and eight in the USA for each crop) in 2012. Supervised trials were conducted on melon/cantaloupe in the USA in 2012. Pyriofenone was applied four times as a foliar spray at 0.083–0.10 kg ai/ha with an interval of 7 days. Seasonal application rates ranged from 0.34–0.37 kg ai/ha.

The Meeting considered that the contribution of the first application to the residues in fruits at harvest would be insignificant; and decided to use these supervised trials with four applications for estimating a maximum residue level and STMR.

Pyriofenone residues in cucumber from trials approximating the above GAP were in rank order (n = 8): 0.01, 0.02, 0.03, 0.03, 0.04, 0.04, 0.06 and 0.06 mg/kg.

Pyriofenone residues in summer squash from trials approximating the above GAP were in rank order (n = 9): 0.01, 0.01, 0.02, 0.04, 0.04, 0.05, 0.06, 0.06 and 0.07 mg/kg.

Pyriofenone residues in cantaloupe from trials approximating the above GAP were in rank order (n = 9): 0.03, 0.04, 0.04, 0.05, 0.05, 0.05, 0.05, 0.06 and 0.17 mg/kg.

Since the median values of the data populations of cucumber, summer squash and cantaloupe do not differ by more than 5-fold, the Meeting considered if it was appropriate to combine the three datasets for estimating a group maximum residue level. As Kruskal-Wallis H test indicated that the three data populations are not significantly different, the Meeting decided to combine the three datasets of cucumber, summer squash and cantaloupe to estimate a maximum residue level and STMR.

Pyriofenone residues from the combined dataset were in rank order (n = 26): 0.01 (3), 0.02 (2), 0.03 (3), 0.04 (6), 0.05 (5), 0.06 (5), 0.07 and 0.17 mg/kg.

Noting that USA GAP is for cucurbit vegetable crop group including cucumber, summer squash and cantaloupe and these crops are representative commodities for fruiting vegetables, cucurbits in the Codex classification, the Meeting estimated a maximum residue level of 0.2 mg/kg and STMR of 0.04 mg/kg for the group of fruiting vegetables, Cucurbits.

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

#### ***High temperature hydrolysis***

The hydrolysis of phenyl-labelled and pyridyl-labelled pyriofenone was studied in sterile buffered aqueous solution under conditions simulating pasteurisation, baking/brewing/boiling, and sterilisation.

Pyriofenone was stable under all the conditions representing pasteurisation (pH 4, 90 °C, 20 minutes), baking/brewing/boiling (pH 5, 100 °C, 60 minutes) and sterilisation (pH 6, 120° C, 20 minutes) with 93–96% recovered at the end of incubation. No degradation products were found.

#### ***Processing***

The Meeting received information on processing of grape to wines, juice and dried grape. Processing factors of grape products from four studies are summarised below.

Processed commodity	Individual processing factor	Best estimate	STMR/STMR-P (mg/kg)
Grape			0.23
White wine (at bottling)	< 0.10, 0.14, < 0.20, < 0.20	0.14	0.032
White wine (after 6 months storage)	< 0.10, 0.14, < 0.20, < 0.20	0.14	
Red wine (at bottling)	0.04, 0.08, < 0.25, < 0.5	0.06 <sup>a</sup>	0.014
Red wine (after 6 months storage)	< 0.08, 0.04, < 0.25, < 0.5	0.04	
Juice	0.04, < 0.07, 0.08, < 0.10, < 0.20, < 0.20, < 0.25, < 0.50	0.06 <sup>a</sup>	0.014
Must	0.43, 0.48	0.46	0.10
Dried grapes	1.5, 1.7, 2.3, 2.8, 2.8, 3.2, 3.6, 5.0	2.8 <sup>b</sup>	0.64
Wet pomace	1.4, 1.9, 2.1, 3.2	2.0 <sup>b</sup>	0.46

<sup>a</sup> mean value of two individual PF calculated from the results above LOQ

<sup>b</sup> median value of individual PF calculated from the results above LOQ

Using the best estimates of processing factors and the STMR of 0.23 mg/kg for grapes, the STMR-P values were calculated for processed commodities of grapes.

As the residues concentrate in dried grapes, the Meeting estimated a maximum residue level of 2.5 mg/kg for dried grapes.

The median residue for grape wet pomace was calculated to be 0.46 mg/kg (as received) for animal dietary burden calculation.

### ***Residues in animal products***

#### ***Estimation of dietary burden***

The maximum and mean dietary burdens were calculated using the mean pyriofenone residues for grape wet pomace estimated at the current Meeting on the basis of the OECD diets listed in Appendix IX of the

2016 edition of the FAO manual. The estimated burdens are presented in Annex 6 and summarised below.

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

	US-Canada		EU		Australia		Japan	
	Max	mean	max	Mean	max	Mean	Max	Mean
Beef cattle	0	0	0	0	0.613 <sup>a</sup>	0.613 <sup>b</sup>	0	0
Dairy cattle	0	0	0	0	0.613 <sup>c</sup>	0.613 <sup>d</sup>	0	0
Broilers	0	0	0	0	0	0	0	0
Layers	0	0	0	0	0	0	0	0

<sup>a</sup> Suitable for estimating maximum residue levels for meat, fat and edible offal of cattle.

<sup>b</sup> Suitable for estimating STMRs for meat, fat and edible offal of cattle.

<sup>c</sup> Suitable for estimating maximum residue level for milk.

<sup>d</sup> Suitable for estimating STMR for milk

*Residues in milk and cattle tissues*

No feeding study was conducted on cattle.

In an animal metabolism study on a goat conducted at a dose equivalent to 10 ppm in the diet (nominal; actual levels were 7.8–13 ppm), pyriofenone was detected at 0.005–0.007 mg/kg from liver extract and 0.001–0.002 mg/kg in kidney extract. TRR in milk, muscle and fat were much lower than those in liver and kidney and were all < 0.004 mg eq/kg. Therefore, no residue of pyriofenone was expected to occur in commodities of cattle origin at the calculated dietary burdens.

Due to the lack of information on analytical methods for animal matrices, the Meeting did not estimate maximum residue levels for commodities of animal origin.

*Residues in egg and poultry tissues*

No feeding study was conducted on laying hens. However, since the dietary burden is zero, no residue of pyriofenone was expected to occur in commodities of poultry origin.

## RECOMENDATIONS

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. The International Estimated Daily Intakes (IEDIs) for pyriofenone 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 2018 JMPR Report. The IEDIs were 0% of the maximum ADI.

The Meeting concluded that 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 is 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.

## 5.27 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.

Pyriproxyfen was scheduled at the Forty-ninth Session of the CCPR for the evaluation of additional uses by the 2018 JMPR. The current Meeting received new information on use patterns for pyriproxyfen in bananas, mangoes, papayas, pineapples, cucumbers, cantaloupe melons, peppers and tomatoes supported by additional analytical methods, storage stability data, supervised field trials and nature of residues studies simulating typical processing conditions.

#### **Methods of analysis**

The current Meeting received additional analytical information for the analysis of pyriproxyfen and 4-OH-pyriproxyfen in plant matrices.

A modification of the QuEChERS-multimethod as well as the applicability of the L-00.00-34 multimethod (formerly “DFG S19”) was tested for matrices with high water and high acid (QuEChERS only) content. GC-MS or GC-MS/MS techniques were successfully validated at a LOQ of 0.01 mg/kg while the LC-MS/MS for the QuEChERS-method achieved a LOQ of 0.02 mg/kg.

In addition, the methods RM-33P-1-3 & RM-33P-1-3a were submitted, utilising GC-NPD for the analysis of pyriproxyfen and HPLC-FLD for the analysis of 4-OH-pyriproxyfen in matrices of high water and high acid content. Samples are extracted with acetone and partitioned first with acetonitrile and hexane and afterwards with dichloromethane. Clean-up is performed with silica gel columns. Both test systems were successfully validated with a LOQ of 0.02 mg/kg. The extraction efficiency of method RM-33P-1-3 was also tested against samples from the apple metabolism study (see JMPR Report 1999). For parent pyriproxyfen an extraction efficiency of 78% was achieved while 4-OH-pyriproxyfen showed a slightly higher extraction rate of 87%.

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

The Meeting received information on the storage stability of pyriproxyfen in pepper, papaya, mango and pineapple. Parent pyriproxyfen was stable in all matrices investigated with maximum storage periods of at least 3 months for peppers, 19 months for papayas, 6 months for mangos and 16 months for pineapples.

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

The Meeting received supervised trial data for applications of pyriproxyfen on various fruit and vegetables

crops conducted in Brunei, Costa Rica, France, Greece, Guatemala, Italy, Malaysia, Panama, Philippines, Spain and the USA.

#### *Banana*

Pyriproxyfen is registered for use in bananas in the USA with a GAP comprising of three foliar applications at 0.12 kg ai/ha, a 14 day RTI and a PHI of 14 days. Supervised field trials, matching GAP, conducted in Costa Rica and Guatemala were submitted.

Residues of parent pyriproxyfen in whole bananas were (n = 1): 0.036 mg/kg.

Residues of parent pyriproxyfen in bananas pulp were (n = 1): < 0.01 mg/kg.

The Meeting considered one trial insufficient to estimate a maximum residue level for the use of pyriproxyfen on bananas.

#### *Mango*

Pyriproxyfen is registered for use on mango in Malaysia with two foliar spraying of 0.05 kg ai/ha each (14 day interval) and a PHI of 1 day. One corresponding supervised field trial conducted in Malaysia was submitted.

Residues of parent pyriproxyfen in mango fruits were (n = 1): < 0.02 mg/kg.

The Meeting considered one trial insufficient to estimate a maximum residue level for the use of pyriproxyfen on mangoes.

#### *Papaya*

Pyriproxyfen is registered for use on papaya in the Philippines with two foliar spraying of 0.1 kg ai/ha each (14 day interval) and a PHI of 1 day. Corresponding supervised field trials conducted in Brunei, Malaysia and the Philippines were submitted.

Residues of parent pyriproxyfen in whole papayas were (n = 6): 0.03, 0.03, 0.04, 0.1, 0.1 and 0.15 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and a STMR of 0.07 mg/kg for pyriproxyfen in papaya.

#### *Pineapple*

Pyriproxyfen is registered for use on pineapple in the USA with two foliar sprays of 0.06 kg ai/ha each (21 day interval) and a PHI of 1 day. Corresponding supervised field trials conducted in Panama were submitted.

Residues of parent pyriproxyfen in whole pineapple fruits were (n = 6): < 0.01 mg/kg.

The Meeting estimated a maximum residue level of 0.01 mg/kg and a STMR of 0.01 mg/kg for pyriproxyfen in pineapples.

#### *Cucumbers, gherkins and summer squash*

Pyriproxyfen is registered for the specific use on protected cucumbers, gherkins and summer squash in Italy with two foliar sprays of 0.12 kg ai/ha each (14 day interval) and a PHI of 3 days. Supervised field trials approximating the GAP (9-11 day intervals) conducted in France, Greece, Italy and Spain were submitted.

Residues of parent pyriproxyfen in cucumbers were (n = 8): < 0.01(7) and 0.02 mg/kg.

The Meeting estimated a maximum residue level of 0.04 mg/kg and a STMR of 0.01 mg/kg for pyriproxyfen in cucumbers, gherkins and summer squash.

#### *Melons, except watermelons*

Pyriproxyfen is registered for use in the USA on field grown cucurbits Group 9 (which include melons) with two foliar spraying of 0.075 kg ai/ha each (14 day interval) and a PHI of 7 days. Corresponding supervised field trials conducted in the USA on cantaloupes were submitted.

Residues of parent pyriproxyfen in whole melons were (n = 7): < 0.01, 0.01, 0.015, 0.016, 0.019, 0.035 and 0.035 mg/kg.

In one trial bearing quantifiable residues in whole melons, corresponding pyriproxyfen residues in melon pulp were < 0.01 mg/kg.

The Meeting estimated a maximum residue level of 0.07 mg/kg and a STMR value of 0.016 mg/kg for pyriproxyfen in melons, except watermelons.

#### *Peppers and eggplants*

Pyriproxyfen is registered for use on protected peppers and eggplants in Italy with two foliar sprays of 0.12 kg ai/ha each (14 day RTI) and a PHI of 3 days. Supervised field trials approximating the GAP rate (9–11 day re-treatment intervals) conducted in France, Greece, Italy and Spain were submitted.

Residues of parent pyriproxyfen in peppers were (n = 8): 0.07, 0.11, 0.12, 0.13, 0.21, 0.25, 0.26 and 0.28 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg and a STMR of 0.17 mg/kg for pyriproxyfen in peppers and decided to extrapolate its recommendations to eggplant also.

Based on a default processing factor of 10, the Meeting also estimated a maximum residue level of 6 mg/kg and a STMR of 1.7 mg/kg for pyriproxyfen in peppers chili, dried.

#### *Tomatoes*

Pyriproxyfen is registered for use on protected tomatoes in Italy with two foliar sprays of 0.12 kg ai/ha each (14 day interval) and a PHI of 3 days. Supervised field trials approximating the GAP (10–11 day re-treatment intervals) conducted in France, Greece, Italy and Spain were provided.

Residues of parent pyriproxyfen in tomatoes were (n = 8): 0.05, 0.06, 0.09, 0.09, 0.11, 0.11, 0.17 and 0.18 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg and a STMR of 0.1 mg/kg for pyriproxyfen in tomatoes.

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

The Meeting received information on the hydrolysis of radio-labelled pyriproxyfen as well as processing studies using unlabelled material on incurred residues in peppers and tomatoes.

In a hydrolysis study using radio-labelled pyriproxyfen typical processing conditions were simulated (pH 4,5 and 6 with 90 °C, 100 °C and 120 °C for 20, 60 and 20 minutes). In duplicate samples of sterile buffer solution no degradation was observed.

The fate of pyriproxyfen residues has been examined simulating household and commercial processing of peppers and tomatoes.

Estimated processing factors for the commodities considered at this Meeting are summarised below.

Raw commodity	Processed commodity	Pyriproxyfen		
		Individual processing factors	Mean or best estimate processing factor	STMR-P in mg/kg
Pepper	Canned pepper	0.08, 0.08	0.08	0.014
Tomato	Juice	< 0.17, < 0.2	< 0.18	0.018
	Puree	0.67, 1.8	1.2	0.12
	Canned tomato	< 0.17, < 0.2	< 0.18	0.018
	Ketchup	0.67	0.67	0.067

### ***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 from supervised trials the Meeting concluded that the residue levels listed in Annex 1 are appropriate for establishing a maximum residue level and for an IEDI assessment.

Definition of the residue for compliance with the MRL and dietary risk assessment in 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 2018 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.



## 5.28 SULFOXAFLO (252)

### RESIDUE AND ANALYTICAL ASPECTS

Sulfoxaflor, a sulfoximine insecticide, was first evaluated by the JMPR in 2011 for residues and toxicology where an ADI and ARfD of 0–0.05 mg/kg bw and 0.3 mg/kg bw respectively were established. A residue definition of *sulfoxaflor* was established for both compliance and dietary risk assessment in plant and animal commodities.

The residue is not fat-soluble.

The latest residue review was done in 2016.

It was scheduled at the Forty-ninth Session of the CCPR for the evaluation of additional new uses at the 2018 JMPR.

For the current Meeting, new GAPs and supervised residue trials on mango, green beans and rice were provided. The current Meeting was also requested to revisit the supervised trials in maize, sorghum, sweet corn, rice and tree nuts, which were previously provided to the 2016 Meeting.

#### ***Methods of analysis***

Unless otherwise specified, residues of sulfoxaflor in all tested commodities including animal feeds were determined using the LC-MS/MS analytical method 091031, previously reviewed by the 2011 JMPR. The limit of quantitation (LOQ) of the method was 0.01 ppm.

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

All samples, collected from each of the supervised field trials, were kept under frozen storage up to a maximum of 467 days from the date of sampling to analysis. Previously conducted storage stability studies of sulfoxaflor and reviewed by the 2011 JMPR, have shown acceptable freezer stability for up to 680 days (in a wide variety of crops).

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

##### ***Mango***

In Taiwan, Province of China, the critical GAP for sulfoxaflor in mango is a maximum of 2 applications, at 7-day re-treatment intervals with a PHI of 14 days. Individual application rates are not specified. The maximum seasonal rate is 106 g ai/ha.

A total of three independent trials were conducted in Taiwan, Province of China, during the 2015 growing season. Sulfoxaflor residues, in ranked order, were 0.03, 0.04 and 0.05 mg/kg.

The Meeting considered three trials insufficient to estimate a maximum residue level for the use of sulfoxaflor in mango.

##### ***Legume vegetables***

###### ***Beans with pods***

The critical GAP for sulfoxaflor is in the USA on Succulent, Edible Podded, and Dry Beans, where the rate is 80 g ai/ha, a maximum of 4 applications, a minimum re-treatment interval of 14 days and a PHI of 7 days. The maximum seasonal rate is 298 g ai/ha.

As none of the trials matched the critical GAP, the Meeting could not estimate a maximum residue level.

### *Cereal grains*

Data from trials on maize, rice (USA), sorghum and sweet corn, provided to the 2016 JMPR were reconsidered at the current Meeting as the 2016 JMPR could not estimate maximum residue levels for these crops as no GAP was provided to the Meeting or trials were not conducted according to GAP.

#### *Maize*

The new critical GAP is in Canada and allows 2 applications at 36 g ai/ha, a 7-day re-treatment interval, seasonal maximum of 72 g ai/ha and 14-day PHI.

The trials were conducted in the USA during the 2012 growing season. Two foliar applications of a water-dispersible granule formulation containing sulfoxaflor were made at a target rate of 50 g ai/ha and a re-treatment interval of 7 days. Maize grain samples were harvested 13–15 days after the final application.

The Meeting agreed to utilise the proportionality approach to estimate residues matching critical GAP. Unscaled sulfoxaflor residues for maize grain, in ranked order, were < 0.01 (12) and 0.01 (2) mg/kg. Using a scaling factors of 1.4, scaled residues are: < 0.007 (12) and 0.007 (2) mg/kg.

The Meeting estimated a maximum residue level and STMR of 0.01(\*) mg/kg and 0.007 mg/kg, respectively, for maize.

#### *Rice*

In addition to the trials conducted on rice in the USA, provided to the 2016 JMPR, supervised residue trials conducted in Argentina, Australia, Brazil, China, India, Malaysia and the Philippines were made available to the current Meeting.

The new critical GAP for sulfoxaflor on rice is in Indonesia allows for 4 applications at 100 g ai/ha, a 7-day re-treatment interval, 400 g ai/ha/season, and a 10-day PHI.

In eight independent trials, conducted in the Philippines and Australia, approximating the critical GAP, residues found of sulfoxaflor in paddy rice in ranked order were (n = 8): 0.96, 1.00, 1.2, 1.7, 2.2, 2.4, 3.8 and 4.0 mg/kg.

The Meeting estimated a maximum residue level and STMR of 7 mg/kg, 1.95 mg/kg, respectively for rice.

#### *Sorghum*

The new critical GAP for sorghum is in Canada and allows for 2 applications at 36 g ai/ha, a 7-day re-treatment interval, 72 g ai/ha/season and a 14-day PHI.

The trials were conducted in the USA in 2012 where two foliar applications of a water-dispersible granule formulation containing sulfoxaflor were made at a target rate of 50 g ai/ha and a re-treatment intervals of 7 days. Sorghum grain samples were harvested 13–15 days after the last application.

The Meeting agreed to utilise the proportionality approach to estimate residues matching critical GAP. Unscaled sulfoxaflor residues in sorghum grain were 0.02, 0.03, 0.04 (3), 0.05, 0.08, 0.14 and 0.15 mg/kg. Using a scaling factor of 1.4, the scaled residues in ranked order were: 0.01, 0.02, 0.03(3), 0.04, 0.06, 0.10 and 0.11 mg/kg.

The Meeting estimated a maximum residue level and STMR of 0.2 mg/kg and 0.03 mg/kg, respectively for sorghum.

*Sweet corn (corn-on-the-cob) (kernels plus cobs with husks removed)*

The new critical GAP for sweet corn is in Canada and allows for 2 applications at 36 g ai/ha, a 7-day re-treatment interval, 72 g ai/ha/season, and a 7-day PHI.

The trials were conducted in the USA in 2012 where two foliar applications of a water-dispersible granule formulation containing sulfoxaflor were made at a target rate of 50 g ai/ha and re-treatment intervals of 7 days. Unscaled sulfoxaflor residues in sweet corn (kernels plus cobs with husks removed) were harvested 7–8 days after the last application were all ( $n = 9$ )  $< 0.01$  mg/kg.

As all residues were below the LOQ, following treatments at exaggerated rates, the Meeting estimated a maximum residue level and STMR of 0.01(\*) mg/kg and 0 mg/kg, respectively for sweet corn (corn on the cob) (kernels plus cobs with husks removed).

*Tree nuts*

*Almonds and Pecans*

Data from ten independent trials on tree nuts (almonds (5) and pecans (5)) were resubmitted. The 2016 JMPR did not estimate a maximum residue level as no GAP had not been provided.

The new critical GAP is in the USA which comprises  $4 \times 101$  g ai/ha, a re-treatment interval of 7 days and a PHI of 7 days. The maximum seasonal rate is 298 g ai/ha.

In five independent trials conducted in the USA on almonds and approximating critical GAP ( $3 \times 100$  g ai/ha, 6–7 day PHI) residues in almond nutmeat were ( $n = 5$ ):  $< 0.01$  mg/kg.

In five independent trials conducted in the USA on pecans and approximating critical GAP ( $3 \times 100$  g ai/ha; 7–8 day PHI) residues were ( $n = 5$ ):  $< 0.01$  (4) and 0.02 mg/kg.

The critical GAP in the USA is for tree nuts and a group maximum residue level recommendation may be possible based on the data for almonds and pecans. As the median residues were equivalent for both datasets, the Meeting agreed to combine the residue trial data to estimate a maximum residue level for the tree nuts crop group.

Based on the combined residue data set ( $< 0.01$  (9) and 0.02 mg/kg), the Meeting estimated a maximum residue level, HR and STMR of 0.03, 0.02 and 0.01 mg/kg, respectively, for the tree nuts group.

***Animal feeds***

Data from trials on maize, rice (USA), sorghum and sweet corn, provided to the 2016 JMPR were reconsidered at the current Meeting as the 2016 JMPR could not estimate residue levels for these feed crops (forage, stover, straw (rice only)) as no GAP was provided to the Meeting or trials were not conducted in accordance with GAP.

*Straw, fodder and forage of cereal grains*

*Maize forage*

The new critical GAP for maize is in Canada; and allows for 2 applications at 36 g ai/ha, a 7-day re-treatment interval, a seasonal maximum of 72 g ai/ha with a 7-day PHI.

The trials were conducted in the USA during the 2012 growing season where two foliar applications of a water-dispersible granule formulation containing sulfoxaflor were made at a target rate of 50 g ai/ha and a re-treatment interval of 7 days. Maize forage samples were harvested 7–8 days after the last application.

The Meeting agreed to utilise the proportionality approach to estimate residues matching critical GAP. Unscaled sulfoxaflor residues for maize forage were (n = 15): 0.03, 0.05, 0.08 (2), 0.09, 0.11 (3), 0.12, 0.13, 0.15, 0.22, 0.31 and 0.35 mg/kg. Using a scaling factor of 1.4, residues were (n = 15): 0.02, 0.04, 0.06 (3), 0.07, 0.08 (3), 0.09(2), 0.11, 0.16, 0.22 and 0.25 mg/kg.

The Meeting estimated a highest residue of 0.25 mg/kg and a median residue of 0.08 mg/kg for maize forage

#### *Sorghum forage*

The new critical GAP for sorghum is in Canada and allows for 2 applications at 36 g ai/ha, a 7-day re-treatment interval, a seasonal maximum of 72 g ai/ha and a 14-day PHI.

The trials were conducted in the USA in 2012 where two foliar applications of a water-dispersible granule formulation containing sulfoxaflor were made at a target rate of 50 g ai/ha and a re-treatment interval of 7 days. Sorghum forage samples were harvested 6–8 days after the last application.

The Meeting agreed to utilise the proportionality approach to estimate residues at critical GAP. Unscaled sulfoxaflor residues for sorghum forage were (n = 9): 0.02, 0.03, 0.07, 0.08 (2), 0.09, 0.13, 0.16 and 0.20 mg/kg. Using a scaling factor of 1.4, the scaled residues in ranked order were (n = 9): 0.01, 0.02, 0.05, 0.06 (3), 0.10, 0.12 and 0.14 mg/kg.

The Meeting estimated a highest residue of 0.14 mg/kg and a median residue of 0.06 mg/kg for sorghum forage (green).

#### *Corn forage (Sweet)*

The new critical GAP for sweet corn is in Canada and allows for 2 applications at 36 g ai/ha, a 7-day re-treatment interval, 72 g ai/ha/season, and a 7-day PHI.

The trials were conducted in the USA in 2012 where two foliar applications of a water-dispersible granule formulation containing sulfoxaflor were made at a target rate of 50 g ai/ha and re-treatment intervals of 7 days. Sweet corn forage samples were harvested 7-8 days after the last application.

The Meeting agreed to utilise the proportionality approach to estimate residues matching cGAP. Unscaled sulfoxaflor residues for sweet corn forage were 0.05, 0.06, 0.08, 0.09, 0.14 (2), 0.23, 0.24 and 0.37 mg/kg. Using a scaling factor of 1.4, residues in ranked order are 0.04 (2), 0.06(2), 0.10(2), 0.16, 0.17 and 0.26 mg/kg.

The Meeting estimated a highest residue of 0.26 mg/kg and median residue of 0.10 mg/kg for corn forage.

#### *Maize fodder (dry)*

The critical GAP is in Canada; 2 applications at 36 g ai/ha, 7-day re-treatment interval, 72 g ai/ha/season and 14-day PHI.

The trials were conducted in the USA during the 2012 growing season where two foliar applications of a water-dispersible granule formulation containing sulfoxaflor were made at a target rate of 50 g ai/ha

and a re-treatment interval of 7 days. Maize stover samples were harvested 13–15 days after the last application.

The Meeting agreed to utilise the proportionality approach to estimate residues at critical GAP. Unscaled sulfoxaflor residues for maize stover were (n = 15): 0.02, 0.06, 0.09, 0.11, 0.15, 0.18, 0.20, 0.22, 0.23 (2), 0.24, 0.31, 0.40, 0.43 and 0.54 mg/kg. Using scaling factors of 1.4, residues, in ranked order, were (n = 15): 0.01, 0.04, 0.06, 0.08, 0.11, 0.13, 0.14, 0.16 (3), 0.17, 0.22, 0.28, 0.31 and 0.38 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg, a highest residue of 0.38 mg/kg and a median residue of 0.16 mg/kg for maize fodder (dry).

#### *Rice straw and fodder (dry)*

In addition to the trials conducted on rice in the USA, provided to the 2016 JMPR, new supervised residue trials on rice conducted in Argentina, Australia, Brazil, China, India, Malaysia and the Philippines were made available to the current Meeting.

The new critical GAP for sulfoxaflor on rice is in Indonesia and allows for 4 applications at 100 g ai/ha, a 7-day re-treatment interval, 400 g ai/ha/season, with a 10-day PHI.

In eight independent trials, conducted in Australia and the Philippines, approximating the critical GAP, residues found of sulfoxaflor in rice straw (as received) were (n = 8): 0.07, 0.10, 0.22, 1.3, 1.7, 4.9, 5.7 and 10.4 mg/kg.

The Meeting estimated a maximum residue level, highest residue and median residue of 20, 10.4 and 1.5 mg/kg, respectively for rice straw and fodder (dry).

#### *Sorghum straw and fodder (dry)*

The new GAP for sulfoxaflor on sorghum is in Canada and allows for 2 applications at 36 g ai/ha, a 7-day re-treatment interval, 72 g ai/ha/season, with a 14-day PHI.

The trials were conducted in the USA in 2012 where two foliar applications of a water-dispersible granule formulation containing sulfoxaflor were made at a target rate of 50 g ai/ha and a re-treatment intervals of 7 days. Sorghum stover samples were harvested 13–15 days after the last application.

The Meeting agreed to utilise the proportionality approach to estimate residues matching critical GAP. Unscaled sulfoxaflor residues in sorghum stover were (n = 9): 0.04, 0.05, 0.10, 0.16, 0.20, 0.27, 0.28, 0.29 and 0.60 mg/kg. Using a scaling factor of 1.4, the scaled residues in ranked order were: 0.03, 0.04, 0.07, 0.11, 0.14, 0.19, 0.20, 0.21 and 0.43 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg, a highest residue of 0.43 mg/kg and a median residue of 0.14 mg/kg for sorghum straw and fodder (dry).

#### *Almond hulls*

Data from five independent trials on almonds were resubmitted. The 2016 JMPR did not estimate a maximum residue level as no GAP was provided to the Meeting. The new critical GAP is in the USA and allows for a maximum of 4 applications at up to 101 g ai/ha, with a re-treatment interval of 7 days and a PHI of 7 days. The maximum seasonal rate is 298 g ai/ha

In five independent trials conducted in the USA on almonds and approximating critical GAP (3 × 100 g ai/ha, 6–7 day PHI), residues in almond hulls, in ranked order, were (n = 5): 0.54, 0.72, 0.76, 1.69 and 1.71 mg/kg.

The Meeting estimated a median residue of 0.76 mg/kg for almond hulls.

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

#### ***Processing***

The Meeting received information on the fate of sulfoxaflor residues during the processing of rice. Processing factors calculated for the processed commodities of paddy rice are shown in the table below. Processing factors, best estimates and STMR-Ps were calculated.

#### **Rice**

Commodity	Calculated Processing Factors	Best Estimate	RAC STMR	STMR-P, mg/kg
Parboiled Rice	0.3, 1.3	0.8 (mean)	1.95	1.6
Hulls	2.4, 4.5, 5.9	4.5 (median)		8.8
Brown Rice	0.10, 0.20, 0.79	0.20 (median)		0.39
Bran	0.74, 0.79, 1.1	0.79 (median)		1.5
Polished Rice	0.01, 0.14, 0.86	0.14 (median)		0.27
Flour	0.01, 0.10, 0.74	0.10 (median)		0.20

Based on the processing factors of 0.20 estimated for husked (brown) rice and 0.14 estimated for polished rice and applying this to the maximum residue level of 7 mg/kg for rice grain, the Meeting estimated maximum residue levels of 1.5 mg/kg for rice, husked and 1 mg/kg for rice, polished.

### ***Estimated dietary burdens of farm animals***

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 OECD diets listed in Appendix IX of the 2016 edition of the FAO manual, are presented in Annex 6 and summarised below.

	Livestock dietary burden, sulfoxaflor							
	US/Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	1.3	0.85	3.5	1.4	8.8 <sup>a</sup>	2.6	6.4	0.95
Dairy Cattle	2.1	1.4	4.0	1.9	6.9 <sup>b</sup>	4.0 <sup>c</sup>	3.1	0.51
Poultry, broiler	0.50	0.50	0.10	0.08	1.2	1.2	0.04	0.04
Poultry, layer	0.50	0.50	1.1	0.45	1.15 <sup>d</sup>	1.15	0.04	0.04

<sup>a</sup> Suitable for maximum residue level estimate for meat, fat and edible offal of mammals

<sup>b</sup> Suitable for maximum residue level estimate for milk

<sup>c</sup> Suitable for STMR estimate for milk, meat, fat and edible offal of mammals

<sup>d</sup> Suitable for maximum residue level and STMR estimates for eggs, meat, fat and edible offal

### ***Animal commodities residue level estimation***

Anticipated residues resulting from the dietary burdens and based on the feeding studies are summarised below:

Sulfoxaflor feeding study	Feed level for milk residues (ppm)	Residues in milk (mg/kg)	Feed level for tissue residues (ppm)	Residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
maximum residue level estimation – Beef and Dairy Cattle							
Feeding Study	6.8	0.288	6.8	0.311	0.758	0.566	0.139
	35.0	1.679	35.0	1.691	4.03	2.422	0.915
Dietary burden and anticipated	6.9	0.293	8.8	0.390	0.952	0.676	0.185

Sulfoxaflo feeding study	Feed level for milk residues (ppm)	Residues in milk (mg/kg)	Feed level for tissue residues (ppm)	Residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
residues							
STMR estimation – Beef and Dairy Cattle							
Feeding Study	2.4	0.090	2.4	0.105	0.283	0.184	0.039
	6.8	0.243	6.8	0.271	0.744	0.461	0.099
Dietary burden and anticipated residues	4.0	0.143	4.0	0.162	0.442	0.280	0.060
maximum residue level and STMR Estimations - Poultry							
Feeding Study	0.76	0.06	0.76	0.42	0.15	0.01	
	2.10	0.10	2.10	1.09	0.23	0.05	
Dietary burden and anticipated residues	1.2	0.07	1.2	0.64	0.18	0.02	

The Meeting estimated maximum residue levels of 0.3 mg/kg for milks, 0.2 mg/kg for mammalian fat (except milk fats), 0.4 mg/kg for meat (from mammals other than marine mammals) and 1 mg/kg for edible offal (mammalian) based on liver residue. These recommended maximum residue levels replaces the Meeting's previous recommendations of 0.2 mg/kg for milks, 0.1 mg/kg for mammalian fat (except milk fats), 0.3 mg/kg for meat (from mammals other than marine mammals) and 0.6 mg/kg for edible offal (mammalian). The estimated STMRs and HRs are 0.14 mg/kg, and (no HR required) for milks, 0.06 mg/kg and 0.19 mg/kg for fat, 0.16 mg/kg and 0.39 mg/kg for muscle, 0.44 mg/kg and 0.95 mg/kg for edible offal (mammalian), based on liver.

For poultry, the Meeting recommends a maximum residue level of 0.7 mg/kg for poultry meat to replace its previous recommendation of 0.1 mg/kg. The Meeting estimated STMRs and HRs of 0.07 mg/kg and 0.07 mg/kg for eggs, 0.02 mg/kg and 0.02 mg/kg for poultry fat, 0.18 mg/kg and 0.18 mg/kg for edible offal (poultry) and 0.64 mg/kg and 0.64 mg/kg for meat of poultry.

## RECOMMENDATIONS

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

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

The residue is not fat-soluble.

## DIETARY RISK ASSESSMENT

### Long-term dietary exposure

The ADI for sulfoxaflo is 0–0.05 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for sulfoxaflo 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 2018 JMPR Report. The IEDIs ranged from 2–9% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of sulfoxaflor from uses considered by the JMPR is unlikely to present a public health concern.

***Acute dietary exposure***

The ARfD for sulfoxaflor is 0.3 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for sulfoxaflor 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 2018 JMPR Report. The IESTIs varied from 0–20% of the ARfD for children and 0–10% for the general population.

The Meeting concluded that acute dietary exposure to residues of sulfoxaflor from uses considered by the present Meeting is unlikely to present a public health concern.



## 5.29 TIOXAZAFEN (311)

### TOXICOLOGY

Tioxazafen is the ISO-approved common name for 3-phenyl-5-thiophen-2-yl-1,2,4-oxadiazole (IUPAC), which has the CAS number 330459-31-9.

Tioxazafen is a seed treatment nematicide for use on corn, soy and cotton. It appears to act through interaction with a nematode-specific insertion of the L3 subunit of the mitochondrial ribosome, leading to disruption of ribosomal translation in nematodes.

Tioxazafen 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***

Following the administration of a single oral [<sup>14</sup>C]tioxazafen dose of 3 or 100 mg/kg bw to rats, absorption was rapid, with a peak concentration after 2 or 4 hours, respectively. Excretion was rapid, with more than 95% of the radioactivity excreted within 48 hours. Urinary excretion was 24–35%, and faecal excretion was 45–69%. In bile duct cannulated rats administered a [<sup>14</sup>C]tioxazafen dose of 100 mg/kg bw, approximately 45–60% of the radiolabel was recovered in the bile, 21–45% in the urine and 3.3–11% in the faeces over 48 hours post-dosing, indicating that at least 89% of the administered dose was absorbed. There were no major differences in excretion or metabolism due to dose, sex or dosing regimen. Tissue distribution was widespread, but levels in tissues were low. Highest levels were found in adrenals, kidneys, liver and thyroid.

Tioxazafen was extensively metabolized to approximately 30 components in rats. No parent compound was found in urine, faeces or bile. Major routes of metabolism of tioxazafen in rats were oxidation (hydroxylation) of the thiophene ring, followed by conjugation primarily with glucuronic acid, and reductive cleavage and subsequent hydrolysis of the oxadiazole ring. The major metabolites were benzamidine, hydroxyl-tioxazafen glucuronide and thenoylglycine. Benzamidine was the only metabolite that was recovered in urine at more than 10% of the administered dose.

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

The acute oral LD<sub>50</sub> in rats was greater than 5000 mg/kg bw, the acute dermal LD<sub>50</sub> was greater than 5000 mg/kg bw and the acute inhalation LC<sub>50</sub> was greater than 5.2 mg/L. Tioxazafen was not irritating to the skin and was mildly irritating to the eyes of rabbits. Tioxazafen was not skin sensitizing in a maximization test in guinea-pigs.

In repeated-dose oral toxicity studies with tioxazafen in mice, rats and dogs, a number of effects were observed, most notably reduced body weight gain, increased liver weight, hepatocellular hypertrophy, increased levels of bilirubin and cholesterol, haematological changes, histopathological changes in the adrenals and hyperostosis (bone thickening).

In a 28-day range-finding study in mice using dietary tioxazafen concentrations of 0, 20, 100, 300, 1000 and 3000 ppm (equal to 0, 4, 19, 58, 184 and 437 mg/kg bw per day for males and 0, 5, 25, 70, 219 and 399 mg/kg bw per day for females, respectively), the NOAEL was 300 ppm (equal to 58 mg/kg bw per day), based on increased bilirubin, liver weights and hepatocellular hypertrophy in both sexes, increased

cholesterol and GGT levels in females, and termination of one female in extremis at 1000 ppm (equal to 184 mg/kg bw per day). All animals in the 3000 ppm group died or were terminated early.

In a 90-day study in mice using dietary tioxazafen concentrations of 0, 10, 50, 200, 600 and 1250 ppm (equal to 0, 2.1, 10.3, 42, 125 and 260 mg/kg bw per day for males and 0, 2.6, 13.8, 54, 174 and 319 mg/kg bw per day for females, respectively), the NOAEL was 600 ppm (equal to 125 mg/kg bw per day), based on increased bilirubin and cholesterol levels in females, increased liver weights and hepatocellular hypertrophy in both sexes, and termination of one female in extremis at 1250 ppm (equal to 260 mg/kg bw per day).

In a 28-day study in rats using dietary tioxazafen concentrations of 0, 50, 200, 1000, 3000 and 10 000 ppm (equal to 0, 4, 15, 76, 201 and 628 mg/kg bw per day for males and 0, 5, 18, 89, 221 and 760 mg/kg bw per day for females, respectively), the NOAEL was 200 ppm (equal to 15 mg/kg bw per day), based on decreases in body weight gain and histopathological changes in the liver in males and decreased feed consumption and feed efficiency, hyperostosis and increased adipose tissue of the sternal bone marrow in both sexes at 1000 ppm (equal to 76 mg/kg bw per day).

In a 90-day study in rats using dietary tioxazafen concentrations of 0, 10, 50, 250, 750 and 1500 ppm (equal to 0, 1, 3, 16, 47 and 91 mg/kg bw per day for males and 0, 1, 4, 19, 55 and 113 mg/kg bw per day for females, respectively), the NOAEL was 250 ppm (equal to 16 mg/kg bw per day), based on a reduction in body weight gain in females and hyperostosis in both sexes at 750 ppm (equal to 47 mg/kg bw per day).

In a 13-week oral toxicity study in dogs administered tioxazafen by gelatine capsule at a dose of 0, 1, 3, 10, 40 or 120 mg/kg bw per day, the NOAEL was 40 mg/kg bw per day, based on an increase in lung weights in both sexes and one female mortality at 120 mg/kg bw per day.

In an 18-month carcinogenicity study in mice using dietary concentrations of 0, 5, 50, 250, 750 (both sexes) and 1750 ppm (males only) (equal to 0, 1, 8, 41, 120 and 282 mg/kg bw per day for males and 0, 1, 10, 50 and 153 mg/kg bw per day for females, respectively), the NOAEL for systemic toxicity was 50 ppm (equal to 10 mg/kg bw per day), based on increases in pigmented macrophages with scattered necrotic hepatocytes and centrilobular hepatocellular hypertrophy in females at 250 ppm (equal to 50 mg/kg bw per day). The NOAEL for carcinogenicity was 250 ppm (equal to 50 mg/kg bw per day), based on an increased incidence of hepatocellular adenomas in females at 750 ppm (equal to 153 mg/kg bw per day). The incidence of hepatocellular carcinomas, but not of adenomas, was increased in males at 1750 ppm, and there was equivocal evidence of increases in the incidence of systemic haemangiosarcomas at 1750 ppm in males and of histiocytic sarcomas at 750 ppm in females.

Three studies were performed to investigate the mode of action for the observed tumours in the carcinogenicity study in mice. Mice were administered tioxazafen in their diet for 4–90 days at doses ranging from 20 to 1750 ppm in males and from 10 to 750 ppm in females. Tumorigenic doses of tioxazafen induced increased liver weights and serum ALT, AST, sorbitol dehydrogenase and total bilirubin levels in mice. Histopathology showed hepatocellular degeneration, centrilobular necrosis, inflammation, fatty changes, increased mitoses and histiocytic infiltration. Tioxazafen also induced marked increases in hepatocellular proliferation (5-bromo-2'-deoxyuridine labelling), in particular in the periportal region, as is commonly observed with chemically induced cytotoxicity. Observed increases in endothelial cell proliferation were considered secondary to the hepatocellular toxicity and increased hepatocellular proliferation. The effects were predominantly observed in males at 1750 ppm and, to a lesser extent, in females at 750 ppm. There was no biologically meaningful activation of the aryl hydrocarbon receptor, CAR, PXR or peroxisome proliferator-activated receptors alpha and gamma, indicating that the tumour induction was unrelated to modes of action involving activation of these nuclear hormone receptors. No effects on

two markers for angiogenesis or hypoxia were observed. Based on these results, the hepatocellular carcinogenicity observed at the high doses in the 18-month mouse feeding study was considered to be a result of a cytotoxic mode of action. This mode of action is relevant to humans, but exhibits a threshold, because tumours would not occur in the absence of hepatotoxicity.

In a 2-year carcinogenicity study in rats using dietary concentrations of 0, 5, 25, 75, 250 and 750 ppm (equal to 0, 0.3, 1.3, 3.9, 13.3 and 39.6 mg/kg bw per day for males and 0, 0.3, 1.6, 4.9, 16.0 and 48.1 mg/kg bw per day for females, respectively), the NOAEL for systemic toxicity was 75 ppm (equal to 4.9 mg/kg bw per day), based on an increased incidence of endometrial stromal polyps in females at 250 ppm (equal to 16.0 mg/kg bw per day). This lesion is a common, benign, noncancerous finding in female rodents. Although certain types of uterine polyps can progress to cancer in rare cases, there is no instance of this occurring in the absence of other indications of malignancy (i.e. evidence of preneoplastic changes in the uterus, tumours at other sites). There was no increase in any tumour type in rats that could be attributed to treatment with tioxazafen. The NOAEL for carcinogenicity was 750 ppm (equal to 39.6 mg/kg bw per day), the highest dose tested.

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

Tioxazafen 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 tioxazafen is unlikely to be genotoxic.

In view of the lack of genotoxicity, the absence of carcinogenicity in rats, the fact that hepatocellular adenomas and carcinomas were increased in mice by a cytotoxic mode of action and the fact that there was an equivocal increase in the incidence of systemic haemangiosarcomas in male mice and of histiocytic sarcomas in female mice only at the highest dose tested, the Meeting concluded that tioxazafen is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation reproductive toxicity study in rats administered tioxazafen in the diet at a dose of 0, 5, 20 or 60 mg/kg bw per day (concentrations were adjusted weekly to provide target test substance doses), the NOAEL for parental toxicity was 20 mg/kg bw per day, based on reduced body weight gains and hyperostosis in F<sub>0</sub> and F<sub>1</sub> males at 60 mg/kg bw per day. The NOAEL for offspring toxicity was 60 mg/kg bw per day, the highest dose tested. The NOAEL for reproductive toxicity was 60 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study of tioxazafen in rats using gavage doses of 0, 10, 50 and 200 mg/kg bw per day from gestational days 6 to 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 200 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in rabbits administered tioxazafen by gavage at a dose of 0, 5, 20 or 100 mg/kg bw per day from gestational days 7 to 28, the NOAEL for maternal toxicity was 5 mg/kg bw per day, based on reduced body weight gain at 20 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 100 mg/kg bw per day, the highest dose tested.

The Meeting concluded that tioxazafen is not teratogenic.

In an acute neurotoxicity study in which rats were administered tioxazafen by gavage at a dose of 0, 250, 750 or 2000 mg/kg bw and then observed for 14 days, no NOAEL could be identified. The LOAEL for neurotoxicity was 250 mg/kg bw, the lowest dose tested, based on a transient decrease in motor activity observed 4 hours after treatment in males and females at this dose in the absence of any neuropathological changes.

In a 13-week neurotoxicity study in rats using dietary tioxazafen concentrations of 0, 100, 300 and 1000 ppm (equal to 0, 7, 20 and 67 mg/kg bw per day for males and 0, 8, 24 and 75 mg/kg bw per day for females, respectively), the NOAEL for systemic toxicity was 100 ppm (equal to 8 mg/kg bw per day), based on decreased body weight gain in females at 300 ppm (equal to 24 mg/kg bw per day). There was no evidence of a neurotoxic effect of tioxazafen, and the NOAEL for neurotoxicity was 1000 ppm (equal to 67 mg/kg bw per day), the highest dose tested.

Although there were no indications of neuropathological effects of tioxazafen, the Meeting concluded that tioxazafen may cause transient, acute neurobehavioural effects at high doses.

In a 28-day immunotoxicity study in female mice using dietary tioxazafen concentrations of 0, 100, 300 and 1000 ppm (equal to 0, 26, 80 and 240 mg/kg bw per day, respectively), no signs of an immunotoxic effect were observed. The NOAEL for systemic toxicity was 300 ppm (equal to 80 mg/kg bw per day), based on an increase in bilirubin levels, higher absolute and relative liver weights (17–18%) and minimal to mild centrilobular hepatocellular hypertrophy at 1000 ppm (equal to 240 mg/kg bw per day).

The Meeting concluded that tioxazafen is not immunotoxic.

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

The major residues in crops and livestock were tioxazafen and benzamidine. No specific toxicity studies on benzamidine were available. However, this metabolite occurs in rat urine at up to about 12.6% of the administered dose.

The Meeting concluded that the toxicity of benzamidine would be covered by that of tioxazafen.

Toxicological data on MON 102130 (3-phenyl-5-thiophen-3-yl-1,2,4-oxadiazole), a photolyte of tioxazafen, were available. The acute oral LD<sub>50</sub> of MON 102130 was greater than 5000 mg/kg bw. In a 28-day study in rats using dietary MON 102130 concentrations of 0, 200, 1000 and 3000 ppm (equal to 0, 15, 72 and 207 mg/kg bw per day for males and 0, 16, 77 and 211 mg/kg bw per day for females, respectively), the NOAEL was 200 ppm (15 mg/kg bw per day), based on decreased body weight, body weight gain and feed consumption, alterations in haematological and clinical chemistry parameters, organ weight changes and histopathological changes in the liver in both sexes at 1000 ppm (equal to 72 mg/kg bw per day). MON 102130 was negative in a bacterial reverse mutation assay and in an in vivo micronucleus test in mice.

The Meeting concluded that MON 102130 is of similar potency to tioxazafen.

#### ***Human data***

Skin rashes were observed in a limited number of individuals who were potentially exposed to tioxazafen.

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

#### **Toxicological evaluation**

The Meeting established an ADI of 0–0.05 mg/kg bw for tioxazafen on the basis of a NOAEL of 4.9 mg/kg bw per day in a 2-year rat study, based on a small increase in the incidence of endometrial stromal polyps in females at 16.0 mg/kg bw per day. A safety factor of 100 was used. The upper bound of the ADI gives a margin of about 3000 relative to the LOAEL for the observed tumours in mice. The ADI is supported by a NOAEL of 5 mg/kg bw per day, based on reduced maternal body weight gain observed at 20 mg/kg bw per day, in a developmental toxicity study in rabbits, and a NOAEL of 8 mg/kg bw per day, based on decreased body weight gain in females at 24 mg/kg bw per day, in a 13-week neurotoxicity study in rats.

The Meeting established an ARfD of 0.5 mg/kg bw for tioxazafen on the basis of a LOAEL of 250 mg/kg bw, based on a reduction in locomotor activity in an acute neurotoxicity study in rats. A safety factor of 500 was used. An additional factor of 5 was applied for the use of a LOAEL instead of a NOAEL. The Meeting noted that no neurobehavioural signs were observed in any of the repeated-dose studies at bolus doses up to 120 mg/kg bw per day.

The ADI and ARfD can be applied to benzamidine.

A toxicological monograph was prepared.

**Levels relevant to risk assessment of tioxazafen**

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of carcinogenicity <sup>a</sup>	Toxicity	50 ppm, equal to 10 mg/kg bw per day	250 ppm, equal to 50 mg/kg bw per day
		Carcinogenicity	250 ppm, equal to 50 mg/kg bw per day	750 ppm, equal to 153 mg/kg bw per day
Rat	Two-year study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	75 ppm, equal to 4.9 mg/kg bw per day	250 ppm, equal to 16.0 mg/kg bw per day
		Carcinogenicity	750 ppm, equal to 39.6 mg/kg bw per day <sup>b</sup>	–
	Two-generation study of reproductive toxicity <sup>a</sup>	Reproductive toxicity	60 mg/kg bw per day <sup>b</sup>	–
		Parental toxicity	20 mg/kg bw per day	60 mg/kg bw per day
		Offspring toxicity	60 mg/kg bw per day <sup>b</sup>	–
	Developmental toxicity study <sup>c</sup>	Maternal toxicity	10 mg/kg bw per day	50 mg/kg bw per day
		Embryo and fetal toxicity	200 mg/kg bw per day <sup>b</sup>	–
	Acute neurotoxicity study <sup>c</sup>	Neurotoxicity	–	250 mg/kg bw <sup>d</sup>
	Thirteen-week neurotoxicity study <sup>a</sup>	Toxicity	100 ppm, equal to 8 mg/kg bw per day	300 ppm, equal to 24 mg/kg bw per day
		Neurotoxicity	1 000 ppm, equal to 67 mg/kg bw per day <sup>b</sup>	–
Rabbit	Developmental toxicity study <sup>c</sup>	Maternal toxicity	5 mg/kg bw per day	20 mg/kg bw per day
		Embryo and fetal toxicity	100 mg/kg bw per day <sup>b</sup>	–
Dog	Thirteen-week study of toxicity <sup>e</sup>	Toxicity	40 mg/kg bw per day	120 mg/kg bw per day

<sup>a</sup> Dietary administration.

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

<sup>c</sup> Gavage administration.

<sup>d</sup> Lowest dose tested.

<sup>e</sup> Capsule administration.

*Acceptable daily intake (ADI) (applies to tioxazafen and benzamidine, expressed as tioxazafen)*

0–0.05 mg/kg bw

*Acute reference dose (ARfD) (applies to tioxazafen and benzamidine, expressed as tioxazafen)*

0.5 mg/kg bw

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

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

***Critical end-points for setting guidance values for exposure to tioxazafen***

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*Absorption, distribution, excretion and metabolism in mammals*

Rate and extent of oral absorption	Rapid ( $T_{\max}$ 2–4 hours) and almost complete (89–97%) in rats
Dermal absorption	7.45%, 1.59% and 1.65% at 4.5, 45 and 450 g/L, respectively (in vivo, rat) 0.52–4.48% (in vitro, human) 8–32% (in vitro, rat)
Distribution	Widely distributed, highest concentrations found in adrenals, kidney, liver and thyroid
Potential for accumulation	None
Rate and extent of excretion	Rapid; 95% in 48 hours
Metabolism in animals	Extensively metabolized, major metabolites are benzamidine, hydroxyl-tioxazafen glucuronide and thenoylglycine
Toxicologically significant compounds in animals and plants	Tioxazafen

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*Acute toxicity*

Rat, LD <sub>50</sub> , oral	>5 000 mg/kg bw
Rat, LD <sub>50</sub> , dermal	>5 000 mg/kg bw
Rat, LC <sub>50</sub> , inhalation	>5.2 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Mildly irritating
Guinea-pig, dermal sensitization	Sensitizing (Buehler maximization test)

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*Short-term studies of toxicity*

Target/critical effect	Body weight gain, liver, haematological effects, adrenals, hyperostosis
Lowest relevant oral NOAEL	15 mg/kg bw per day (rat)
Lowest relevant dermal NOAEL	100 mg/kg bw per day (rat)

Lowest relevant inhalation NOAEC	15 mg/m <sup>3</sup> (rat)
<i>Long-term studies of toxicity and carcinogenicity</i>	
Target/critical effect	Uterus, liver
Lowest relevant NOAEL	4.9 mg/kg bw per day (rat)
Carcinogenicity	Carcinogenic in mice, but not in rats <sup>a</sup>
<i>Genotoxicity</i>	
	No evidence of genotoxicity <sup>a</sup>
<i>Reproductive toxicity</i>	
Target/critical effect	No reproductive effects
Lowest relevant parental NOAEL	20 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	60 mg/kg bw per day, highest dose tested (rat)
Lowest relevant reproductive NOAEL	60 mg/kg bw per day, highest dose tested (rat)
<i>Developmental toxicity</i>	
Target/critical effect	No developmental toxicity
Lowest relevant maternal NOAEL	5 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	100 mg/kg bw per day, highest dose tested (rabbit)
<i>Neurotoxicity</i>	
Acute neurotoxicity NOAEL	250 mg/kg bw, lowest dose tested (rat)
Subchronic neurotoxicity NOAEL	67 mg/kg bw per day, highest dose tested (rat)
Developmental neurotoxicity NOAEL	No data
<i>Immunotoxicity</i>	
Twenty-eight-day immunotoxicity NOAEL	240 mg/kg bw per day, highest dose tested (mouse)
<i>Studies on metabolites</i>	
MON 102130 (photolyte of tioxazafen)	LD <sub>50</sub> > 5 000 mg/kg bw 28-day oral toxicity NOAEL 15 mg/kg bw per day No evidence of genotoxicity
<i>Human data</i>	
	Skin rashes were observed in a limited number of individuals who were potentially exposed to tioxazafen

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

## Summary

	Value	Study	Safety factor
ADI	0–0.05 mg/kg bw <sup>a</sup>	Two-year toxicity study in rats	100
ARfD	0.5 mg/kg bw <sup>a</sup>	Acute neurotoxicity study in rats	500

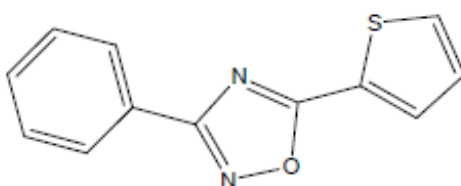
<sup>a</sup> Applies to tioxazafen and benzamidine, expressed as tioxazafen.

### RESIDUE AND ANALYTICAL ASPECTS

Tioxazafen is a seed treatment nematicide to control a broad-spectrum of nematodes in maize, soya bean, and cotton. Tioxazafen is a disubstituted oxadiazole, which represents a new class of nematicidal chemistry demonstrating activity against soya bean cyst, root knot and reniform nematodes in soya bean; lesion, root knot and needle nematodes in maize; as well as reniform and root knot nematodes in cotton.

Tioxazafen was scheduled at the Forty-ninth Session of the CCPR for new evaluation, as a new compound, for residues and toxicology by the 2018 JMPR. The meeting received information on the physical and chemical properties, metabolism in crops, rotational crop studies, metabolism in animals, environmental fate in soil and water, methods of residue analysis, stability in stored analytical samples, use patterns, supervised residue trials, fate of residue during storage and processing, and livestock feeding studies.

The IUPAC name of tioxazafen is 3-phenyl-5-thiophen-2-yl-1,2,4-oxadiazole

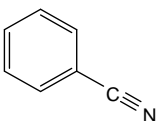
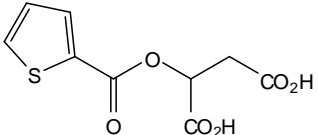
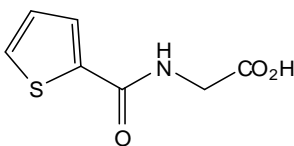
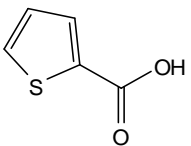
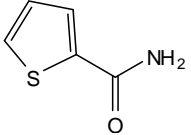


The following abbreviations are used for the metabolites discussed in the appraisal:

Trivial Name	Chemical Name	Structure	Where Found
3-Thienyl tioxazafen (MON 102130)	3-phenyl-5-(3-thienyl)-1,2,4-oxadiazole		Aqueous photolysis, soil photolysis
Hydroxy tioxazafen Glucuronide	(Isomeric position of glucuronide not confirmed in metabolite isolated from goat)		Goat skim milk, goat milk fat
Hydroxy tioxazafen Malonylglucoside	5-[5-[6-O-(2-carboxyacetyl)-β-D-glucopyranosyloxy]-2-thienyl]-3-phenyl-1,2,4-oxadiazole		Soya bean foliage, soya bean seed
Hydroxy tioxazafen Sulfate	(Isomeric position of sulfate not confirmed in metabolite isolated from hen and goat)		Hen egg, goat milk fat
MON tioxazafen Iminoamide	N-(iminophenylmethyl)-2-thiophenecarboxamide		Rotational crops anaerobic aquatic, aerobic aquatic, anaerobic soil



Trivial Name	Chemical Name	Structure	Where Found
Thenoylbenzamidoxime Malonylglucoside (hydroxy iminoamide malonyl glucoside)	<i>O</i> -[6- <i>O</i> -(2-carboxyacetyl)- $\beta$ -D-glucopyranosyl]- <i>N</i> -(2-thenoyl)-benzamidoxime		Maize foliage, soya bean foliage
Tioxazafen Imide	<i>N</i> -benzoyl-2-thiophene		Rotational crops, hen liver, hen egg, hen excreta aerobic aquatic, aerobic soil, anaerobic aquatic, anaerobic soil
Benzoylmalic acid	2-(benzoyloxy)butanedioic acid		Soya bean foliage
Benzamidoxime	<i>N</i> -hydroxybenzene		Maize foliage, cotton foliage
Benzamidine	benzenecarboximidamide		Maize foliage, soya bean foliage, soya bean seed, cotton foliage, rotational crops, hen liver, hen muscle, hen egg, hen excreta, goat liver, goat kidney, goat muscle, goat skim milk, goat fat anaerobic aquatic, aerobic aquatic, anaerobic soil
Benzamide	benzamide		Maize foliage, cotton foliage, rotational crops, hen liver, hen egg, hen excreta, goat liver, goat kidney, goat skim milk
Benzoic acid	benzoic acid		Maize foliage, cotton foliage, rotational crops; Hen excreta, goat liver, goat skim milk anaerobic soil

Trivial Name	Chemical Name	Structure	Where Found
Benzonitrile	benzonitrile		Hen fat, goat fat
Thenoylmalic acid (Thenoylmalate)	2-(2-thienylcarbonyloxy) acid		Soya bean foliage
Thenoylglycine (2-Thenoylglycine)	<i>N</i> -(2-thienylcarbonyl) glycine		Goat liver, goat kidney, goat skim milk, goat milk fat (glycine conjugate of thiophene acid)
Thiophene acid	2-thiophenecarboxylic acid		Maize foliage, cotton foliage, rotational crops; present as conjugates  Hen excreta, goat liver, goat kidney (as thenoylglycine)  anaerobic aquatic, aerobic aquatic, anaerobic soil
Thiophene amide	2-thiophenecarboxamide		Maize foliage, rotational crops

Tioxazafen is a compound with low solubility in water and low volatility, and a potential for bioaccumulation. Tioxazafen is hydrolytically and photolytically stable.

Tioxazafen is only registered as a seed treatment.

Studies on the metabolism in plants, livestock and environmental fate utilised either [oxadiazole-3-<sup>13</sup>C, phenyl-U-<sup>14</sup>C]-tioxazafen (PH-T) or [oxadiazole-5-<sup>13</sup>C, thiophene-2-<sup>14</sup>C]-tioxazafen (TH-T).

### Environmental fate

The Meeting received studies on the degradation of tioxazafen under aerobic condition, anaerobic condition, hydrolysis and photolysis.

Tioxazafen is stable to hydrolysis in sterile aqueous buffer solutions at pH 4, 7 and 9 at 50 °C in the dark for 5 days.

Tioxazafen, applied at a rate of 1.4 kg ai/ha is photolytically stable on non-sterile Hoyleton silt loam soil surfaces (pH 7.3, 2.1% organic matter) after 15 days of sunlight exposure. The only degradate observed after 15 days irradiation was 3-thienyl tioxazafen (3.0–3.6% AR).

Tioxazafen dissipated in aerobic soil conditions at a moderate rate (DT<sub>50</sub> of 51–57.1 days and DT<sub>90</sub> of 169–190 days at 20 °C) in silt loam soil, while at a much slower rate in sandy clay loam and clay loam

soil with DT<sub>50s</sub> of 141–144 days and 221–277 days, respectively, and DT<sub>90s</sub> ranging from 524 days to >1000 days. In a field dissipation study, the DT<sub>50</sub> values ranged from 15 days to 289 days with a median of 70 days and an average of 111 days in the treated seed plot. In the treated in-furrow plot, the DT<sub>50</sub> values ranged from 40 to 101 days with a median of 89 days and an average of 80 days. The DT<sub>90</sub> values for tioxazafen dissipation in both treated seed and in-furrow treatment plots were less than a year except in treated seed plots in Manitoba where the DT<sub>90</sub> was 960 days.

The formation of bound residues and mineralization to <sup>14</sup>CO<sub>2</sub> were principal routes of dissipation. The total of the unidentified components never exceeded 2.4% AR. The dissipation of tioxazafen was characterised by a rapid initial decline of approximately 10–20% over the first 3–5 days followed by a slower dissipation phase.

The pattern of tioxazafen decline showed a slowing of the dissipation rate during the fall/winter months. Dissipation of tioxazafen occurred at a moderate rate in the treated seed plots and treated in-furrow plots. There were no residues of benzamidine above 0.0015 mg/kg in 15–30cm soil, and less than 0.024 mg/kg in 0–7.5cm soil.

Therefore, the potential for significant amounts of tioxazafen to carry over into the following season is relatively low except in cold climate conditions. The carry-over of benzamidine would be insignificant.

### ***Plant metabolism***

The Meeting received plant metabolism studies with seed treatment of tioxazafen to genetically modified (GM) soya bean, GM maize and cotton.

#### ***Soya bean***

GM soya bean seeds were treated with a suspension concentrate (SC) formulation of <sup>14</sup>C-tioxazafen, labelled in the phenyl ring (PH-T) or the thiophene ring (TH-T), at rates of 1.30 mg ai/seed (≈0.81 kg ai/ha) for the PH-T treatment and 1.26 mg ai/seed (≈0.78 kg ai/ha) for the TH-T treatment. Treated soya bean seeds were planted outdoors in loamy sand soil. Samples of plant thinnings (immature foliage at BBCH 12), forage (BBCH 17), hay (at mid-to-full bloom stage or pods are approximately 50% developed) and seed were collected at 28, 48, 88 and 147 days after planting, respectively.

Residue levels (expressed as parent tioxazafen equivalents) were highest in thinnings (9.0–11 mg eq/kg), decreased substantially in forage (0.43–0.51 mg eq/kg) and hay (0.78–1.1 mg eq/kg), and were lowest in seed (0.070–0.16 mg eq/kg). Extractability was moderate with 56–62% of TRR in forage and 52–56% of TRR in hay extracted with acetone and water while 70% of TRR in seeds was extracted with hexane and acetone.

Tioxazafen was extensively metabolised in thinnings, forage, hay and seed. Tioxazafen (parent) levels in thinnings were 5.6% of the TRR (0.51 mg eq/kg) for the PH-T and 4.7% (0.51 mg eq/kg) for TH-T while levels in the forage and hay were 4.3–13% of the TRR (0.026–0.054 mg eq/kg). Based on solvent partitioning properties, tioxazafen in seeds would have represented no more than 0.9% of the TRR (0.0006 mg eq/kg) for the PH-T and 0.5% of the TRR (0.0008 mg eq/kg) for the TH-T label.

Benzamidine was the only metabolite identified in seed (11% TRR, 0.0076 mg eq/kg).

Benzamidine was also the major metabolite in thinnings (11% TRR, 0.96 mg eq/kg), forage (8.5% TRR, 0.036 mg eq/kg) and hay (8.1% TRR, 0.063 mg eq/kg) from PH-T treatment. Other metabolites identified were thenoylbenzamidoxime malonylglucoside (2.4–4.1% TRR, 0.011–0.45 mg eq/kg), hydroxy (thiophene) tioxazafen malonylglucoside (0.9–4.9% TRR, 0.0067–0.54 mg eq/kg), benzoylmalic acid (8.5%

TRR, 0.77mg eq/kg, thinnings only) and thenoylmalic acid (3.6% TRR, 0.40mg eq/kg, thinnings only). An unknown metabolite with MW 365 (5% of TRR, 0.45 mg eq/kg) was characterised in PH-T thinnings, and an unknown metabolite (5.6% of TRR, 0.614 mg eq/kg) was characterised in TH-T thinnings.

Most of the radioactivity in PES in forage and hay was associated with lignin (15.7–17.8% of TRR) and hemicellulose (6.9–14.5% of TRR).

The Meeting noted that a genetically modified variety of soya bean was used in the metabolism study. However, the modification is designed to increase the tolerance to glyphosate and acetolactate synthase inhibitor herbicides, and is unlikely to impact the metabolism of tioxazafen in soya bean.

### *Maize*

GM maize seeds were treated with an SC formulation of  $^{14}\text{C}$  tioxazafen containing PH-T or TH-T labelled compound at rates of 1.09 mg ai/seed ( $\approx 0.26$  kg ai/ha) for the PH-T treatment and 1.28 mg ai/seed ( $\approx 0.30$  kg ai/ha) for the TH-T treatment. Treated seeds were planted outdoors in loamy sand soil. Samples of thinnings (immature foliage), forage, stover and grain were collected 24, 101 and 130 days after planting.

Similar to soya bean, tioxazafen is extensively metabolised in maize. Residue levels in thinnings were 1.72–1.97 mg eq/kg, forage 0.0084–0.015 mg eq/kg, stover 0.042–0.064 mg eq/kg and grain 0.0012–0.0020 mg eq/kg. Extractability in the solvent system employed (acetone/water) was 83–84% TRR for thinnings, 68–71% TRR for forage, 67–68% TRR for stover and 12–42% TRR for grain. The characterisation and identification of residues in grain was not conducted due to very low levels of radioactivity.

Parent tioxazafen was a major residual component in thinnings harvested about two weeks after emergence (33–46% TRR, 0.57–0.91 mg eq/kg), but did not exceed 1% of TRR in forage or stover.

Benzamidine was identified as the only major metabolite in thinnings (8.8% TRR, 0.15 mg eq/kg), forage (12% of TRR, 0.0018 mg eq/kg) and stover (11% of TRR, 0.0072 mg eq/kg). Other minor metabolites identified were thenoylbenzamidoxime malonyl glucoside (0.083–0.12 mg eq/kg, 4.2–7.1% TRR) in the thinnings; benzamide in thinnings (1.9% TRR, 0.033 mg eq/kg), forage (4.8% TRR, 0.0007 mg eq/kg) and stover (4.0% TRR, 0.0026 mg eq/kg); and benzoic acid and thiophene-2-carboxylic acid at trace levels. No single metabolite exceeded 0.01 mg eq/kg in maize forage or stover.

The Meeting noted that genetically modified variety of maize was used in the metabolism study. However, the modification is designed to increase the tolerance to glyphosate and acetolactate synthase inhibitor herbicides, and is unlikely to impact the metabolism of tioxazafen in maize.

### *Cotton*

Pima cotton seeds were treated with an SC formulation of  $^{14}\text{C}$  tioxazafen at rates of 1.20 mg ai/seed ( $\approx 0.28$  kg ai/ha) for the PH-T treatment and 1.30 mg ai/seed ( $\approx 0.31$  kg ai/ha) for the TH-T treatment. Treated cotton seeds were planted outdoors in loamy sand soil. Samples of thinnings, leaves/stems and undelinted seed were collected at 39 and 182 days after planting.

Radioactivity levels were highest in thinnings (1.04–2.40 mg eq/kg) followed by leaves/stems (0.063–0.065 mg eq/kg) and undelinted seed (0.0087–0.009 mg eq/kg). Solvent extractability was 69–74% TRR for thinnings and 71–79% TRR for leaves and stems using acetone/water and 38–43% TRR for undelinted seed (recombined seed and lint) using hexane, acetone and acetone/water. Harsh treatment of PES from PH-T and TH-T thinnings with 0.1 M KOH and 24% KOH released a further 12–13% and 13–16% TRR, respectively, while for leaves/stems the treatments released a further 2.8–3.0% and 9.4–13% TRR, respectively.

Tioxazafen is extensively metabolized in cotton. Parent tioxazafen was only identified in thinnings (6.3–16% TRR, 0.065–0.38 mg eq/kg) and was not detected in leaves/stems. Due to the low levels of solvent extracted radioactivity in undelinted seed (0.004 mg eq/kg) identification was not conducted for this matrix. Based on solvent partitioning properties, if tioxazafen was present in undelinted seed accounted for no more than 1% TRR (< 0.001 mg eq/kg). No single metabolite exceeded 0.01 mg eq/kg in leaves/stems.

Benzamidine was identified as a major metabolite in thinnings (6.2% TRR, 0.064 mg eq/kg) and leaves/stems (11% TRR, 0.0071 mg eq/kg). Thiophene-2-carboxylic acid was identified as a major metabolite in thinnings (9.4% TRR, 0.226 mg eq/kg) and leaves/stem (7.9% TRR, 0.005 mg eq/kg). Other minor metabolites identified were benzamide in thinnings (4.0% TRR, 0.042 mg eq/kg) and leaves/stems (7.6% TRR, 0.005 mg eq/kg); benzoic acid in thinnings (7.5% TRR, 0.078 mg eq/kg) and in leaves and stem (3.7% TRR, 0.0024 mg eq/kg); and 2-thiophenecarboxamide only in thinnings (0.8% TRR, 0.019 mg eq/kg). Low levels of benzoic acid and thiophene-2-carboxylic acid were presented as conjugates.

In summary, the metabolism of tioxazafen following seed treatment of the crops investigated is well understood consisting of cleavage of the oxadiazole ring and/or oxidation of the thiophene ring of tioxazafen, followed by hydrolysis of benzamidine and its conjugation. In addition, hydroxylation of the phenyl ring of tioxazafen was also observed. The concentration of parent tioxazafen was too low to be identified in seed and grain. The predominant metabolite identified is benzamidine, which is also found in the rat study.

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

The meeting received a confined rotational crop study and a field rotational crop study.

#### ***Confined rotational crop studies***

Maize seeds treated with phenyl or thiophene-<sup>14</sup>C labelled tioxazafen at a rate of 0.5 mg ai/seed (≈0.320 kg ai/ha based on 64 seeds in 1 m<sup>2</sup>) were planted in sandy loam soil. The maize seedlings were cut off near the soil surface at approximately two weeks after emergence, and were chopped and tilled into the soil 30 days prior to planting of the rotational crop. Leaf lettuce, radish and wheat were grown in the soil after intervals of 30, 120 and 360 days (413 days for lettuce) as rotational crops. Immature lettuce was harvested at approximately half-size compared to commercial harvest with all remaining lettuce harvested at maturity. The tops and roots of radishes were harvested at maturity. The wheat forage was sampled prior to boot stage, the wheat hay was harvested at early flower to soft dough stage and the remaining wheat was harvested at maturity.

The TRRs in lettuce planted at 30, 120 and 413 days were all less than 0.01 mg eq/kg, with the highest TRR of 0.0095 mg eq/kg in 120-day immature lettuce from the TH treatment. The TRRs in radish foliage reached maximum values of 0.010 and 0.018 mg eq/kg in the 120-day PH and TH samples, respectively, while TRRs from the 30-day and 360-day plantings were <0.006 mg eq/kg. TRRs in radish roots reached the highest values of 0.050 and 0.057 mg eq/kg for the PH and TH samples, respectively, in the 120-day planting. TRRs in radish roots were <0.015 mg eq/kg for the 30-day and 360-day plantings. The TRRs in wheat grain were all less than 0.01 mg eq/kg with the maximum of 0.007 mg eq/kg in the 120-day PH grain. The TRRs from the 120-day planting were the highest, in the wheat forage, hay and straw. TRRs in wheat straw were higher than that in forage or hay, and were 0.077 and 0.087 mg eq/kg for PH-T and TH-T, respectively, in the 120-day planting.

The residues of parent tioxazafen were less than 0.001 mg eq/kg in lettuce, radish and wheat, generally well below 1% TRR, except in the immature lettuce from the 120-day PH plot (4.4% TRR,

0.0003 mg eq/kg) and the wheat forage from the 120-day planting in the PH plot (2.5% TRR, 0.0011 mg eq/kg). Benzamidine, benzoic acid, benzamide and 2-thiophenecarboxylic acid were identified as the primary metabolites but at levels less than 0.01 mg eq/kg in lettuce, radish and wheat. One metabolite above 10% TRR in wheat forage, hay and straw for both PH and TH reached a maximum of 0.008 mg eq/kg, a level too low to permit identification.

The Meeting noted that the actual PBI for rotational crops is about 20 days more, and the residues of tioxazafen and benzamidine in rotational crops were at very low levels. The Meeting concluded that no potential residues of tioxazafen and benzamidine are expected in rotational crops.

A field rotational crop study with lettuce, radish, sorghum and wheat confirmed the conclusions from the confined rotational crop study. Tioxazafen and benzamidine are not expected to be detected in rotational crops

### ***Animal metabolism***

Metabolism in rats was evaluated by the WHO Core Assessment Group.

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

Two lactating goats were dosed daily for five days with either the PH or TH-labelled tioxazafen at a rate of 11 ppm feed. Milk, urine and faeces were collected twice daily in the morning before dosing and in the evening. The goats were sacrificed approximately 18–19 hours after administration of the last dose.

The total recovery of radiolabel was 87–91% with most of the administered dose recovered in faeces (64% for PH and 33% for TH) and urine (20% for PH and 50% for TH).

The TRRs were highest for liver (0.33–1.1 mg eq/kg), kidney (0.22–0.38 mg eq/kg) and milk fat (maximum 0.26–0.28 mg eq/kg). The TRRs were lower for skim milk (maximum 0.032–0.083 mg eq/kg). Milk residues reached a plateau after the second dose. The TRRs for the PH label in muscle and fats were 0.052–0.055 and 0.014–0.018 mg eq/kg, respectively while the TRRs for the TH-label were < 0.001 mg eq/kg for both muscle and fat.

Solvent extractabilities with the respective solvent systems were 16–30% TRR for liver (acetonitrile/water), 36–59% for kidney (acetonitrile/water), 99–100% for muscle (acetonitrile/water and acetonitrile), 50–63% for fat (hexane/acetone followed by partitioning with acetonitrile), 92–94% for skim milk (acetonitrile/water) and 73–88% for milk fat (acetone/hexane).

Tioxazafen is extensively metabolised in lactating goats. Parent tioxazafen was not found in milk or tissues, except fat, where it was present only at low levels (9–11% TRR, 0.001–0.002 mg eq/kg).

In milk fat, a major metabolite was the sulfate conjugate of hydroxylated tioxazafen (56–68% TRR, 0.15–0.17 mg eq/kg) for both labels. The glucuronic acid conjugate of hydroxylated tioxazafen (3.9% TRR, 0.01 mg eq/kg) was a major metabolite for the PH-label. Thenoylglycine (13% TRR, 0.034 mg eq/kg) was a major component for the TH label.

In skim milk, benzamidine (29% TRR, 0.007 mg eq/kg) and the glucuronic acid conjugate of hydroxylated tioxazafen (19% TRR, 0.005 mg eq/kg) were the major metabolites for the PH-label. Thenoylglycine (65% TRR, 0.054 mg eq/kg) was the major component with the TH label. Other metabolites were found at low levels (< 10% TRR, < 0.01 mg eq/kg).

The primary metabolite from the PH-label in all tissues was free benzamidine with residues in liver 25% TRR and 0.27 mg eq/kg, kidney 44% TRR and 0.17 mg eq/kg, muscle 99% TRR and 0.052–0.054 mg eq/kg, fat 26–56% TRR and 0.006–0.008 mg eq/kg. Another 5.3% TRR (0.058 mg eq/kg) and

8.7% TRR (0.033 mg eq/kg) of benzamidine was released after harsh treatment of liver and kidney PES, respectively. Other minor metabolites found in liver and kidney were benzoic acid conjugates (liver 12% TRR, 0.13 mg eq/kg and kidney 7.0% TRR, 0.027 mg eq/kg) and benzamide (free 0.6–4.9% TRR, 0.007–0.019 mg eq/kg and conjugated 1.5–3.2% TRR, 0.010–0.035 mg eq/kg). Other metabolites were found at low levels (< 10% TRR, < 0.01 mg eq/kg).

The primary metabolite from the TH-label in kidney was thenoylglycine (22% TRR and 0.047 mg eq/kg). Other metabolites were found at low levels (< 10% TRR, < 0.01 mg eq/kg).

### *Laying hens*

Laying hens were administered daily doses of either phenyl-<sup>14</sup>C- or thiophene-<sup>14</sup>C-tioxazafen via capsule for seven days at a level equivalent to 10 ppm feed. Hens were sacrificed approximately 19–21.5 hours after the last dose was administered.

The total recovery of the radioactivity was 90–91% of the administered dose. Most of the administered dose was recovered in excreta (88%). TRR in eggs reached plateau at day 6 with the highest residue of 0.18 mg eq/kg on day 7. Radioactive residues in tissues were 0.61–0.66 mg eq/kg in liver, 0.039–0.045 mg eq/kg in fat and 0.009–0.015 mg eq/kg in muscle.

Solvent extractabilities with the respective solvent systems were 17–20% TRR for liver, 34–48% for muscle, and 22–27% TRR for egg (acetonitrile/water 1:1, v/v, 2× and acetonitrile 1×), and 88–92% for fat (acetone/hexane 1:4, v/v, 1× and acetone 2×).

Tioxazafen is extensively metabolised in laying hens. Parent tioxazafen was found at trace levels in eggs or tissues, except fat, where it was the major compound (49–76% TRR, 0.021–0.034 mg eq/kg).

The major compound from the PH-label in liver, muscle and eggs was benzamidine (3.4–18% TRR, 0.002–0.035 mg eq/kg), while benzonitrile (21–30% TRR, 0.010–0.013 mg eq/kg) was the major metabolite in fat. Other metabolites were found at low levels (<10% TRR, < 0.01 mg eq/kg).

The primary metabolite from the TH-label was an unknown compound M4, likely a mixture of polar metabolites, at 12–13% TRR (0.001–0.002 mg eq/kg) in muscle and 3.5% TRR (0.023 mg eq/kg) in liver. Other metabolites were found at low levels (<10% TRR, < 0.01 mg eq/kg).

In summary, the metabolism of tioxazafen by livestock is well understood consisting of cleavage of the oxadiazole ring and/or oxidation of the thiophene ring of tioxazafen, followed by hydrolysis. In addition, hydroxylation of the phenyl ring or thiophene ring of tioxazafen was also observed. The predominant metabolite identified were benzamidine and benzonitrile in hen fat; sulfate conjugate of hydroxylated tioxazafen in milk fat; and thenoylglycine in goat liver, kidney and skim milk.

### **Methods of analysis**

Analytical methods have been developed and validated for the determination of tioxazafen and major metabolites in plant and animal commodities. Data generation methods involved extraction with acetonitrile:water and analysis by GC-MS/MS or LC-MS/MS for tioxazafen and benzamidine in plant matrices. The LOQs for tioxazafen and benzamidine (as tioxazafen equivalents) were 0.0025–0.01 mg/kg in all matrices.

A comparison of the extractability of residues in soya bean hay, maize stover and soya bean seed by acetone/water versus acetonitrile/water extraction showed that <sup>14</sup>C-tioxazafen and <sup>14</sup>C-benzamidine could be recovered equally well with the solvent system used in metabolism studies (acetone/water) and in the analytical method (acetonitrile/water).

An enforcement method was also validated for tioxazafen and benzamidine in plant matrices. The method involves the extraction of homogenised raw agricultural commodities with 65% acetonitrile in water, with benzamidine analysis by LC-MS/MS and tioxazafen analysis by GC-MS/MS. The limit of quantitation (LOQ) is 0.0050 mg/kg for each analyte, tioxazafen and benzamidine (in tioxazafen equivalents) for plant matrices.

An analytical method was developed and validated for the determination of tioxazafen and its major metabolites, benzamidine, benzonitrile and 2-thenoylglycine in animal matrices, including milk, fat, liver, kidney, muscle and egg. The analytical method involves the extraction of fat with acetonitrile:hexane and other animal matrices with acetonitrile, analysis of tioxazafen and benzonitrile by GC-MS/MS, and analysis of benzamidine and/or 2-thenoylglycine by LC-MS/MS. The LOQs for tioxazafen and benzamidine (as tioxazafen equivalents) were 0.010 mg/kg in all matrices. The LOQ for benzonitrile (as tioxazafen equivalents) was 0.025 mg/kg in fat. The LOQs for 2-thenoylglycine (as tioxazafen equivalents) were 0.010 mg/kg for milk, and 0.025 mg/kg for kidney. The LOQ for 2-thenoylglycine (as tioxazafen equivalents) in liver was 0.06 mg/kg.

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

The Meeting received information on the stability of tioxazafen and its major metabolites in various matrices during freezer storage (-20 °C).

Tioxazafen or benzamidine in homogenised maize grain, lettuce leaves, radish root, soya bean seed, lentil seed and whole orange fruit are stable at < -20 °C for at least nine months, which covered the storage duration in the crop metabolism studies, residue trials and processing studies. Tioxazafen, benzamidine, 2-thenoylglycine and benzonitrile are stable in animal matrices (milk, kidney, fat from cattle, liver, muscle and eggs) at -18 °C for at least six months, which covered the storage duration in the livestock metabolism and feeding studies.

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

The nature of the tioxazafen residues was investigated in soya bean, maize and cotton after seed treatment, and in livestock following oral administration of the test substance.

Tioxazafen was extensively metabolised to a number of metabolites and their conjugates in soya bean, maize and cotton. The <sup>14</sup>C residues in edible parts such as soya bean seed, maize grain and cotton seed were much lower than that in feed commodities such as thinning, forage, hay and stover. Parent tioxazafen was not detected in samples of seed. Tioxazafen was detected in forage and fodder commodities investigated with highest levels in maize thinnings (46% TRR).

Benzamidine (6.2–12.4%) was identified as the major metabolite in soya bean, maize and cotton forage and fodder. Other minor metabolites identified were less than 5% TRR or not consistently identified in different commodities. Therefore, none of them are suitable as a marker compound.

Confined and field rotational crop studies showed that no potential residues of tioxazafen and its metabolites are expected in rotational crops. Suitable analytical methods are available to analyse the parent compound and benzamidine.

The toxicity of benzamidine is considered to be covered by that of tioxazafen. Information available to the Meeting indicated that benzamidine is not naturally occurring. The Meeting considered that the residue definition for compliance with the MRL for plant commodities should be tioxazafen and benzamidine.



In deciding which additional compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence of the compounds in human foods. Levels of radioactivity in grain were too low for identification. Tioxazafen and metabolites, if present are at extremely low levels.

The Meeting decided that the residue definition for dietary risk assessment for plant commodities should be the sum of tioxazafen and benzamidine.

In the lactating goat metabolism study, tioxazafen is extensively metabolised. Parent tioxazafen was not found in milk or tissues except in fat, where it was present only at low levels (9–11% TRR, 0.001–0.002 mg eq/kg). The primary metabolite in skim milk, liver, kidney, and most other tissues were benzamidine (25–99% TRR, 0.007–0.27 mg eq/kg) and thenoylglycine (1.5–65% TRR, 0.005–0.054 mg eq/kg) and glucuronic acid conjugate (18.7% TRR, 0.005 mg eq/kg). The sulfate conjugate of hydroxy tioxazafen (56–68% TRR, 0.15–0.17 mg eq/kg) is found as the major metabolite in milk fat. Minor metabolites found include benzoic acid, benzamide, 2-thiophenecarboxylic acid (1.1–1.5% TRR, 0.003–0.004 mg eq/kg in liver) and benzonitrile (1.9–8.3% TRR, 0.001 mg eq/kg).

In the laying hen metabolism study, parent tioxazafen was the major component in fat (estimated as high as 49.3–75.7% TRR, 0.021–0.034 mg eq/kg), and was found at low level in liver (0.3–0.5% TRR, 0.002–0.003 mg eq/kg) and muscle (3.7–5.6% TRR, 0.0003–0.001 mg eq/kg).

Benzamidine was found as the predominant metabolites in muscle (17.5–18.1% TRR, 0.002 mg eq/kg), in liver (6% TRR, 0.035 mg eq/kg, the only significant metabolite), and in egg (3.4–4.0% TRR, 0.003–0.006 mg eq/kg). Benzonitrile was the major metabolite in fat (21.2–30.1% TRR, 0.010–0.013 mg eq/kg). M4, likely a mixture of polar metabolites, was the major metabolite in muscle (TH label only, 11.8–13.2% TRR, 0.001–0.002 mg eq/kg) and liver (3.5% TRR, 0.023 mg eq/kg). Minor metabolites found include benzamide, benzoic acid, benzonitrile, glucuronic acid conjugate) and sulfate conjugate.

In goats, the sulfate conjugate of hydroxyl-tioxazafen was the predominant residue in milk fat (up to 68% TRR, 0.17 mg eq/kg), following administration of 11 ppm of the parent in the diet. The Meeting noted that the maximum estimated dietary burden (0.19 ppm) is approximately 60 times lower than the dose administered in the metabolism study and milk fat represents only 4% of whole milk. The Meeting concluded that no significant levels of the sulfate conjugate of hydroxyl-tioxazafen have to be expected in milk.

Additionally, in the cattle feeding study 2-thenoylglycine was only quantified in kidneys for the 3 ppm (up to 0.048 mg/kg) and 12 ppm group (up to 0.12 mg/kg), but was not found at dose levels of 0.12 and 0.6 ppm in kidneys or in any other matrix (up to 12 ppm). The Meeting concluded that due to its singular occurrence in kidney and the low levels anticipated at the actual dietary burden, no significant residues ( $\geq 0.01$  mg/kg) are expected for this compound.

In laying hens, benzonitrile was found in major proportions in the fat (up to 30% TRR and up to 0.013 mg eq/kg). The Meeting noted that the laying hens metabolism study conducted at 21 ppm is overdosed by a factor of more than 700 compared to the estimated poultry dietary burden and concluded that no residues of benzonitrile have to be expected in poultry matrices.

The analytical method was developed for tioxazafen, benzamidine, benzonitrile and 2-thenoylglycine in animal matrices, including milk, fat, liver, kidney, muscle and egg.

The Meeting considered the residue definition for compliance with the MRL and dietary risk assessment for animal commodities was the sum of tioxazafen and benzamidine, expressed as tioxazafen.

In summary, based on the above, the Meeting recommended the following residue definitions.

Definition of the residue for compliance with the MRL and dietary risk assessment for plant commodities: *sum of tioxazafen and benzamidine, expressed as tioxazafen.*

Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: *sum of tioxazafen and benzamidine, expressed as tioxazafen.*

The ratio of residues in muscle to fat in the laying hen metabolism study and the cow feeding study were 0.4–0.9 fold. Therefore, the Meeting considered the residues not fat-soluble.

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

Supervised residue trial data were available for tioxazafen on maize, soya bean and cotton. The residues are reported separately for tioxazafen and benzamidine. For estimation of maximum residue level, HR and STMR, the sum of tioxazafen and benzamidine (expressed as tioxazafen) is needed. When residues were below LOQ in a commodity, the sum of LOQs is applied. The method for calculation of the total residues (the sum of tioxazafen and benzamidine) is illustrated as follows:

Tioxazafen, mg/kg	Benzamidine, mg/kg (expressed as tioxazafen)	Total, mg/kg
< 0.0025	< 0.0025	< 0.005
0.005	< 0.0025	0.0075
0.01	0.005	0.015

### ***Maize***

The critical GAP for maize in the USA is a seed treatment at rate of 1.0 mg ai/seed (maximum seasonal rate of 99 g ai/ha). The Meeting received supervised residue trial data for tioxazafen on maize conducted in the USA.

In 22 trials conducted at rates approximating critical GAP or at rates double the critical GAP, in the USA, the total residues of tioxazafen and benzamidine in maize grain (in both scenarios) were (n = 22): < 0.005 mg/kg.

The Meeting noted that the LOQs of the analytical method for enforcement are 0.005 mg/kg for each analyte, and combined the LOQs for tioxazafen and benzamidine to estimate a maximum residue level of 0.01(\*) mg/kg, and a STMR of 0 mg/kg for maize grain.

### ***Soya bean seed (dry)***

The critical GAP for soya bean in the USA is a seed treatment at a rate of 0.5 mg ai/seed (maximum seasonal rate of 309 g ai/ha). The Meeting received supervised residue trial data for tioxazafen on soya bean conducted in the USA.

In trials conducted at rates approximating critical GAP in the USA, the total residues of tioxazafen and benzamidine in soya bean seed were (n = 22): 0.0055, 0.0062, 0.0063, 0.0074(2), 0.0080, 0.0092, 0.0094, 0.0096, 0.0099, 0.012, 0.013(2), 0.015(2), 0.016(2), 0.017, 0.018, 0.020, 0.022 and 0.031 mg/kg.

The Meeting estimated a maximum residue level of 0.04 mg/kg and a STMR of 0.0125 mg/kg for soya bean (dry).

### ***Cottonseed***

The critical GAP for cotton in the USA is a seed treatment at a rate of 1.0 mg ai/seed (maximum seasonal

rate of 210 g ai/ha). The Meeting received supervised residue trial data for tioxazafen on cotton conducted in the USA.

In trials conducted at rates approximating critical GAP or at rates double critical GAP in the USA, the total residues of tioxazafen and benazamidine in cotton seed (in both scenarios) were (n = 12): < 0.005 mg/kg.

The Meeting noted that the LOQs of the analytical method for enforcement are 0.005 mg/kg for each analyte, and combined the LOQs for tioxazafen and benazamidine to estimate a maximum residue level of 0.01(\*) mg/kg and a STMR of 0 mg/kg for cottonseed.

### ***Animal feed items***

#### ***Maize forage and stover***

The critical GAP for maize in the USA is a seed treatment at rate of 1.0 mg ai/seed (maximum seasonal rate of 99 g ai/ha). The Meeting received supervised residue trial data for tioxazafen on maize conducted in the USA.

In trials conducted at rates approximating critical GAP in the USA, the total residues of tioxazafen and benazamidine in maize stover were (n = 22): < 0.005 (13), 0.0052, 0.0056, 0.006, 0.0061, 0.007, 0.0086, 0.0087, 0.0098 and 0.013 mg/kg.

The total residue of tioxazafen and benazamidine in maize forage were (n = 22): < 0.005 (17), 0.005, 0.0055, 0.0053, 0.0054 and 0.0081 mg/kg.

The Meeting estimates a maximum residue level of 0.03 mg/kg (DM) and median residue of 0.005 mg/kg (as received) and a high residue of 0.013 mg/kg for maize stover (as received).

The Meeting estimated a median residue of 0.005 mg/kg and a high residue of 0.0081 mg/kg for maize forage (as received).

#### ***Soya bean forage and hay***

The critical GAP for soya bean in the USA is a seed treatment at a rate of 0.5 mg ai/seed (maximum seasonal rate of 309 g ai/ha). The Meeting received supervised residue trial data for tioxazafen on soya bean conducted in the USA.

In trials conducted at rates approximating critical GAP in the USA, the total residues of tioxazafen and benazamidine in soya bean hay were (n = 22): 0.010, 0.026, 0.031(2), 0.032, 0.038, 0.043, 0.044, 0.045, 0.059, 0.068, 0.07, 0.077, 0.079, 0.082, 0.087, 0.095, 0.10, 0.11, 0.12(2) and 0.17 mg/kg.

The total residue of tioxazafen and benazamidine in soya bean forage were (n = 22): 0.0088, 0.0099, 0.011(2), 0.013, 0.016, 0.021, 0.023, 0.025, 0.028, 0.031, 0.034, 0.035, 0.038(2), 0.040, 0.044(2), 0.045, 0.066, 0.074 and 0.078 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg (DM), a median residue of 0.069 mg/kg (as received) and a high residue of 0.17 mg/kg for soya bean hay (as received).

The Meeting estimated a median residue of 0.029mg/kg and a high residue of 0.078 mg/kg for soya bean forage (as received).

#### ***Cotton gin by products***

The critical GAP for cotton in the USA is a seed treatment at rate of 1.0 mg ai/seed (maximum seasonal rate of 210 g ai/ha). The Meeting received supervised residue trial data for tioxazafen on cotton conducted

in the USA.

In trials conducted at rates approximating critical GAP in the USA, the total residues of tioxazafen and benzamidine in gin by-products were (n = 4): 0.0052, 0.0062, 0.0065 and 0.0098 mg/kg.

The Meeting estimated a maximum residue level of 0.02 mg/kg, a median residue of 0.00635 mg/kg and a high residue of 0.0098 mg/kg for gin by-product (as received).

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

The Meeting received processing studies on soya bean. A summary of the processing factors is provided below.

Commodity	Processed Fraction	Processing Factor	Best estimate PF	RAC STMR or STMR-P
Soya bean	Seeds (RAC)			0.012
	Meal	1.33, 1.49	1.41	0.017
	Hulls	0.12, 0.70	0.41	0.0049
	Refined oil	< 0.06, < 0.09	< 0.06	0

The residues of tioxazafen concentrated in soya bean meal and meal (toasted), the Meeting estimated a maximum residue level of 0.06 mg/kg (0.04 mg/kg × 1.41) for soya bean meal.

### ***Residues in animal commodities***

#### ***Farm animal feeding studies***

The Meeting received feeding studies on lactating dairy cows and laying hens.

#### ***Lactating dairy cow study***

The residue levels in tissues and milk of lactating dairy cows dosed with tioxazafen at the equivalent of 0.12, 0.60, 3.0 and 12 ppm in the feed for 28 consecutive days are summarised in the following table.

Matrix	Analyte	Residues by Feeding Level <sup>a</sup> (mg/kg)			
		0.12 ppm (1×)	0.60 ppm (5×)	3.00 ppm (25×)	12.0 ppm (100×)
Milk	Tioxazafen	ND <sup>b</sup>	ND	ND	< 0.010 <sup>c</sup>
	Benzamidine	< 0.010	< 0.010	0.0266 (0.0234)	0.0801 (0.0676)
Liver	Tioxazafen	ND	ND	ND	< 0.010
	Benzamidine	< 0.010	0.0185 (0.0143)	0.0541 (0.0473)	0.163 (0.131)
Kidney	Tioxazafen	ND	ND	ND	< 0.010
	Benzamidine	< 0.010	0.0177 (0.0150)	0.0688 (0.0650)	0.194 (0.174)
Muscle	Tioxazafen	ND	ND	ND	< 0.010
	Benzamidine	< 0.010	< 0.010	0.0141 (0.0118)	0.0410 (0.0329)
Fat <sup>d</sup>	Tioxazafen	ND	ND	ND	< 0.010
	Benzamidine	< 0.010	0.0114 (< 0.010)	0.0179 (< 0.010)	0.0495 (0.0211)

<sup>a</sup> Maximum daily average for milk. Maximum individual value for all other tissues, with dose group average in parentheses. The residues of benzamidine are reported as tioxazafen equivalents.

<sup>b</sup> ND = Not determined (samples not analysed because samples in higher dose group had residues less than the limit of

quantitation [LOQ])

<sup>c</sup> Values below the LOQ are listed as '< 0.0xx', where 0.0xx is the LOQ value for that matrix.

<sup>d</sup> Highest maximum value of either subcutaneous, mesenteric, or perirenal fat; average across all fat.

### *Laying hens study*

The residue levels in tissues and eggs of laying hens dosed with tioxazafen at the equivalent of 0.81, 4.0, 21 and 79 ppm in the feed for 28 consecutive days are summarised in the following table.

Matrix	Analyte	Residues by Feeding Level (mg/kg) <sup>a</sup>			
		0.81 ppm (1×)	4.0 ppm (5×)	20.8 ppm (25×)	79.1 ppm (100×)
Egg	Tioxazafen	ND <sup>b</sup>	ND	< 0.010	0.0120 (0.0239)
	Benzamidine	ND	< 0.010	< 0.010 <sup>c</sup>	0.0162 (0.0273)
Liver	Tioxazafen	< 0.010	< 0.010	< 0.010	< 0.010
	Benzamidine	< 0.010	0.0135 (0.0148)	0.0714 (0.0787)	0.807 (1.03)
Muscle	Tioxazafen	ND	ND	ND	< 0.010
	Benzamidine	< 0.010	< 0.010	< 0.010	0.0176 (0.0177)
Fat	Tioxazafen	< 0.010	< 0.010 (0.0106)	0.0442 (0.0519)	0.325 (0.362)
	Benzamidine	ND	ND	ND	< 0.010

<sup>a</sup> The overall average is listed for egg, with the maximum daily average in parentheses. The overall averages are listed for all other tissues, with the maximum individual value in parentheses. Values below the LOQ are listed as '< 0.0xx', where 0.0xx is the LOQ value for that matrix; Residues of benzamidine and benzonitrile are reported as tioxazafen equivalents.

<sup>b</sup> ND = Not determined. Samples not analysed because samples in the higher dose group had residues <LOQ

<sup>c</sup> All daily average values for benzamidine in the 25 group were < 0.010 mg/kg, but one subgroup had residues of 0.0111 mg/kg on Day 19.

### *Estimation of livestock dietary burdens*

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR. Potential cattle feed items include: maize grain, forage and stover; soya bean seed, meal, hull, forage and hay; and cotton gin by products. 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

#### Summary of livestock dietary burden (ppm tioxazafen equivalents of dry matter diet)

	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	mean	max	Mean	max	Mean
Beef cattle	0.006	0.0044	0.02	0.014	0.19 <sup>A</sup>	0.077 <sup>C</sup>	0.014	0.014
Dairy cattle	0.052	0.025	0.018	0.014	0.092 <sup>B</sup>	0.041 <sup>D</sup>	0.019	0.016
Broilers	0.007	0.007	0.01	0.01	0.007	0.007	0.006	0.006
Layers	0.007	0.007	0.027 <sup>E</sup>	0.015 <sup>F</sup>	0.007	0.007	0.006	0.006

<sup>A</sup> Highest maximum beef or dairy 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 mammalian milk

<sup>C</sup> Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat.

<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 maximum residue level estimates for poultry meat and eggs

<sup>F</sup> Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs

### ***Animal commodity maximum residue levels***

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

	Feed level ppm) for milk residues	Residues (mg/kg) in milk	Feed level (ppm) for tissue residues	Residues of benzamidine (mg/kg)*			
				Muscle	liver	Kidney	Fat
maximum residue level (mg/kg), beef or dairy cattle							
Feeding study	0.12	< 0.01	0.12	< 0.01	< 0.01	< 0.01	< 0.01
	0.6	< 0.01	0.6	< 0.01	0.0185	0.017	0.0114
Dietary burden and high residue estimation	0.092	< 0.01	0.19	< 0.01	0.0133	0.0128	0.01055
STMR (mg/kg), beef or dairy cattle							
Feeding study	0.12	< 0.01	0.12	< 0.01	< 0.01	< 0.01	< 0.01
Dietary burden and median residue estimated	0.041	< 0.01	0.077	< 0.01	< 0.01	< 0.01	< 0.01

\*LOQs for tioxazafen and benzamidine are 0.01mg/kg; residues of tioxazafen are less than LOQ. Calculation for cattle is based on residues of benzamidine.

The maximum dietary burden calculated for cattle is 0.19 ppm for beef cattle and 0.092 ppm for dairy cattle. The mean dietary burden calculated is 0.077 ppm for beef cattle and 0.041 ppm for dairy cattle.

To estimate maximum residue levels, the LOQ for tioxazafen (0.01 mg/kg) is added to estimated benzamidine levels. The Meeting estimated a maximum residue level of 0.02 mg/kg for milk, and meat from mammals other than marine mammals; and 0.03 mg/kg (0.015 + 0.01 to nearest "step") for edible offal (mammalian) and mammalian fat. The Meeting estimated a STMR of 0.01 mg/kg for milk, meat from mammals other than marine mammals, edible offal (mammalian), and mammalian fat. The Meeting estimated a HR of 0.02 mg/kg for meat from mammals other than marine mammals, and 0.025 mg/kg for both edible offal (mammalian) and mammalian fat.

The maximum and mean dietary burden calculated for poultry (layer) are 0.027 ppm and 0.015 ppm, respectively, much lower than the lowest dose level (0.81ppm) in the feeding study, which results in residues below LOQs.

The Meeting estimated maximum residue levels of 0.02(\*) mg/kg for tioxazafen in egg, poultry meat, poultry fat and poultry edible offal. The Meeting estimated STMRs of 0 mg/kg for eggs, 0.01 mg/kg for poultry meat and fat, and 0.02 mg/kg for poultry edible offal. The Meeting estimated HRs of 0.02 mg/kg for egg, poultry meat, poultry fat and poultry edible offal.

### **RECOMMENDATIONS**

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

The Meeting recommended the following residue definitions for tioxazafen.

Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: *sum of tioxazafen and benzamidine (benzenecarboximidamide), expressed as tioxazafen.*

The residue is not fat-soluble.

## DIETARY RISK ASSESSMENT

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

The ADI for tioxazafen is 0–0.05 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for tioxazafen 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 2018 JMPR Report. The IEDIs ranged from 0% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of tioxazafen from uses considered by the JMPR is unlikely to present a public health concern.

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

The ARfD for tioxazafen is 0.5 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for tioxazafen 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 2018 JMPR Report. The IESTIs were 0% of the ARfD.

The Meeting concluded that acute dietary exposure to residues of tioxazafen from uses considered by the present Meeting is unlikely to present a public health concern.





## 6 Future work

The items listed below are tentatively scheduled to be considered by the Meetings 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>27</sup>.

### NEW COMPOUNDS

TOXICOLOGY EVALUATIONS	RESIDUE EVALUATIONS
Broflanilide (Insecticide) USA	Broflanilide
Ethalfuralin (Herbicide) Canada	Ethalfuralin
Fluoxapiprolin/BCS-CS55621 (fungicide)	Fluoxapiprolin/BCS-CS55621
Inpyrfluxam (fungicide)	Inpyrfluxam
Isoflucypram/BCS-CN88460 (Fungicide) Germany	Isoflucypram/BCS-CN88460
Mefentrifluconazole/BAS 750 F (Fungicide) USA	Mefentrifluconazole/BAS 750 F
Pyraziflumid (fungicide) Japan	Pyraziflumid
Pyrasulfutole (Herbicide) Canada	Pyrasulfutole
Tetraniliprole (Insecticide) Germany	Tetraniliprole

PERIODIC RE-EVALUATIONS	
TOXICOLOGY	RESIDUE
Aldicarb (117)	Aldicarb (117)
Diazinon (022)	Diazinon (022)
Ethoxyquin (035)	Ethoxyquin (035)
Fipronil (202)	Fipronil (202)
Methidathion (51)	Methidathion (51)
Pirimicarb (101)	Pirimicarb (101)
Prochloraz (142)	Prochloraz (142)
Quintozene (064)	Quintozene (064)

NEW USES AND OTHER EVALUATIONS	
TOXICOLOGY EVALUATIONS	RESIDUE EVALUATIONS
	Chlorfenapyr (254)
	Clofentezine (156)
	Clothianidin (238)
	Cypermethrin (118)
	Deltamethrin (35)
	Diazinon (22)
	Dicofol (26)
	Dimethoate (27)
	Fenpropathrin (185)

<sup>27</sup> <http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/en/>

NEW USES AND OTHER EVALUATIONS	
TOXICOLOGY EVALUATIONS	RESIDUE EVALUATIONS
	Fenpyroximate (193)
	Fluensulfone (265)
	Fluopyram (243)
	Flupyradifurone (285)
	indoxacarb (216)
	Isoprothiolane
	Isoxaflutole (268)
	Lambda-cyhalothrin (146)
	Metalaxyl (138)
	Metalaxyl-M (212)
	Methomyl (94)
	Parathion (59)
	Phorate (112)
	Phosalone (60)
	Profenofos (171)
	Propiconazole (160)
	Prothioconazole (232)
	Pydiflumetofen (309)
	Pyraclostrobin (210)
	Spiromesifen (294)
	Sulfoxaflor (252)
	Tebuconazole (189)
	Thiamethoxam (245)
	Triazophos (143)
	Trifloxystrobin (213)

**Annex 1: Acceptable daily intakes, short-term dietary intakes, acute reference doses, recommended maximum residue limits and supervised trials median residue values recorded by the 2018 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>Abamectin (177)</b> ADI: 0–0.001 mg/kg bw  ARfD: 0.003 mg/kg bw	FB 0264	Blackberries	W	0.05		
	FB 2005	Cane berries, subgroup of (includes all commodities in this subgroup)	0.2		0.018	0.11
		Chives, dried	0.08		0.015	
	DF 0269	Dried grape (=currants, raisins and sultanas)	0.1	0.03	0.0059	0.045
	JF 0269	Grape juice	0.05	0.015	0.0029	
	FB 0269	Grapes	0.03	0.01	0.0021	0.016
	VA 2032	Green onions, subgroup of (includes all commodities in this subgroup)	0.01		0.002	0.004
	HH 2095	Herbs, subgroup of, (includes all commodities in this subgroup)	0.015		0.003	0.008
	VA 0384	Leek	W	0.005		
	OR 0001	Orange oil	0.1			
	FI 0353	Pineapple	0.002*		0	0
	FB 0272	Raspberries, Red, Black	W	0.05		
	VD 0541	Soya bean (dry)	0.002*		0.002	
	VP 2062	Succulent beans without pods, subgroup of (includes all commodities in this subgroup)	0.002*		0.002	0.002
	GC 2090	Sweet corns, subgroup of (includes all commodities in this subgroup)	0.002*		0.002	0.002
		Soya bean			0.002	0.002
Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: <i>Avermectin B1a</i> .						
<i>The residue is fat-soluble.</i>						
<b>Bentazone (172)</b> ADI: 0–0.09 mg/kg bw  ARfD: 0.5 mg/kg bw	VD 0071	Beans (dry)	W	0.04		
	VD 2065	Dry beans, subgroup of (includes all commodities in this subgroup)	0.5		0.09	
	VD 2066	Dry peas, subgroup of (includes all commodities in this subgroup)	0.5		0.09	
	MO 0105	Edible offal (Mammalian)	0.04		0.01	0.035
	MF 0100	Mammalian fats (except milk fats)	0.01*		0	0
	MM 0095	Meat (from mammals other than marine mammals)	0.01*		0	0
	ML 0106	Milks	0.01*		0	

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		
	VD 0541	Soya bean	W	0.01*		
Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: <i>bentazone</i> .						
<i>The residue is not fat-soluble.</i>						
<b>Benzovindiflupyr (261)</b>	VD 0071	Beans (dry)	W	0.15		
ADI: 0–0.05 mg/kg bw	VD 2065	Dry beans, subgroup of, except soya bean, dry	0.15		0.011	
ARfD: 0.1 mg/kg bw	VD 2066	Dry peas, subgroup of (includes all commodities in this subgroup)	0.2		0.014	
	VD 0072	Peas (dry)	W	0.2		
Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: <i>benzovindiflupyr</i>						
<b>Chlorfenapyr (254)</b>	HS 0444	Chili pepper, dry	3		0.5	1.5
ADI: 0–0.03 mg/kg bw	MO 0105	Edible offal (Mammalian)	0.05		Liver: 0.54 Kidney: 0.48	Liver: 0.54 Kidney: 0.48
ARfD: 0.03 mg/kg bw	PE 0112	Eggs	0.01		0.02	0.047
	VA 0381	Garlic	0.01*		0.01	0.01
	FC 0002	Lemons and Limes, subgroup of (includes all commodities in this subgroup)	0.8		Whole fruit: 0.23 Pulp: 0.004	Whole fruit: 0.71 Pulp: 0.012
	MF 0100	Mammalian fats	0.6		1.0	1.0
	MM 0095	Meat (from mammals other than marine mammals)	0.6 (fat)		0.026 (muscle)	0.026 (muscle)
	VC 0046	Melons, except Watermelon	0.4		0.01	0.01
	ML 0106	Milks	0.03		0.043	
	VA 0385	Onion, bulb	0.01*		0.01	0.01
	FC 0004	Oranges, Sweet, Sour, subgroup of (includes all commodities in this subgroup)	1.5		0.011	0.021
	FI 0350	Papaya	0.3		0.072	0.17
	VO 0051	Peppers	0.3		0.05	0.15
	PO 0111	Poultry, edible offal of	0.01		Liver: 0.025 Kidney: 0.009	Liver: 0.058 Kidney: 0.022
	PF 0111	Poultry, fats	0.02		0.008	0.018
	PM 0110	Poultry, meat	0.02 (fat)		0.003 (muscle)	0.007 (muscle)
	VR 0589	Potato	0.01*		0.01	0.01
	VD 0541	Soya bean (dry)	0.08		0.01	
	AL 0541	Soya bean fodder	7 (DM)		Median: 1.6 (as)	Highest: 3.9 (as)
	OC 0541	Soya bean, crude oil	0.4		0.045	
	VO 0448	Tomatoes	0.4		0.065	0.19
	DT 1114	Tea, Green, Black (black, fermented and dried)	60		12	

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>chlorfenapyr</i> .						
Definition of the residue for dietary risk assessment for plant and animal commodities: <i>sum of chlorfenapyr plus 10 × 4-bromo-2-(p-chlorophenyl)-5-(trifluoromethyl)-pyrrole-3-carbonitrile (tralopyril)</i>						
The residue is fat-soluble.						
<b>Cyantraniliprole (263)</b>	FB 0265	Cranberries	0.08		0.012	
ADI: 0–0.03 mg/kg bw	VC 0045	Fruiting vegetables, Cucurbits	W	0.3		
ARfD: Unnecessary	VC 0045	Fruiting vegetables, Cucurbits, Group of (includes all commodities in this group)	0.3		0.065 <sup>a</sup> 0.01 <sup>b</sup>	
	FI 0345	Mango	0.7		0.01	
	GM 0649	Rice, Husked	0.01*		0.01	
	CM 1205	Rice, polished	0.01*		0.01	
	AS 0649	Rice straw & fodder (dry)	1.7 (dw)		Median: 0.099 (dw)	Highest: 0.84 (dw)
	FB 0275	Strawberry	1.5		0.455	
	FB 1236	Wine-grapes	1		0.21	
	JF 0269	Grape, juice			0.11	
	DF 0269	Dried grapes (=currants, raisins and sultanas)			0.088	
	-	Grape, wine			0.21	
	-	Grape, must			0.32	
Definition of the residue for compliance with the MRL for plant and animal commodities: <i>cyantraniliprole</i>						
Definition of the residue for dietary risk assessment for unprocessed plant commodities: <i>cyantraniliprole</i>						
Definition of the residue for dietary risk assessment for processed plant commodities: <i>sum of cyantraniliprole and IN-J9Z38, expressed as cyantraniliprole</i>						
Definition of the residue for dietary risk assessment for animal commodities: <i>sum of cyantraniliprole, 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile [IN-J9Z38], 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1Hpyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazolinecarbonitrile [IN-MLA84], 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide [IN- N7B69] and 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2[(hydroxymethyl)amino]carbonyl]-6-methylphenyl]-1H-pyrazole-5-carboxamide [IN- MYX98],expressed as cyantraniliprole</i>						
The residue is not fat-soluble.						
<sup>a</sup> edible peel						
<sup>b</sup> inedible peel						
(dw) Dry weight						
<b>Cyazofamid (281)</b>	VA 0035	Bulb onions, Subgroup of (includes all commodities in this subgroup)	1.5		0.0615 0.01 (CCIM)	0.03 (CCIM)
ADI: 0–0.2 mg/kg bw	VA 2032	Green onions, Subgroup of (includes all commodities in this subgroup)	6		1.5 0.044 (CCIM)	0.2 (CCIM)
ARfD: Unnecessary						



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>Ethiprole (304)*</b> ADI: 0–0.005 mg/kg bw ARfD: 0.005 mg/kg bw	SB 0716	Coffee beans	0.07		0.0245	-
	SM 0716	Coffee beans, roasted	0.2		0.044	-
	MO 0105	Edible offal (mammalian)	0.1		Kidney: 0.029 Liver: 0.076	Kidney: 0.030 Liver: 0.079
	PE 0112	Eggs	0.05		0.030	0.038
	MF 0100	Mammalian fats (except milk fats)	0.15		Fat: 0.094	Fat: 0.10
	MM 0095	Meat (from mammals other than marine mammals)	0.15 (fat)		Muscle: 0.021 Fat: 0.094	Muscle: 0.021 Fat: 0.10
	FM 0183	Milk fats	0.5		0.33	-
	ML 0106	Milks	0.015		0.011	-
	PM 0110	Poultry meat	0.05 (fat)		0.02 (Muscle) Fat: 0.037	0.02 (Muscle) Fat: 0.039
	PO 0111	Poultry, edible offal of	0.05		Liver: 0.031	Liver: 0.033
	PF 0111	Poultry fats	0.05		Fat: 0.037	Fat: 0.039
	GC 0659	Rice	3		0.44	
	CM 0649	Rice, husked	1.5		0.14	
	GC 1205	Rice, polished	0.4		0.040	
		Coffee beans, instant			0.048	
	CM 1206	Rice bran, unprocessed			0.53	
Definition of the residue for compliance with the MRL for plant commodities: <i>Ethiprole</i>						
Definition of the residue for dietary risk assessment for plant commodities: <i>Sum of ethiprole, 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-(ethylsulfinyl)-1H-pyrazole-3-carboxamide (ethiprole-amide) and 5-amino-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-ethylsulfonylpyrazole-3-carbonitrile (ethiprole-sulfone), expressed as parent equivalents</i>						
Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: <i>Sum of ethiprole and 5-amino-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-ethylsulfonylpyrazole-3-carbonitrile (ethiprole-sulfone), expressed as parent equivalents</i>						
<i>The residue is fat soluble</i>						
<b>Fenpicoxamid (305)*</b> ADI: 0–0.05 mg/kg bw ARfD: Unnecessary	FI 0327	Banana	0.15		0.01	
Definition of the residue for compliance with the MRL and dietary risk assessment for plant commodities: <i>Fenpicoxamid</i>						
<b>Fenpyroximate (193)</b> ADI: 0–0.01 mg/kg bw ARfD: 0.01 mg/kg bw	VO 2700	Cherry tomato	W	0.3		
	MO 0105	Edible offal (mammalian)	0.5	0.5	Liver: 0.272 Kidney: 0.252	Liver: 0.501 Kidney: 0.404
	MF 0100	Mammalian fats (except milk fats)	0.1	0.1	0.029	0.089
	MM 0095	Meat (from mammals other than marine mammals)	0.1 (fat)	0.1	0.0110.02 (Muscle)	0.020.02 (Muscle)
	ML 0106	Milks	0.01	0.01*	0.0015	
	VO 0448	Tomato	W	0.3		

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		
	VO 2045	Tomatoes, subgroup of (includes all commodities in this subgroup)	0.3		0.1	0.17
Definition of the residue for compliance with the MRL for plant commodities: <i>fenpyroximate</i>						
Definition of the residue for dietary risk assessment for plant commodities: <i>sum of parent fenpyroximate and itert-butyl (Z)-α-(1,3-dimethyl-5-phenoxy-pyrazol-4-yl)methyleneamino-oxy)-p-toluate (its Z-isomer M-1), expressed as fenpyroximate</i> .						
Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: <i>sum of fenpyroximate, 2-hydroxymethyl-2-propyl (E)-4-[(1,3-dimethyl-5-phenoxy-pyrazol-4-yl)-methylenamino-oxy-methyl]benzoate (Fen-OH), and (E)-4-[(1,3-dimethyl-5-phenoxy-pyrazol-4-yl)methyleneamino-oxy-methyl]benzoic acid (M-3), expressed as fenpyroximate</i> .						
<i>The residue is fat-soluble</i>						
<b>Fluazinam (306)*</b>						
ADI: Not established						
ARfD: Not established						
Definition of the residue for compliance with the MRL for plant commodities: <i>fluazinam</i>						
<b>Fludioxonil (211)</b> ADI: 0–0.4 mg/kg bw ARfD: Unnecessary	FI 0326	Avocado	1.5	0.4	0.01	
	FB 0020	Blueberries	2	2	0.6	
	VA 2031	Bulb onions, Subgroup of (includes all commodities in this subgroup)	0.5		0.04	
	VB 0041	Cabbages, head	0.7	0.7	0.24	
	VR 0577	Carrot	1	0.7	0.19	
	VS 0624	Celery	15		4.55	
	VD 0524	Chick-pea (dry)	0.3		0.11	
	FB 0021	Currants	3		0.62	
	MO 0105	Edible offal (Mammalian)	0.1	0.05*	0.02	
	PE 0112	Eggs	0.02	0.01*	0.01	
	VA 2032	Green onion, Subgroup of (includes all commodities in this subgroup)	0.8		0.14	
	FT 0336	Guava	0.5		0.125	
	VL 0054	Leaves of Brassicaceae, subgroup of (includes all commodities in this subgroup)	15		1.2	
	VD 0533	Lentils	0.3		0.11	
	MF 0100	Mammalian fats (except milk fats)	0.02		0.003	
	MM 0095	Meat (from mammals other than marine mammals)	0.02 (fat)	0.01	0.01	
	ML 0106	Milks	0.04	0.01	0.008	
	VL 0485	Mustard greens	W	10		
	VA 0385	Onion, bulb	W	0.5		
	FI 0353	Pineapple	5 Po		2	
	FI 0355	Pomegranate	3 Po	2	1.75	



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		
	PF 0111	Poultry fats	0.01*		0	
	PM 0110	Poultry meat	0.01*	0.01*	0	
	PO 0111	Poultry, edible offal of	0.1	0.05	0.028	
	VD 0541	Soya bean (dry)	0.2		0.01	
		Carrots (canned)			0.027	
		Juice (pasteurised)			0.034	
		Carrots (cooked)			0.023	
	Definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities: <i>fludioxonil</i> . Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: <i>fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluoro-1,3-benzodioxole-4-carboxylic acid and expressed as fludioxonil</i> . The residue is fat-soluble.					
<b>Fluopyram (243)</b> ADI: 0–0.01 mg/kg bw ARfD: 0.5 mg/kg bw	VO 2700	Cherry tomato	W	0.4		
	CM 0649	Rice, husked	1.5		0.18	
	CM 1205	Rice, polished	0.5		0.068	
	VO 0448	Tomato	W	0.5		
	VO 2045	Tomatoes, subgroup of (includes all commodities in this subgroup)	0.5		0.11	0.37
Definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities: <i>fluopyram</i> Definition of the residue for compliance with the MRL for animal commodities: <i>Sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram</i> Definition of the residue for dietary risk assessment for animal commodities: <i>Sum of fluopyram, 2-(trifluoromethyl) benzamide and the combined residues of N-((E)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl)-2-trifluoromethyl benzamide and N-((Z)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl)-2-trifluoromethyl benzamide, all expressed as fluopyram</i> . The residue is not fat-soluble.						
<b>Fluxapyroxad (256)</b> ADI: 0–0.02 mg/kg bw ARfD: 0.3 mg/kg bw	AL 3350	Alfalfa hay	20 (DM)		0.04 (as)	9.9 (as)
	FC 0001	Citrus fruit, Group of (includes all commodities in this group)	1		0.33	0.59
	OR 0001	Citrus oil, edible	60		22	
	SB 0716	Coffee beans	0.15		0.042	
	SO 0691	Cotton seed	0.5	0.3	0.08	
	FI 0345	Mango	0.6		0.145	0.37
	FC 0002	Oranges, Sweet, Sour (including Orange-like hybrids)	W	0.3		
	FI 0350	Papaya	1		0.054	0.51
	VR 0589	Potato	0.07	0.03	0.035	0.06
	VR 2071	Tuberous and corm vegetables, except potato, Subgroup of (includes all commodities in this subgroup)	0.03		0.01	0.03
		Citrus juice			0.015	
		Citrus peel			0.72	1.1

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		
		Cotton seed refined oil			0.0036	
		Marmalade			0.025	
		Potato baked tuber (with peel)			0.018	0.03
		Potato boiled tuber (with peel)			0.018	0.03
		Potato chips			0.018	
		Potato fried tuber (with peel)			0.018	0.03
		Potato granules/flakes			0.018	
		Potato peeled tuber			0.018	0.03
Definition of the residue (for compliance with the MRL) for plant and animal commodities: <i>Fluxapyroxad</i> .						
Definition of the residue (for estimation of dietary exposure) 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'-trifluorobipheny-2-yl)-1H-pyrazole-4-carboxamide (M700F048), expressed as parent equivalents.</i>						
Definition of the residue (for estimation of dietary exposure) for animal commodities: <i>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.</i>						
<i>The residue is fat soluble.</i>						
<b>Imazalil (1108)**</b> ADI: 0–0.03 mg/kg bw ARfD: 0.05 mg/kg bw	F00327	Banana	3 Po	2 Po	0.05	0.10
	GC 0640	Barley	0.01*		0	
	AS 0640	Barley straw and fodder (dry)	0.01		0.01	0.01
	FC0001	Citrus Fruit	W	5 Po		
	VC 0424	Cucumber	W	0.5		
	MO 0096	Edible offal (mammalian)	0.3		Liver: 0.34 Kidney: 0.06	Liver: 0.50 Kidney: 0.09
	PE 0112	Eggs	0.01*		0.02	0.02
	VC0425	Gherkins	W	0.5		
	FC0002	Lemons and limes, Subgroup of (includes all commodities in this subgroup)	15 Po		0.18	0.36
	MF 0100	Mammalian fats (except milk fats)	0.02		0.04	0.04
	MM 0095	Meat (from mammals other than marine mammals)	0.02*		0.04	0.04
	VC 0046	Melons, except Watermelon	W	2 Po		
	ML 0106	Milks	0.02*		0	
	FC0004	Oranges, sweet, sour, Subgroup of (includes all commodities in this subgroup)	8 Po		0.09	0.26
	FT 0307	Persimmon, Japanese	W	2 Po		
	FP 0009	Pome fruits	W	5 Po		
	VR0589	Potato	9 Po	5 Po	2.2	4.6
	PO 0111	Poultry, edible offal of	0.02*		0.04	0.04
	PF 0111	Poultry fats	0.02*		0.04	0.04
	PM 0110	Poultry meat	0.02*		0.04	0.04
	FB 0272	Raspberries, red and black	W	2		
	FB 0275	Strawberry	W	2		
	VO0448	Tomato	0.3		0.13	0.24
	GC 0653	Triticale	0.01*		0	
	AS 0653	Triticale straw and fodder (dry)	0.01		0.01	0.01
	AS 0654	Wheat straw and fodder (dry)	0.01	0.1	0.01	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		
	JF 0004	Orange juice			0.01	0.03
	HS 3382	Orange, peel			0.04	0.10
	OR 0004	Orange oil, edible			2.6	7.4
		Marmalade			0.02	0.07
		Jam			0.004	0.01
		Canned orange			0.003	0.008
		Peeled potato			0.02	0.05
		Baked potato with peel			1.3	2.8
		Boiled potato with peel			0.86	1.8
		Potato fries			0.04	0.09
		Potato crisps			0.04	0.09
		Potato flakes			0.004	0.009
Definition of the residue for compliance with the MRL for plant and animal commodities: <i>imazalil</i>						
Definition of the residue for dietary risk assessment for plant commodities: <i>free and conjugated imazalil</i> .						
Definition of the residue for dietary risk assessment for animal commodities: <i>sum of imazalil and the metabolite R061000 ((RS)-3-[2-(2,4-dichlorophenyl)-2-(2,3-dihydroxypropoxy)ethyl]imidazolidine-2,4-dione (+)-1-[2-(2,4-dichlorophenyl)-2-[(2,3-dihydroxypropyl)oxy]ethyl]-2,5-imidazolidinedione), expressed as imazalil equivalents.</i>						
<i>The residue is not fat-soluble</i>						
<b>Isofetamid (290)</b>	VP 2060	Beans with pods, subgroup of (includes all commodities in this subgroup)	0.6		0.096	0.36
ADI: 0–0.05 mg/kg bw	FB 2006	Bush berries, subgroup of (includes all commodities in this subgroup)	5		0.31	3
ARfD: 3 mg/kg bw	FB 2005	Cane berries, subgroup of (includes all commodities in this subgroup)	3		0.68	1.2
	FS 0013	Cherries, subgroup of (includes all commodities in this subgroup)	4		1.1	3.4
	VD 2065	Dry beans, subgroup of (except soya bean (dry))	0.05		0.01	
	VD 2066	Dry peas, subgroup of (includes all commodities in this subgroup)	0.05		0.01	
	FS 2001	Peaches, subgroup of (including Nectarine and Apricots)(includes all commodities in this subgroup)	3		0.76	1.7
	VP 2061	Peas with pods, subgroup of (includes all commodities in this subgroup)	0.6		0.096	0.36
	FS 0014	Plums, subgroup of (including fresh Prunes) (includes all commodities in this subgroup)	0.8		0.175	0.39

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		
	FP 0009	Pome fruits, group of (includes all commodities in this group)	0.6		0.135	0.42
	DF 0014	Prunes, dried	3		0.56	1.5
		Apple juice			0.04	
Definition of the residue for compliance with the MRL and dietary risk assessment for plant commodities: <i>Isfetamid</i> .						
Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: <i>the sum of isfetamid and 2-[3-methyl-4-[2-methyl-2-(3-methylthiophene-2-carboxamido) propanoyl] phenoxy] propanoic acid (PPA), expressed as isfetamid</i> .						
<i>The residue is fat-soluble.</i>						
<b>Kresoxim-methyl (199)**</b>	GC 0640	Barley	W	0.1		
ADI: 0–0.3 mg/kg bw	GC 2087	Barley, subgroup of (includes all commodities in this subgroup)	0.15		0.035	
ARfD: Unnecessary	VR 0574	Beet root	0.05*		0	
	VC 0424	Cucumber	W	0.05		
	FB 0021	Currant	0.9		0.21	
	DF 0269	Dried grapes (=currants, raisins and sultanas)	3	2	0.58	
	MO 0105	Edible offal (Mammalian)	0.05	0.05*	0.009	
	PE 0112	Eggs	0.02*		0	
	VC 0045	Fruiting vegetables, Cucurbits, Group of (includes all commodities in this group)	0.5		0.105	
	VA 0381	Garlic	0.01		0.02	
	FB 0269	Grape	1.5	1	0.365	
	FC 0203	Grapefruit	W	0.5		
	VA 0384	Leek	10		3.2	
	MF 0100	Mammalian fats (except milk fats)	0.02*	0.05*	0	
	FI 0345	Mango	0.1		0.024	
	MM 0095	Meat (from mammals other than marine mammals)	0.02*	0.05*	0	
	ML 0106	Milks	0.02*	0.01*	0	
	OC 0305	Olive oil, Virgin	1		0.34	
	SO 0305	Olives for oil production	0.2		0.10	
	VC 0045	Fruiting vegetables, Cucurbits, Group of (includes all commodities in this group)	0.5		0.105	
	FS 0247	Peach	1.5		0.37	
	TN 0672	Pecan nuts	0.05*		0.10	
	VO 0445	Peppers, sweet	0.3		0.045	
	FP 0009	Pome fruits	W	0.2		
	PF 0111	Poultry fats	0.02*		0	
	PM 0110	Poultry meat	0.02*	0.05*	0	
	PO 0111	Poultry, Edible offal of	0.02*		0	
	AS 0081	Straw and fodder (dry) of cereal grains	3 (DM)	5	Median: 0.50 (as)	Highest: 2.3 (as)

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		
	VR 0596	Sugar beet	0.05*		0	
	FT 0305	Table olives	0.2		0.10	
	VR 0497	Turnip	0.05*		0	
	GC 0654	Wheat	W	0.05*		
	GC 2086	Wheat, subgroup of (includes all commodities in this subgroup)	0.05		0.02	
		Grape Wine			0.095	
		Grape Juice			0.18	
		Grape Must			0.11	
	Definition of the residue for compliance with the MRL for plant commodities: <i>Kresoxim-methyl</i>					
	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>					
	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>					
	<i>The residue is not fat-soluble</i>					
	<b>Lambda-cyhalothrin (146)</b>					
	ADI: 0–0.02 mg/kg bw					
	ARfD: 0.02 mg/kg bw					
	Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: <i>Cyhalothrin (sum of all isomers).</i>					
	<b>Lufenuron (286)</b>	SB 0716 Coffee beans	0.07		0.01	
	ADI: 0–0.02 mg/kg bw	MO 0105 Edible offal (Mammalian)	0.15	0.04	Liver: 0.09	
					Kidney: 0.05	
ARfD: Unnecessary	FC 0205	Lime	0.4		0.10	
	MF 0100	Mammalian fats	2	0.7	1.07	
	MM 0095	Meat (mammalian except marine mammals)	2 (fat)	0.7	0.04 muscle	1.07 fat
	GC 0645	Maize	0.01		0.01	
	ML 0106	Milks	0.15	0.1	0.117	
	FM 0103	Milk fats	5	2	4.58	
	FC 0004	Oranges sweet, sour, Subgroup of (includes all commodities in this subgroup)	0.3		0.09	
	OR 0004	Orange oil, edible	8		2.16	
	FP 0009	Pome fruits, Group of (includes all commodities in this group)	1		0.29	
	JF 0004	Orange juice			0.01	
	JF 0226	Apple juice			0.06	

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		
Apple purée			0.06			
Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: <i>lufenuron</i> .						
<i>The residue is fat soluble</i>						
<b>Mandestrobin (307)*</b> ADI: 0–0.2 mg/kg bw ARfD: 3 mg/kg bw <sup>a</sup>						
<sup>a</sup> Applies to women of childbearing age only.						
<b>Mandipropamid (231)</b>  ADI: 0–0.2 mg/kg bw ARfD: Unnecessary	VP 2060	Beans with pods, subgroup of (includes all commodities in this subgroup)	1		0.22	
	SB 0715	Cacao bean	0.06		0.01	
	MO 0105	Edible offal (mammalian)	0.01*		0	
	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	
	ML0106	Milks	0.01*		0	
	VR 0589	Potato	0.1	0.01*	0.0185	
	PO 0111	Poultry edible offal	0.01*		0	
	PF 0111	Poultry fats	0.01*		0	
	PM 0110	Poultry meat	0.01*		0	
	DM1215	Cocoa butter			0.005	
	DM 0715	Cocoa powder			0.005	
Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: <i>mandipropamid</i>						
<i>The residue is not fat-soluble.</i>						
<b>Norflurazon (308)*</b> ADI: 0–0.005 mg/kg bw  ARfD: 0.3 mg/kg bw	AL 1020	Alfalfa fodder	7 (DW)		Median: 3 (as)	Highest: 11 (as)
	MO 0105	Edible offal (Mammalian)	0.3		Liver: 0.065	Liver: 0.22
					Kidney:	Kidney: 0.0012
					0.00038	
	PE 0112	Eggs	0.02 *		0	0
	MM 0100	Mammalian fats (except milk fats)	0.02 *		0.00043	0.0014
	MM 0095	Meat (from mammals other than marine mammals)	0.02 *		muscle:	muscle: 0.004
					0.0012	fat: 0.0014
					fat: 0.00043	
	ML 0106	Milks	0.02 *		0.0014	
	PF 0111	Poultry fat	0.02 *		0	0
	PM 0110	Poultry meat	0.02 *		0	0
	PO 0111	Poultry, Edible offal of	0.02 *		0	0

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 2086	Wheat, Subgroup of (includes all commodities in this subgroup)			0.04	
	GC 2091	Maize cereals, Subgroup of (includes all commodities in this subgroup)			0.04	
	GC 2089	Sorghum grain and Millet, Subgroup of (includes all commodities in this subgroup)			0.04	
	GC 2088	Rice cereals, Subgroup of (includes all commodities in this subgroup)			0.1	
	VL 2050	Leafy greens, Subgroup of (includes all commodities in this subgroup)			0.053	0.53
	VL 0054	Leaves of Brassicaceae, Subgroup of (includes all commodities in this subgroup)			0.096	0.22
	VR 2070	Root vegetables, Subgroup of (includes all commodities in this subgroup)			0.04	0.21
Definition of the residue for compliance with the MRL for plant commodities: <i>Sum of norflurazon and desmethyl norflurazon, expressed as norflurazon</i>						
Definition of the residue for dietary risk assessment for plant commodities: <i>Sum of norflurazon and desmethyl norflurazon (free and conjugated), expressed as norflurazon</i>						
Definition of the residue for compliance with the MRL for animal commodities: <i>Sum of norflurazon and desmethyl norflurazon (free and conjugated), expressed as norflurazon</i>						
Definition of the residue for dietary risk assessment for animal commodities: <i>Sum of desmethyl norflurazon (free and conjugated) and 6-methyl sulfoxide norflurazon, expressed as norflurazon</i>						
<i>The residue is not fat-soluble.</i>						
(as) – as received						
<b>Oxathiapiprolin (291)</b>  ADI: 0–4 mg/kg bw  ARfD: Unnecessary	HH 0722	Basil (fresh)	10		3.08	
	DH 0722	Basil, dry	80		27.33	
	FB 2005	Cane berries, Subgroup of (includes all commodities in this subgroup)	0.5		0.056	
	FC 0001	Citrus fruit, Group of (includes all commodities in this group)	0.05		0.056	
	OR 0004	Citrus oil, edible	3		1.5	
	AB 0001	Citrus pulp, dry	0.15		0.10	
	MO 0105	Edible offal (mammalian)	W	0.01*		
	PE 0112	Eggs	0.01*	0.01*	0	
	VL 0054	Leaves of Brassicaceae, Subgroup of (includes all	10		3.28	

[illegible]



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>Propamocarb (148)</b>	MO 0105	Edible offal (Mammalian)	1.5	0.01*	0.45	1.2
ADI: 0–0.4 mg/kg bw	MF 0100	Mammalian fats (except milk fats)	0.03	-	0.016	0.021
ARfD: 2 mg/kg bw	MM 0095	Meat from mammals (other than marine mammals)	0.03	0.01*	Muscle: 0.016	Muscle: 0.023
	ML 0106	Milks	0.01*	0.01*	0	
Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: <i>Propamocarb</i> .						
<i>The residue is not fat-soluble.</i>						
<b>Propiconazole (160)</b>	FS 0013	Cherries, Subgroup of (including all commodities in this subgroup)	3 Po	3 Po	1.0	1.8
ADI: 0–0.07 mg/kg bw	FC 0002	Lemons and Limes (including Citron) Subgroup of (including all commodities in this subgroup)	10 Po	15 Po	0.22	0.43
ARfD: 0.3 mg/kg bw	FC 0003	Mandarins (including Mandarin-like hybrids) Subgroup of (including all commodities in this subgroup)	10 Po	15 Po	0.22	0.43
	OR 0001	Orange oil	1850	2800	777	
	FC 0004	Oranges, Sweet, Sour (including orange-like hybrids) Subgroup of (including all commodities in this subgroup)	10 Po	15 Po	0.22	0.43
	FS 0247	Peach	0.7 Po	1.5 Po	0.59	0.60
	FS 0353	Pineapple	2 Po	4 Po	0.16	0.19
	FS 0014	Plums, Subgroup of (includes all commodities in this subgroup)	0.4 Po	0.5 Po	0.15	0.23
	FC 0005	Pumelo and grapefruit (including Shaddock-like hybrids) Subgroup of (including all commodities in this subgroup)	4 Po	6 Po	0.11	0.16
Definition of the residue for compliance with the MRL for plant and animal commodities: <i>propiconazole</i> .						
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> .						
<i>The residue is fat-soluble</i>						
<b>Pydiflumetofen (309)*</b>	DF 0269	Dried grapes (= Currants, Raisins and Sultanas)	4	-	0.71	2.1
ADI: 0–0.1 mg/kg bw	FB 2008	Small fruit vine climbing, Subgroup of (includes all commodities in this subgroup)	1.5	-	0.29	0.85

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		
ARfD: 0.3 mg/kg bw						
	JF 0269	Grape juice			0.017	
		Grape must			0.31	
		Grape seed oil, refined			0.30	
		Red wine			0.039	
		White wine			0.091	
Definition of the residue for compliance with the MRL and dietary risk assessment for plant commodities: <i>Pydiflumetofen</i>						
Definition of the residue for compliance with the MRL for animal commodities: <i>Pydiflumetofen</i>						
Definition of the residue for dietary risk assessment for animal commodities other than mammalian liver and kidney: <i>Sum of pydiflumetofen and 2,4,6-trichlorophenol (2,4,6-TCP) and its conjugates, expressed as pydiflumetofen</i>						
Definition of the residue for dietary risk assessment for mammalian liver and kidney: <i>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</i>						
<i>The residue is fat-soluble</i>						
<b>Pyraclostrobin (210)</b>	FP 0226	Apple	W	0.5		
ADI: 0–0.03 mg/kg bw	VS 0621	Asparagus	0.01*	-	0.01	0.01
ARfD: 0.7 mg/kg bw	FI 0326	Avocado	0.2	-	0.053	0.104
	VP 2060	Beans with pods, subgroup of, except common bean	0.3	-	0.07	0.11
	VP 0523	Broad bean, without pods (succulent seeds)	0.01	-	0.01	0.01
	SB 0715	Cacao beans	0.01	-	0.01	-
	VR 0577	Carrot	W	0.5		
	VS 0624	Celery	1.5	-	0.15	0.61
	VP 0526	Common bean	0.6	-	0.13	0.37
	VP 2845	Common beans (succulent seeds)	0.3	-	0.01	0.27
	VD 2066	Dry peas, Subgroup of (includes all commodities in this subgroup)	0.3	-	0.059	-
	MO 0105	Edible offal (Mammalian)	0.05	0.05*	0.015	0.044
	VL 0482	Lettuce, head	40	2	9.33	19.7
	MF 0100	Mammalian fats (except milk fats)	0.5	-	0.166	0.48
	MM 0095	Meat (from mammals other than marine mammals)	0.5 (fat)	0.5 (fat)	Muscle: 0.0181 Fat: 0.166	Muscle: 0.052 Fat: 0.48
	FI 0345	Mango	0.6	0.05*	0.11	0.35
	ML 0106	Milks	0.03	0.03	0.0095	-
	SO 0305	Olives for oil production	0.01	-	0.01	0.01
	OC 0305	Olive oil, Virgin	0.07	-	0.062	-
	VP 2061	Peas with pods, Subgroup of	0.3	-	0.075	0.12
	VP0063	Peas (pods and succulent=immature seeds)	W	0.02*		
	FI 0351	Passion fruit	0.2	-	0.045	0.1
	FI 0353	Pineapple	0.3	-	0.002	0.002

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			
	FP 0009	Pome fruits (includes all commodities in this group)	0.7	-	0.12	0.69	
	VR 0589	Potato	W	0.02*			
	VR 0494	Radish	W	0.5			
	GC 0649	Rice	1.5	-	0.195	-	
	CM 0649	Rice, Husked	0.09	-	0.02	-	
	CM 1205	Rice, Polished	0.03	-	0.01	-	
	AS 0649	Rice straw and fodder, dry	5 (dw)	-	Median: 0.856 (as)	Highest: 2.65 (as)	
	VR 2070	Root vegetables, Subgroup of (includes all commodities in this subgroup)	0.5	-	0.12	0.3	
	VL 0502	Spinach	1.5	-	0.09	0.91	
	VP 2063	Succulent peas without pods, Subgroup of (includes all commodities in this subgroup)	0.08	-	0.01	0.07	
	GS 0659	Sugar cane	0.08	-	0.0265	0.045	
	FT 0305	Table olives	0.01	-	0.01	0.01	
	DT 1114	Tea, Green, Black (black, fermented and dried)	6	-	0.965	-	
	VR 2071	Tuberous and corm vegetables, subgroup of (includes all commodities in this subgroup)	0.02*	-	0	0	
	VL 2832	Witloof chicory (leaves/sprouts)	0.09	-	0.029	0.04	
	CM 1206	Cooked spinach			0.07	0.72	
		Rice Bran, Unprocessed			0.14		
		Rice flour			0.004		
		Refined sugar			0.0025		
		Tea infusion			0.0009		
	Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: <i>Pyraclostrobin</i> .						
	<i>The residue is fat-soluble.</i> (as) as received						
<b>Pyriofenone (310)*</b>	FB 0264	Cane berries, Subgroup of (includes all commodities in this subgroup)	0.9		0.265		
ADI: 0–0.09 mg/kg bw	FB 2006	Bush berries, Subgroup of (includes all commodities in this subgroup)	1.5		0.34		
ARfD: Unnecessary	DF 0226	Dried grapes (=Currants, Raisins and Sultanas)	2.5		0.64		
	VC 0045	Fruiting vegetables, Cucurbits, Group of (includes all commodities in this group)	0.2		0.04		
	FB 2009	Low growing berries, Subgroup of (includes all commodities in	0.5		0.17		

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		
		this subgroup)				
	FB 2008	Small fruit vine climbing, Subgroup of (includes all commodities in this subgroup)	0.8		0.23	
	JF 0269	Grape juice			0.014	
		Grape must			0.10	
		Grape wine			0.032	
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>	VC 0424	Cucumbers	0.04		0.01	
ADI: 0–0.1 mg/kg bw	VO 0440	Eggplant	0.6		0.17	
ARfD: Unnecessary	VC 0425	Gherkins	0.04		0.01	
	VC 0046	Melons, except Watermelon	0.07		0.016	
	FI 0350	Papaya	0.3		0.07	
	VO 0051	Peppers	0.6		0.17	
	HS 0444	Peppers chili, dried	6		1.7	
	FI 0353	Pineapple	0.01		0.01	
	VC 0431	Summer squash	0.04		0.01	
	VO 0448	Tomato	0.4		0.1	
		Canned pepper			0.014	
		Canned tomato			0.018	
		Ketchup			0.067	
		Tomato Juice			0.018	
		Tomato Purée			0.12	
Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: <i>pyriproxyfen</i>						
<i>The residue is fat-soluble.</i>						
<b>Sulfoxaflor (252)</b>	MO 0105	Edible offal (Mammalian)	1	0.6	Liver: 0.44 Kidney: 0.28	Liver: 0.95 Kidney: 0.68
ADI: 0–0.05 mg/kg bw	GC 0645	Maize	0.01*		0.007	
ARfD: 0.3 mg/kg bw	AS 0645	Maize fodder (dry)	0.6	-	Median: 0.16 (as)	Highest: 0.38 (as)
	MF 0100	Mammalian fats	0.2	0.1	0.06	0.19
	MM 0095	Meat (mammalian except marine mammals)	0.4	0.3	0.16 muscle 0.06 fat	0.39 muscle 0.19 fat
	ML 0106	Milks	0.3	0.2	0.14	-
	PM 0110	Poultry meat	0.7	0.1	0.64	0.64
	GC 0649	Rice	7		1.95	
	CM 1205	Rice, polished	1		0.27	
	CM 0649	Rice, husked	1.5		0.39	
	AS 0649	Rice straw and fodder (dry)	20	-	Median 1.5 (as)	Highest: 10.4 (as)
	GC 0651	Sorghum	0.2		0.03	
	AS 0651	Sorghum straw and fodder (dry)	0.7	-	Median 0.14 (as)	Highest: 0.43 (as)

[illegible]



## Annex 2: Index of reports and evaluations of pesticides by the JMPR

Numbers in parentheses after the names of pesticides are Codex classification numbers. The abbreviations used are:

T, evaluation of toxicology

R, evaluation of residue and analytical aspects

E, evaluation of effects on the environment

Abamectin (177)	1992 (T,R), 1994 (T,R), 1995 (T), 1997 (T,R), 2000 (R), 2015 (R), 2017 (T), 2018 (R)
Acephate (095)	1976 (T,R), 1979 (R), 1981 (R), 1982 (T), 1984 (T,R), 1987 (T), 1988 (T), 1990 (T,R), 1991 (corr. to 1990 R evaluation), 1994 (R), 1996 (R), 2002 (T), 2003 (R), 2004 (corr. to 2003 report), 2005 (T), 2006 (R), 2011 (R)
Acetamiprid (246)	2011 (T,R), 2012 (R), 2015 (R), 2017 (R)
Acetochlor (280)	2015 (T,R)
Acibenzolar-S-methyl (288)	2016 (T,R)
Acrylonitrile	1965 (T,R)
Aldicarb (117)	1979 (T,R), 1982 (T,R), 1985 (R), 1988 (R), 1990 (R), 1991 (corr. to 1990 evaluation), 1992 (T), 1993 (R), 1994 (R), 1996 (R), 2001 (R), 2002 (R), 2006 (R)
Aldrin (001)	1965 (T), 1966 (T,R), 1967 (R), 1974 (R), 1975 (R), 1977 (T), 1990 (R), 1992 (R)
Allethrin	1965 (T,R)
Ametoctradin (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)
Atrazine2007 (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)
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)
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)
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)
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)
sec-Butylamine (089)	1975 (T,R), 1977 (R), 1978 (T,R), 1979 (R), 1980 (R), 1981 (T), 1984 (T,R: withdrawal of temporary ADI, but no evaluation)



Cadusafos (174)	1991 (T,R), 1992 (R), 1992 (R), 2009 (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)
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)
Chlorbenside	1965 (T)
Chlordane (012)	1965 (T), 1967 (T,R), 1969 (R), 1970 (T,R), 1972 (R), 1974 (R), 1977 (T,R), 1982 (T), 1984 (T,R), 1986 (T)
Chlordimeform (013)	1971 (T,R), 1975 (T,R), 1977 (T), 1978 (T,R), 1979 (T), 1980 (T), 1985 (T), 1986 (R), 1987 (T)
Chlorfenapyr (254)	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)
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)
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)
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)
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)
Cyromazine (169)	1990 (T,R), 1991 (corr. to 1990 R evaluation), 1992 (R), 2006 (T), 2007 (R), 2012 (R)
2,4-D (020)	1970 (T,R), 1971 (T,R), 1974 (T,R), 1975 (T,R), 1980 (R), 1985 (R), 1986 (R), 1987 (corr. to 1986 report, Annex I), 1996 (T), 1997 (E), 1998 (R), 2001 (R), 2017 (R)
Daminozide (104)	1977 (T,R), 1983 (T), 1989 (T,R), 1991 (T)
DDT (021)	1965 (T), 1966 (T,R), 1967 (T,R), 1968 (T,R), 1969 (T,R), 1978 (R), 1979 (T), 1980 (T), 1983 (T), 1984 (T), 1993 (R), 1994 (R), 1996 (R)
Deltamethrin (135)	1980 (T,R), 1981 (T,R), 1982 (T,R), 1984 (R), 1985 (R), 1986 (R), 1987 (R), 1988 (R), 1990 (R), 1992 (R), 2000 (T), 2002 (R), 2016 (R)
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)
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)
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)
Eamectin 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)
Etrifos (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)
Fenazaquin (297)	2017 (T, 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)
Flonicamid (282)	2015 (T,R), 2016 (R), 2017 (R)
Fluazifop-P-butyl	2016 (T,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)
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)
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)
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)
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)
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)
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)
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,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)
Metaflumizone (236)	2009 (T,R)



Metalaxyl (138)	1982 (T,R), 1984 (R), 1985 (R), 1986 (R), 1987 (R), 1989 (R), 1990 (R), 1992 (R), 1995 (R)
Metalaxyl –M (212)	2002 (T), 2004 (R)
Methacrifos (125)	1980 (T,R), 1982 (T), 1986 (T), 1988 (T), 1990 (T,R), 1992 (R)
Methamidophos (100)	1976 (T,R), 1979 (R), 1981 (R), 1982 (T,R), 1984 (R), 1985 (T), 1989 (R), 1990 (T,R), 1994 (R), 1996 (R), 1997 (R), 2002 (T), 2003 (R), 2004 (R, corr. to 2003 report)
Methidathion (051)	1972 (T,R), 1975 (T,R), 1979 (R), 1992 (T,R), 1994 (R), 1997 (T)
Methiocarb (132)	1981 (T,R), 1983 (T,R), 1984 (T), 1985 (T), 1986 (R), 1987 (T,R), 1988 (R), 1998 (T), 1999 (R), 2005 (R)
Methomyl (094)	1975 (R), 1976 (R), 1977 (R), 1978 (R), 1986 (T,R), 1987 (R), 1988 (R), 1989 (T,R), 1990 (R), 1991 (R), 2001 (T,R), 2004 (R), 2008 (R)
Methoprene (147)	1984 (T,R), 1986 (R), 1987 (T and corr. to 1986 report), 1988 (R), 1989 (R), 2001 (T), 2005 (R), 2016 (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)
Penthiopyrad (253)	2011 (T), 2012 (R), 2013 (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)
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)
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)
Pymetrozine (279)	2014 (T,R)
Pyraclostrobin (210)	2003 (T), 2004 (R), 2006 (R), 2011 (R), 2012 (R), 2014 (R), 2018 (T,R)
Pyrazophos (153)	1985 (T,R), 1987 (R), 1992 (T,R), 1993 (R)

Pyrethrins (063)	1965 (T), 1966 (T,R), 1967 (R), 1968 (R), 1969 (R), 1970 (T), 1972 (T,R), 1974 (R), 1999 (T), 2000 (R), 2003 (T,R), 2005 (R)
Pyrimethanil (226)	2007 (T,R), 2013 (R)
Pyriofenone (310)	2018 (T,R)
Pyriproxyfen (200)	1999 (R,T), 2000 (R), 2001 (T), 2018 (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)
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)
Tebufozide (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)
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)
Tolfenpyrad (269)	2013 (T), 2016 (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)
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
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

ABAMECTIN (177)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.001 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	0.005	34.91	0.17	16.51	0.08	17.23	0.09	104.48	0.52	35.57	0.18	98.49	0.49
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.002	19.79	0.04	38.25	0.08	17.96	0.04	32.56	0.07	8.08	0.02	64.45	0.13
FS 0013	Subgroup of Cherries, raw	RAC	0.009	0.92	0.01	9.15	0.08	0.10	0.00	0.61	0.01	0.10	0.00	6.64	0.06
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.002	2.67	0.01	8.77	0.02	0.10	0.00	3.03	0.01	0.70	0.00	4.34	0.01
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.004	8.01	0.03	5.87	0.02	0.18	0.00	8.19	0.03	1.64	0.01	22.46	0.09
FB 2005	Subgroup of Caneberries, raw	RAC	0.018	0.42	0.01	1.05	0.02	0.10	0.00	0.10	0.00	0.10	0.00	1.24	0.02
FB 0269	Grapes, raw (incl must, incl dried, incl wine, excl juice)	RAC	0.0021	16.07	0.03	28.60	0.06	2.81	0.01	23.85	0.05	9.03	0.02	68.58	0.14
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.0059	0.51	0.00	0.51	0.00	0.10	0.00	1.27	0.01	0.12	0.00	2.07	0.01
JF 0269	Grape juice (from wine grapes)	PP	0.0029	0.14	0.00	0.29	0.00	0.10	0.00	0.30	0.00	0.24	0.00	0.10	0.00
FB 0275	Strawberry, raw	RAC	0.027	0.70	0.02	2.01	0.05	0.10	0.00	1.36	0.04	0.37	0.01	2.53	0.07
FI 0326	Avocado, raw	RAC	0.004	0.13	0.00	0.10	0.00	2.05	0.01	2.54	0.01	2.34	0.01	0.12	0.00
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.002	10.48	0.02	0.10	0.00	7.24	0.01	6.87	0.01	19.98	0.04	6.25	0.01
FI 0350	Papaya, raw	RAC	0	0.35	0.00	0.10	0.00	3.05	0.00	0.80	0.00	7.28	0.00	1.00	0.00
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0	0.61	0.00	1.56	0.00	7.89	0.00	9.36	0.00	8.76	0.00	1.30	0.00
VA 2031	Subgroup of bulb onions	RAC	0.002	31.65	0.06	43.28	0.09	3.68	0.01	38.48	0.08	20.46	0.04	47.29	0.09
VA 0381	Garlic, raw	RAC	0.002	2.29	0.00	5.78	0.01	0.11	0.00	3.69	0.01	1.65	0.00	3.91	0.01
VA 2032	Subgroup of Green Onions	RAC	0.002	2.64	0.01	3.09	0.01	1.05	0.00	2.89	0.01	0.61	0.00	5.24	0.01
VC 0424	Cucumber, raw	RAC	0.002	8.01	0.02	30.66	0.06	1.45	0.00	19.84	0.04	0.27	0.00	34.92	0.07
VC 0425	Gherkin, raw	RAC	0.002	1.73	0.00	6.64	0.01	0.31	0.00	4.29	0.01	0.29	0.00	7.56	0.02
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.002	8.90	0.02	8.64	0.02	0.80	0.00	17.90	0.04	2.80	0.01	29.17	0.06
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.004	51.75	0.21	81.80	0.33	16.99	0.07	102.02	0.41	26.32	0.11	214.77	0.86
-	Peppers, chili, dried	PP	0.005	0.42	0.00	0.53	0.00	0.84	0.00	0.50	0.00	0.95	0.00	0.37	0.00
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.009	4.49	0.04	6.44	0.06	7.21	0.06	5.68	0.05	9.52	0.09	8.92	0.08
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.004	5.58	0.02	4.31	0.02	0.89	0.00	9.31	0.04	13.64	0.05	20.12	0.08
VL 0502	Spinach, raw	RAC	0.024	0.74	0.02	0.22	0.01	0.10	0.00	0.91	0.02	0.10	0.00	2.92	0.07
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.007	0.68	0.00	NC	-	NC	-	0.39	0.00	0.22	0.00	0.49	0.00

**ABAMECTIN (177)**

## International Estimated Daily Intake (IEDI)

ADI = 0 - 0.001 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
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.002	5.07	0.01	1.02	0.00	0.49	0.00	1.78	0.00	1.19	0.00	8.57	0.02
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.002	2.39	0.00	1.61	0.00	10.47	0.02	1.84	0.00	12.90	0.03	7.44	0.01
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.002	72.79	0.15	59.05	0.12	20.55	0.04	74.20	0.15	61.12	0.12	73.24	0.15
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
VR 0508	Sweet potato, raw (incl dried)	RAC	0	0.18	0.00	0.18	0.00	42.16	0.00	1.61	0.00	3.06	0.00	6.67	0.00
VR 0600	Yams, raw (incl dried)	RAC	0	0.10	0.00	NC	-	90.40	0.00	6.45	0.00	0.74	0.00	0.65	0.00
VS 0624	Celery	RAC	0.005	2.14	0.01	3.79	0.02	2.35	0.01	5.69	0.03	0.10	0.00	2.75	0.01
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0.001	45.40	0.05	14.99	0.01	84.88	0.08	111.73	0.11	194.75	0.19	93.12	0.09
GC 2090	Subgroup of Sweet Corns	RAC	0.002	0.14	0.00	0.94	0.00	5.70	0.01	2.61	0.01	1.94	0.00	0.22	0.00
TN 0085	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 0691	Cotton seed, raw (incl oil)	RAC	0.002	20.53	0.04	9.80	0.02	6.42	0.01	4.73	0.01	7.14	0.01	18.68	0.04
OR 0691	Cotton seed oil, edible	PP	0	3.22	0.00	1.54	0.00	1.01	0.00	0.74	0.00	1.12	0.00	2.93	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0	1.30	0.00	1.23	0.00	12.62	0.00	2.87	0.00	6.59	0.00	2.67	0.00
HH 0720	Herbs, raw (incl dried)	RAC	0.003	1.69	0.01	1.91	0.01	1.18	0.00	3.35	0.01	0.55	0.00	1.64	0.00
DH 1100	Hops, dry	RAC	0.038	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	NC	-	0.10	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (µg//person)=				1.0		1.2		0.5		1.8		1.0		2.7	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (µg/person)=				60		60		60		60		60		60	
%ADI=				1.7%		2.0%		0.8%		3.0%		1.6%		4.5%	
Rounded %ADI=				2%		2%		1%		3%		2%		5%	



**ABAMECTIN (177)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.001 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	0.005	114.42	0.57	62.91	0.31	26.97	0.13	96.72	0.48	96.22	0.48	563.19	2.82
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.002	71.38	0.14	81.73	0.16	42.91	0.09	58.89	0.12	103.85	0.21	12.48	0.02
FS 0013	Subgroup of Cherries, raw	RAC	0.009	1.40	0.01	4.21	0.04	0.10	0.00	2.93	0.03	1.50	0.01	NC	-
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.002	5.55	0.01	4.37	0.01	6.08	0.01	3.66	0.01	3.93	0.01	0.46	0.00
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.004	13.03	0.05	16.29	0.07	8.29	0.03	12.95	0.05	5.35	0.02	0.10	0.00
FB 2005	Subgroup of Caneberries, raw	RAC	0.018	0.56	0.01	1.43	0.03	0.14	0.00	1.23	0.02	1.14	0.02	0.10	0.00
FB 0269	Grapes, raw (incl must, incl dried, incl wine, excl juice)	RAC	0.0021	141.53	0.30	103.35	0.22	7.85	0.02	49.67	0.10	106.42	0.22	10.53	0.02
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.0059	3.09	0.02	1.51	0.01	0.10	0.00	1.38	0.01	4.26	0.03	0.42	0.00
JF 0269	Grape juice (from wine grapes)	PP	0.0029	0.56	0.00	1.96	0.01	0.10	0.00	2.24	0.01	2.27	0.01	0.34	0.00
FB 0275	Strawberry, raw	RAC	0.027	4.49	0.12	5.66	0.15	0.10	0.00	6.63	0.18	5.75	0.16	0.10	0.00
FI 0326	Avocado, raw	RAC	0.004	2.65	0.01	0.87	0.00	0.46	0.00	1.64	0.01	1.30	0.01	0.96	0.00
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.002	1.80	0.00	0.63	0.00	10.05	0.02	1.07	0.00	3.52	0.01	16.44	0.03
FI 0350	Papaya, raw	RAC	0	0.31	0.00	0.18	0.00	1.50	0.00	0.51	0.00	0.54	0.00	1.08	0.00
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0	13.13	0.00	11.13	0.00	6.94	0.00	14.36	0.00	36.74	0.00	18.81	0.00
VA 2031	Subgroup of bulb onions	RAC	0.002	20.67	0.04	31.32	0.06	37.52	0.08	35.08	0.07	11.77	0.02	13.74	0.03
VA 0381	Garlic, raw	RAC	0.002	0.98	0.00	1.49	0.00	12.88	0.03	3.74	0.01	2.05	0.00	1.14	0.00
VA 2032	Subgroup of Green Onions	RAC	0.002	5.57	0.01	5.15	0.01	1.77	0.00	4.28	0.01	17.34	0.03	6.48	0.01
VC 0424	Cucumber, raw	RAC	0.002	6.72	0.01	11.03	0.02	32.10	0.06	15.10	0.03	4.05	0.01	9.57	0.02
VC 0425	Gherkin, raw	RAC	0.002	0.41	0.00	5.89	0.01	NC	-	0.10	0.00	0.37	0.00	2.07	0.00
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.002	9.20	0.02	11.95	0.02	14.63	0.03	8.99	0.02	7.86	0.02	2.46	0.00
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.004	64.74	0.26	68.31	0.27	36.05	0.14	82.09	0.33	54.50	0.22	11.69	0.05
-	Peppers, chili, dried	PP	0.005	0.11	0.00	0.21	0.00	0.36	0.00	0.21	0.00	0.25	0.00	0.15	0.00
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.009	0.82	0.01	1.53	0.01	10.85	0.10	4.59	0.04	1.84	0.02	2.00	0.02
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.004	1.01	0.00	1.69	0.01	21.37	0.09	3.00	0.01	1.40	0.01	NC	-
VL 0502	Spinach, raw	RAC	0.024	2.20	0.05	1.76	0.04	13.38	0.32	2.94	0.07	5.53	0.13	0.10	0.00
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.007	5.07	0.04	0.83	0.01	0.17	0.00	3.70	0.03	NC	-	NC	-
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.002	2.42	0.00	6.09	0.01	4.33	0.01	2.09	0.00	18.99	0.04	0.17	0.00

**ABAMECTIN (177)**

## International Estimated Daily Intake (IEDI)

ADI = 0 - 0.001 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	0.002	1.51	0.00	1.50	0.00	1.90	0.00	5.11	0.01	1.36	0.00	23.43	0.05
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.002	106.33	0.21	117.78	0.24	42.12	0.08	195.70	0.39	222.52	0.45	80.47	0.16
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
VR 0508	Sweet potato, raw (incl dried)	RAC	0	0.93	0.00	0.32	0.00	64.65	0.00	5.37	0.00	0.30	0.00	3.13	0.00
VR 0600	Yams, raw (incl dried)	RAC	0	NC	-	NC	-	0.10	0.00	0.71	0.00	NC	-	17.57	0.00
VS 0624	Celery	RAC	0.005	7.68	0.04	2.85	0.01	NC	-	3.34	0.02	16.83	0.08	4.04	0.02
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0.001	20.96	0.02	16.04	0.02	339.67	0.34	75.51	0.08	16.86	0.02	86.13	0.09
GC 2090	Subgroup of Sweet Corns	RAC	0.002	11.43	0.02	3.71	0.01	0.74	0.00	13.63	0.03	3.07	0.01	1.50	0.00
TN 0085	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 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
OR 0691	Cotton seed oil, edible	PP	0	1.68	0.00	0.66	0.00	1.13	0.00	1.18	0.00	0.89	0.00	0.37	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0	5.63	0.00	2.75	0.00	9.58	0.00	5.82	0.00	13.71	0.00	1.84	0.00
HH 0720	Herbs, raw (incl dried)	RAC	0.003	2.61	0.01	2.31	0.01	8.89	0.03	3.92	0.01	1.16	0.00	2.06	0.01
DH 1100	Hops, dry	RAC	0.038	NC	-	NC	-	0.10	0.00	0.10	0.00	NC	-	NC	-
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Total intake (µg//person)=	2.0	1.8	1.6	2.2	2.2	3.4
Bodyweight per region (kg bw) =	60	60	55	60	60	60
ADI (µg//person)=	60	60	55	60	60	60
%ADI=	3.4%	3.0%	3.0%	3.6%	3.7%	5.6%
Rounded %ADI=	3%	3%	3%	4%	4%	6%

## ABAMECTIN (177)

## International Estimated Daily Intake (IEDI)

ADI = 0 - 0.001 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	0.005	21.16	0.11	2.94	0.01	58.52	0.29	0.44	0.00	5.13	0.03
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.002	68.89	0.14	11.06	0.02	80.62	0.16	189.82	0.38	19.56	0.04
FS 0013	Subgroup of Cherries, raw	RAC	0.009	0.10	0.00	0.10	0.00	5.96	0.05	0.10	0.00	NC	-
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.002	0.10	0.00	0.10	0.00	16.65	0.03	0.10	0.00	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.004	0.10	0.00	0.10	0.00	10.76	0.04	0.10	0.00	NC	-
FB 2005	Subgroup of Caneberries, raw	RAC	0.018	0.10	0.00	7.30	0.13	2.29	0.04	0.10	0.00	NC	-
FB 0269	Grapes, raw (incl must, incl dried, incl wine, excl juice)	RAC	0.0021	0.59	0.00	1.24	0.00	102.74	0.22	0.74	0.00	44.23	0.09
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.0059	0.10	0.00	0.13	0.00	1.06	0.01	0.10	0.00	0.10	0.00
JF 0269	Grape juice (from wine grapes)	PP	0.0029	0.10	0.00	0.10	0.00	0.41	0.00	0.10	0.00	NC	-
FB 0275	Strawberry, raw	RAC	0.027	0.10	0.00	0.10	0.00	3.35	0.09	0.10	0.00	0.10	0.00
FI 0326	Avocado, raw	RAC	0.004	1.12	0.00	0.10	0.00	0.84	0.00	0.10	0.00	6.60	0.03
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.002	12.25	0.02	6.83	0.01	0.76	0.00	0.10	0.00	20.12	0.04
FI 0350	Papaya, raw	RAC	0	6.47	0.00	0.25	0.00	0.19	0.00	0.10	0.00	26.42	0.00
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0	8.51	0.00	6.27	0.00	6.89	0.00	0.18	0.00	24.94	0.00
VA 2031	Subgroup of bulb onions	RAC	0.002	9.83	0.02	22.30	0.04	34.69	0.07	9.65	0.02	2.39	0.00
VA 0381	Garlic, raw	RAC	0.002	0.82	0.00	2.06	0.00	3.79	0.01	0.10	0.00	0.29	0.00
VA 2032	Subgroup of Green Onions	RAC	0.002	1.45	0.00	1.50	0.00	1.42	0.00	0.10	0.00	6.30	0.01
VC 0424	Cucumber, raw	RAC	0.002	0.68	0.00	1.81	0.00	10.40	0.02	0.10	0.00	0.10	0.00
VC 0425	Gherkin, raw	RAC	0.002	0.15	0.00	0.39	0.00	3.15	0.01	0.10	0.00	0.10	0.00
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.002	0.19	0.00	0.10	0.00	4.98	0.01	0.10	0.00	NC	-
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.004	15.50	0.06	5.78	0.02	71.52	0.29	2.00	0.01	12.50	0.05
-	Peppers, chili, dried	PP	0.005	0.58	0.00	1.27	0.01	1.21	0.01	0.12	0.00	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.009	5.49	0.05	10.57	0.10	8.84	0.08	0.91	0.01	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.004	1.31	0.01	8.26	0.03	3.95	0.02	0.10	0.00	NC	-
VL 0502	Spinach, raw	RAC	0.024	0.17	0.00	0.10	0.00	0.81	0.02	0.10	0.00	NC	-
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.007	NC	-	NC	-	NC	-	NC	-	NC	-
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.002	0.37	0.00	3.14	0.01	4.88	0.01	0.10	0.00	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.002	7.11	0.01	2.33	0.00	3.76	0.01	44.70	0.09	3.27	0.01



## BENTAZONE (172)

## 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
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.01	1.56	0.02	0.60	0.01	0.49	0.00	1.18	0.01	0.90	0.01	7.79	0.08
VD 2065	Subgroup of dry beans, raw (incl processed)	RAC	0.09	78.20	7.04	60.68	5.46	35.89	3.23	80.34	7.23	75.90	6.83	87.62	7.89
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.09	2.39	0.22	1.61	0.14	10.47	0.94	1.84	0.17	12.90	1.16	7.44	0.67
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.09	72.79	6.55	59.05	5.31	20.55	1.85	74.20	6.68	61.12	5.50	73.24	6.59
VD 2066	Subgroup of dry peas, raw	RAC	0.09	9.09	0.82	3.35	0.30	1.06	0.10	9.48	0.85	15.11	1.36	10.58	0.95
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 0080	Group of Cereal grains, raw, (incl processed) (incl sweet corn)	RAC	0.01	484.43	4.84	464.63	4.65	262.36	2.62	486.81	4.87	469.62	4.70	614.04	6.14
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
SO 0693	Linseed, raw (incl oil)	RAC	0.02	0.10	0.00	NC	-	NC	-	0.10	0.00	0.13	0.00	NC	-
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0	1.30	0.00	1.23	0.00	12.62	0.00	2.87	0.00	6.59	0.00	2.67	0.00
HH 0720	Herbs, raw (incl dried)	RAC	0.0435	1.69	0.07	1.91	0.08	1.18	0.05	3.35	0.15	0.55	0.02	1.64	0.07
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	31.20	0.00	72.44	0.00	20.88	0.00	47.98	0.00	33.08	0.00	36.25	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	3.29	0.00	6.14	0.00	0.82	0.00	1.57	0.00	2.23	0.00	1.07	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.01	4.79	0.05	9.68	0.10	2.97	0.03	5.49	0.05	3.84	0.04	5.03	0.05
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	289.65	0.00	485.88	0.00	26.92	0.00	239.03	0.00	199.91	0.00	180.53	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	14.63	0.00	29.76	0.00	8.04	0.00	129.68	0.00	25.04	0.00	35.66	0.00
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)=

20.5

19.6

9.0

21.0

20.4

24.1

Bodyweight per region (kg bw) =

60

60

60

60

60

60

ADI (µg/person)=

5400

5400

5400

5400

5400

5400

%ADI=

0.4%

0.4%

0.2%

0.4%

0.4%

0.4%

Rounded %ADI=

0%

0%

0%

0%

0%

0%

**BENTAZONE (172)**

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
-	Onions, dry, raw	RAC	0.01	19.69	0.20	29.83	0.30	24.64	0.25	31.35	0.31	9.72	0.10	12.59	0.13
-	Onions, green, raw	RAC	0.01	1.55	0.02	0.74	0.01	1.05	0.01	3.74	0.04	0.94	0.01	6.45	0.06
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.01	5.07	0.05	0.83	0.01	0.17	0.00	3.70	0.04	NC	-	NC	-
<b>014B</b>	<b>Peas with pods</b>	-	0.05	-	-	-	-	-	-	-	-	-	-	-	-
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.01	2.21	0.02	5.25	0.05	4.17	0.04	1.61	0.02	16.95	0.17	0.17	0.00
VD 2065	Subgroup of dry beans, raw (incl processed)	RAC	0.09	107.87	9.71	119.29	10.74	45.91	4.13	201.31	18.12	224.04	20.16	104.90	9.44
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.09	1.51	0.14	1.50	0.14	1.90	0.17	5.11	0.46	1.36	0.12	23.43	2.11
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.09	106.33	9.57	117.78	10.60	42.12	3.79	195.70	17.61	222.52	20.03	80.47	7.24
VD 2066	Subgroup of dry peas, raw	RAC	0.09	5.01	0.45	3.76	0.34	1.82	0.16	3.44	0.31	3.49	0.31	5.15	0.46
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 0080	Group of Cereal grains, raw, (incl processed) (incl sweet corn)	RAC	0.01	345.63	3.46	386.16	3.86	514.33	5.14	402.72	4.03	295.30	2.95	359.97	3.60
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
SO 0693	Linseed, raw (incl oil)	RAC	0.02	NC	-	NC	-	0.10	0.00	0.10	0.00	NC	-	NC	-
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0	5.63	0.00	2.75	0.00	9.58	0.00	5.82	0.00	13.71	0.00	1.84	0.00
HH 0720	Herbs, raw (incl dried)	RAC	0.0435	2.61	0.11	2.31	0.10	8.89	0.39	3.92	0.17	1.16	0.05	2.06	0.09
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	140.03	0.00	150.89	0.00	79.32	0.00	111.24	0.00	120.30	0.00	51.27	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	6.44	0.00	15.51	0.00	3.79	0.00	8.29	0.00	18.44	0.00	8.00	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.01	15.17	0.15	5.19	0.05	6.30	0.06	6.78	0.07	3.32	0.03	3.17	0.03
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	388.92	0.00	335.88	0.00	49.15	0.00	331.25	0.00	468.56	0.00	245.45	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	73.76	0.00	53.86	0.00	23.98	0.00	87.12	0.00	53.38	0.00	84.45	0.00
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)=	26.2	28.6	14.9	43.1	46.3	23.6
Bodyweight per region (kg bw) =	60	60	55	60	60	60
ADI (µg/person)=	5400	5400	4950	5400	5400	5400
%ADI=	0.5%	0.5%	0.3%	0.8%	0.9%	0.4%

**BENTAZONE (172)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.09 mg/kg bw

		STMR		Diets as g/person/day				Intake as µg/person/day							
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
Rounded %ADI=				0%		1%		0%		1%		1%		0%	

**BENTAZONE (172)**

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
-	Onions, dry, raw	RAC	0.01	9.01	0.09	20.24	0.20	30.90	0.31	9.61	0.10	2.11	0.02
-	Onions, green, raw	RAC	0.01	1.43	0.01	0.10	0.00	0.20	0.00	NC	-	6.30	0.06
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
<b>014B</b>	<b>Peas with pods</b>	-	0.05	-	-	-	-	-	-	-	-	-	-
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.01	0.30	0.00	3.13	0.03	4.11	0.04	0.10	0.00	NC	-
VD 2065	Subgroup of dry beans, raw (incl processed)	RAC	0.09	41.93	3.77	19.42	1.75	108.31	9.75	66.18	5.96	42.47	3.82
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.09	7.11	0.64	2.33	0.21	3.76	0.34	44.70	4.02	3.27	0.29
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.09	15.80	1.42	14.29	1.29	104.36	9.39	17.11	1.54	35.20	3.17
VD 2066	Subgroup of dry peas, raw	RAC	0.09	4.43	0.40	11.36	1.02	4.22	0.38	9.36	0.84	1.21	0.11
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 0080	Group of Cereal grains, raw, (incl processed) (incl sweet corn)	RAC	0.01	407.04	4.07	417.04	4.17	402.79	4.03	195.30	1.95	263.26	2.63
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	0.10	0.00	0.17	0.00
SO 0693	Linseed, raw (incl oil)	RAC	0.02	0.10	0.00	NC	-	0.10	0.00	NC	-	NC	-
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0	18.82	0.00	0.57	0.00	2.28	0.00	6.90	0.00	0.53	0.00
HH 0720	Herbs, raw (incl dried)	RAC	0.0435	1.85	0.08	1.67	0.07	2.80	0.12	1.24	0.05	2.75	0.12
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	29.18	0.00	50.89	0.00	121.44	0.00	22.58	0.00	72.14	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	1.05	0.00	1.14	0.00	18.69	0.00	0.94	0.00	3.12	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.01	4.64	0.05	1.97	0.02	10.01	0.10	3.27	0.03	3.98	0.04
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	108.75	0.00	70.31	0.00	436.11	0.00	61.55	0.00	79.09	0.00

**BENTAZONE (172)**

## 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
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
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)=	10.8	9.1	26.7	15.5	10.4
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (µg/person)=	5400	5400	5400	5400	5400
%ADI=	0.2%	0.2%	0.5%	0.3%	0.2%
Rounded %ADI=	0%	0%	0%	0%	0%

**CHLORFENAPYR (254)**

## International Estimated Daily Intake (IEDI)

ADI = 0 - 0.00 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, excl kumquat commodities)	RAC	0.004	2.46	0.01	2.18	0.01	0.74	0.00	10.99	0.04	7.09	0.03	14.51	0.06
FC 0303	Kumquats, raw (incl juice)	RAC	0.23	2.36	0.54	0.27	0.06	3.19	0.73	14.44	3.32	1.66	0.38	1.71	0.39
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.011	23.26	0.26	9.71	0.11	12.09	0.13	62.02	0.68	22.09	0.24	59.91	0.66
FI 0350	Papaya, raw	RAC	0.072	0.35	0.03	0.10	0.01	3.05	0.22	0.80	0.06	7.28	0.52	1.00	0.07
VA 0381	Garlic, raw	RAC	0.01	2.29	0.02	5.78	0.06	0.11	0.00	3.69	0.04	1.65	0.02	3.91	0.04
-	Onions, dry, raw	RAC	0.01	29.36	0.29	37.50	0.38	3.56	0.04	34.78	0.35	18.81	0.19	43.38	0.43
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
VO 0448	Tomato, raw	RAC	0.065	41.73	2.71	75.65	4.92	10.66	0.69	82.87	5.39	24.75	1.61	200.93	13.06
VO 0444	Peppers, chili, raw	RAC	0.05	3.99	0.20	7.30	0.37	2.93	0.15	5.62	0.28	NC	-	17.44	0.87
-	Peppers, chili, dried	PP	0.5	0.42	0.21	0.53	0.27	0.84	0.42	0.50	0.25	0.95	0.48	0.37	0.19
VO 0445	Peppers, sweet, raw	RAC	0.05	1.43	0.07	2.61	0.13	1.05	0.05	2.01	0.10	2.59	0.13	6.24	0.31
-	Peppers, sweet, dried	PP	0.5	0.42	0.21	0.53	0.27	0.84	0.42	0.50	0.25	0.95	0.48	0.37	0.19
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
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
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	12	2.28	27.36	1.98	23.76	0.46	5.52	2.43	29.16	1.29	15.48	3.04	36.48



**CHLORFENAPYR (254)**

## International Estimated Daily Intake (IEDI)

ADI = 0 - 000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as 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) -80% as muscle	RAC	0.026	24.96	0.65	57.95	1.51	16.70	0.43	38.38	1.00	26.46	0.69	29.00	0.75
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	1	6.24	6.24	14.49	14.49	4.18	4.18	9.60	9.60	6.62	6.62	7.25	7.25
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	1	3.29	3.29	6.14	6.14	0.82	0.82	1.57	1.57	2.23	2.23	1.07	1.07
MO 0105	Edible offal (mammalian), raw	RAC	0.54	4.79	2.59	9.68	5.23	2.97	1.60	5.49	2.96	3.84	2.07	5.03	2.72
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.043	289.65	12.45	485.88	20.89	26.92	1.16	239.03	10.28	199.91	8.60	180.53	7.76
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.003	13.17	0.04	26.78	0.08	7.24	0.02	116.71	0.35	22.54	0.07	32.09	0.10
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.008	1.46	0.01	2.98	0.02	0.80	0.01	12.97	0.10	2.50	0.02	3.57	0.03
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.008	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	0.025	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	0.02	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)=	58.8	83.0	17.0	67.7	41.2	74.9
Bodyweight per region (kg bw) =	60	60	60	60	60	60
ADI (µg//person)=	1800	1800	1800	1800	1800	1800
%ADI=	3.3%	4.6%	0.9%	3.8%	2.3%	4.2%
Rounded %ADI=	3%	5%	1%	4%	2%	4%

**CHLORFENAPYR (254)**

## International Estimated Daily Intake (IEDI)

ADI = 0 - 000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as 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, excl kumquat commodities)	RAC	0.004	5.45	0.02	9.83	0.04	0.92	0.00	10.85	0.04	5.27	0.02	5.23	0.02
FC 0303	Kumquats, raw (incl juice)	RAC	0.23	4.67	1.07	5.86	1.35	1.96	0.45	1.45	0.33	17.05	3.92	1.37	0.32
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.011	83.66	0.92	27.64	0.30	7.37	0.08	67.80	0.75	43.97	0.48	187.74	2.07
FI 0350	Papaya, raw	RAC	0.072	0.31	0.02	0.18	0.01	1.50	0.11	0.51	0.04	0.54	0.04	1.08	0.08
VA 0381	Garlic, raw	RAC	0.01	0.98	0.01	1.49	0.01	12.88	0.13	3.74	0.04	2.05	0.02	1.14	0.01
-	Onions, dry, raw	RAC	0.01	19.69	0.20	29.83	0.30	24.64	0.25	31.35	0.31	9.72	0.10	12.59	0.13
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

CHLORFENAPYR (254)				International Estimated Daily Intake (IEDI)				ADI = 0 - 000 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as 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 0448	Tomato, raw	RAC	0.065	32.13	2.09	51.27	3.33	34.92	2.27	73.37	4.77	15.15	0.98	8.88	0.58
VO 0444	Peppers, chili, raw	RAC	0.05	5.57	0.28	14.00	0.70	8.25	0.41	5.77	0.29	6.44	0.32	2.53	0.13
-	Peppers, chili, dried	PP	0.5	0.11	0.06	0.21	0.11	0.36	0.18	0.21	0.11	0.25	0.13	0.15	0.08
VO 0445	Peppers, sweet, raw	RAC	0.05	NC	-	NC	-	8.25	0.41	3.03	0.15	NC	-	0.91	0.05
-	Peppers, sweet, dried	PP	0.5	0.11	0.06	0.21	0.11	0.36	0.18	0.21	0.11	0.25	0.13	0.15	0.08
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
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
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	12	2.91	34.92	1.73	20.76	1.14	13.68	1.85	22.20	2.29	27.48	0.74	8.88
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.026	112.02	2.91	120.71	3.14	63.46	1.65	88.99	2.31	96.24	2.50	41.02	1.07
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	1	28.01	28.01	30.18	30.18	15.86	15.86	22.25	22.25	24.06	24.06	10.25	10.25
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	1	6.44	6.44	15.51	15.51	3.79	3.79	8.29	8.29	18.44	18.44	8.00	8.00
MO 0105	Edible offal (mammalian), raw	RAC	0.54	15.17	8.19	5.19	2.80	6.30	3.40	6.78	3.66	3.32	1.79	3.17	1.71
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.043	388.92	16.72	335.88	14.44	49.15	2.11	331.25	14.24	468.56	20.15	245.45	10.55
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.003	66.38	0.20	48.47	0.15	21.58	0.06	78.41	0.24	48.04	0.14	76.01	0.23
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.008	7.38	0.06	5.39	0.04	2.40	0.02	8.71	0.07	5.34	0.04	8.45	0.07
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.008	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	0.025	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	0.02	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)=				106.1		97.5		46.9		84.7		106.2		45.7	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (µg//person)=				1800		1800		1650		1800		1800		1800	
%ADI=				5.9%		5.4%		2.8%		4.7%		5.9%		2.5%	
Rounded %ADI=				6%		5%		3%		5%		6%		3%	

**CHLORFENAPYR (254)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 000 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, excl kumquat commodities)	RAC	0.004	0.62	0.00	0.74	0.00	4.44	0.02	0.10	0.00	NC	-
FC 0303	Kumquats, raw (incl juice)	RAC	0.23	18.35	4.22	0.23	0.05	1.78	0.41	0.10	0.02	3.35	0.77
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.011	1.34	0.01	1.65	0.02	40.03	0.44	0.33	0.00	1.76	0.02
FI 0350	Papaya, raw	RAC	0.072	6.47	0.47	0.25	0.02	0.19	0.01	0.10	0.01	26.42	1.90
VA 0381	Garlic, raw	RAC	0.01	0.82	0.01	2.06	0.02	3.79	0.04	0.10	0.00	0.29	0.00
-	Onions, dry, raw	RAC	0.01	9.01	0.09	20.24	0.20	30.90	0.31	9.61	0.10	2.11	0.02
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.01	0.19	0.00	0.10	0.00	4.98	0.05	0.10	0.00	NC	-
VO 0448	Tomato, raw	RAC	0.065	12.99	0.84	4.79	0.31	58.40	3.80	0.92	0.06	0.10	0.01
VO 0444	Peppers, chili, raw	RAC	0.05	3.47	0.17	3.56	0.18	16.30	0.82	0.10	0.01	NC	-
-	Peppers, chili, dried	PP	0.5	0.58	0.29	1.27	0.64	1.21	0.61	0.12	0.06	NC	-
VO 0445	Peppers, sweet, raw	RAC	0.05	1.24	0.06	1.27	0.06	NC	-	0.10	0.01	NC	-
-	Peppers, sweet, dried	PP	0.5	0.58	0.29	1.27	0.64	1.21	0.61	0.12	0.06	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
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
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	12	0.53	6.36	5.25	63.00	0.86	10.32	0.56	6.72	0.88	10.56
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 80% as muscle	RAC	0.026	23.34	0.61	40.71	1.06	97.15	2.53	18.06	0.47	57.71	1.50
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	1	5.84	5.84	10.18	10.18	24.29	24.29	4.52	4.52	14.43	14.43
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	1	1.05	1.05	1.14	1.14	18.69	18.69	0.94	0.94	3.12	3.12
MO 0105	Edible offal (mammalian), raw	RAC	0.54	4.64	2.51	1.97	1.06	10.01	5.41	3.27	1.77	3.98	2.15
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.043	108.75	4.68	70.31	3.02	436.11	18.75	61.55	2.65	79.09	3.40
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.003	3.53	0.01	10.83	0.03	51.36	0.15	4.53	0.01	50.00	0.15
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.008	0.39	0.00	1.20	0.01	5.71	0.05	0.50	0.00	5.56	0.04
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.008	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.025	0.10	0.00	0.70	0.02	0.97	0.02	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.02	3.84	0.08	4.41	0.09	27.25	0.55	1.13	0.02	7.39	0.15
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (µg//person)=				28.0		82.0		91.0		18.6		38.7	

**CHLORFENAPYR (254)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 000 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
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg//person)=				1800		1800		1800		1800		1800
	%ADI=				1.6%		4.6%		5.1%		1.0%		2.1%
	Rounded %ADI=				2%		5%		5%		1%		2%

**CYANTRANILIPROLE (263)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		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	0.041	34.91	1.43	16.51	0.68	17.23	0.71	104.48	4.28	35.57	1.46	98.49	4.04
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.16	19.35	3.10	34.06	5.45	17.87	2.86	25.74	4.12	7.69	1.23	56.85	9.10
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.05	0.32	0.02	3.07	0.15	0.10	0.01	5.00	0.25	0.29	0.01	5.57	0.28
FS 0013	Subgroup of Cherries, raw	RAC	0.93	0.92	0.86	9.15	8.51	0.10	0.09	0.61	0.57	0.10	0.09	6.64	6.18
FS 0014	Subgroup of Plums, raw	RAC	0.07	2.40	0.17	8.60	0.60	0.10	0.01	2.52	0.18	0.58	0.04	4.16	0.29
DF 0014	Plums, dried (prunes)	PP	0.54	0.10	0.05	0.10	0.05	0.10	0.05	0.18	0.10	0.10	0.05	0.10	0.05
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.34	8.01	2.72	5.87	2.00	0.18	0.06	8.19	2.78	1.64	0.56	22.46	7.64
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.75	0.53	0.40	1.31	0.98	0.40	0.30	1.66	1.25	0.10	0.08	0.99	0.74
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.21	12.68	2.66	9.12	1.92	0.10	0.02	16.88	3.54	3.70	0.78	54.42	11.43
JF 0269	Grape juice (from wine grapes)	PP	0.11	0.14	0.02	0.29	0.03	0.10	0.01	0.30	0.03	0.24	0.03	0.10	0.01
-	Graps must (from wine-grapes)	PP	0.32	0.33	0.11	0.13	0.04	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.21	0.67	0.14	12.53	2.63	2.01	0.42	1.21	0.25	3.53	0.74	4.01	0.84
FB 0265	Cranberry, raw	RAC	0.012	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
FB 0275	Strawberry, raw	RAC	0.455	0.70	0.32	2.01	0.91	0.10	0.05	1.36	0.62	0.37	0.17	2.53	1.15
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.01	10.48	0.10	0.10	0.00	7.24	0.07	6.87	0.07	19.98	0.20	6.25	0.06
FI 0355	Pomegranate, raw, (incl processed)	RAC	0.01	3.40	0.03	2.10	0.02	2.65	0.03	10.89	0.11	NC	-	6.67	0.07
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
-	Onions, dry, raw	RAC	0.02	29.36	0.59	37.50	0.75	3.56	0.07	34.78	0.70	18.81	0.38	43.38	0.87
-	Onions, green, raw	RAC	1.3	2.45	3.19	1.49	1.94	1.02	1.33	2.60	3.38	0.60	0.78	2.03	2.64
VB 0040	Group of Brassica vegetables (except Brassica leafy vegetables), raw	RAC	0.56	6.43	3.60	40.26	22.55	0.80	0.45	9.94	5.57	12.07	6.76	17.73	9.93

**CYANTRANILIPROLE (263)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		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
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.065	10.52	0.68	39.36	2.56	2.07	0.13	25.74	1.67	2.80	0.18	44.83	2.91
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.01	42.62	0.43	46.85	0.47	4.21	0.04	67.02	0.67	12.84	0.13	110.47	1.10
VO 0448	Tomato, raw	RAC	0.08	41.73	3.34	75.65	6.05	10.66	0.85	82.87	6.63	24.75	1.98	200.93	16.07
-	Tomato, canned (& peeled)	PP	0.004	0.20	0.00	0.31	0.00	0.10	0.00	1.11	0.00	0.11	0.00	1.50	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.07	2.34	0.16	1.33	0.09	1.57	0.11	4.24	0.30	0.34	0.02	2.83	0.20
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.014	0.29	0.00	0.29	0.00	0.10	0.00	0.38	0.01	0.10	0.00	0.14	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers) (Capsicum spp. Only)	RAC	0.08	8.48	0.68	13.74	1.10	10.13	0.81	11.29	0.90	9.52	0.76	26.36	2.11
-	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
VO 2046	Subgroup of eggplants	RAC	0.08	5.58	0.45	4.31	0.34	0.89	0.07	9.31	0.74	13.64	1.09	20.12	1.61
VL 0053	Group of Leafy vegetables, raw	RAC	4.7	8.47	39.81	22.36	105.09	7.74	36.38	25.51	119.90	45.77	215.12	21.22	99.73
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.29	0.68	0.20	NC	-	NC	-	0.39	0.11	0.22	0.06	0.49	0.14
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.07	5.07	0.35	1.02	0.07	0.49	0.03	1.78	0.12	1.19	0.08	8.57	0.60
VP 2063	Subgroup of succulent peas without pods	RAC	0.07	1.97	0.14	0.51	0.04	0.10	0.01	0.79	0.06	3.68	0.26	3.80	0.27
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.01	2.39	0.02	1.61	0.02	10.47	0.10	1.84	0.02	12.90	0.13	7.44	0.07
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.033	72.79	2.40	59.05	1.95	20.55	0.68	74.20	2.45	61.12	2.02	73.24	2.42
VR 2070	Subgroup of Root vegetables, raw	RAC	0.01	24.72	0.25	57.71	0.58	17.01	0.17	49.58	0.50	9.33	0.09	114.41	1.14
VR 0573	Arrowroot, raw	RAC	0.01	1.53	0.02	0.10	0.00	0.93	0.01	1.33	0.01	0.47	0.00	0.10	0.00
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.01	0.10	0.00	0.10	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	0.10	0.00	0.96	0.01	1.36	0.01	0.48	0.00	0.10	0.00
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.02	59.74	1.19	316.14	6.32	9.78	0.20	60.26	1.21	54.12	1.08	119.82	2.40
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	-	0.10	0.00	0.26	0.00	1.27	0.01
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.01	0.10	0.00	NC	-	25.12	0.25	0.10	0.00	0.10	0.00	0.97	0.01
VR 0600	Yams, raw (incl dried)	RAC	0.01	0.10	0.00	NC	-	90.40	0.90	6.45	0.06	0.74	0.01	0.65	0.01
VR 2072	Subgroup of Aquatic root and tuber vegetables	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-

**CYANTRANILIPROLE (263)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		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
VS 0624	Celery	RAC	2	2.14	4.28	3.79	7.58	2.35	4.70	5.69	11.38	0.10	0.20	2.75	5.50
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	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 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	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 (incl oil)	RAC	0.077	0.93	0.07	1.16	0.09	0.49	0.04	2.53	0.19	9.32	0.72	2.02	0.16
SO 0691	Cotton seed, raw (incl oil)	RAC	0.16	20.53	3.28	9.80	1.57	6.42	1.03	4.73	0.76	7.14	1.14	18.68	2.99
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.067	7.40	0.50	35.86	2.40	1.15	0.08	8.76	0.59	5.45	0.37	13.62	0.91
SB 0716	Coffee beans 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
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.041	24.96	1.02	57.95	2.38	16.70	0.68	38.38	1.57	26.46	1.09	29.00	1.19
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.1	6.24	0.62	14.49	1.45	4.18	0.42	9.60	0.96	6.62	0.66	7.25	0.73
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.1	3.29	0.33	6.14	0.61	0.82	0.08	1.57	0.16	2.23	0.22	1.07	0.11
MO 0105	Edible offal (mammalian), raw	RAC	0.38	4.79	1.82	9.68	3.68	2.97	1.13	5.49	2.09	3.84	1.46	5.03	1.91
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.21	289.65	60.83	485.88	102.03	26.92	5.65	239.03	50.20	199.91	41.98	180.53	37.91
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.0039	13.17	0.05	26.78	0.10	7.24	0.03	116.71	0.46	22.54	0.09	32.09	0.13
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.0083	1.46	0.01	2.98	0.02	0.80	0.01	12.97	0.11	2.50	0.02	3.57	0.03
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0083	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	0.0321	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.17	0.24	0.01	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.0426	7.84	0.33	23.08	0.98	2.88	0.12	14.89	0.63	9.81	0.42	14.83	0.63
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Total intake (µg//person)=	143.6	297.5	68.1	234.2	287.9	239.8
Bodyweight per region (kg bw) =	60	60	60	60	60	60
ADI (µg//person)=	1800	1800	1800	1800	1800	1800
%ADI=	8.0%	16.5%	3.8%	13.0%	16.0%	13.3%
Rounded %ADI=	8%	20%	4%	10%	20%	10%

**CYANTRANILIPROLE (263)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		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	0.041	114.42	4.69	62.91	2.58	26.97	1.11	96.72	3.97	96.22	3.95	563.19	23.09
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.16	51.09	8.17	65.40	10.46	42.71	6.83	45.29	7.25	62.51	10.00	7.74	1.24
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	0.93	1.40	1.30	4.21	3.92	0.10	0.09	2.93	2.72	1.50	1.40	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.07	3.75	0.26	3.33	0.23	5.94	0.42	2.64	0.18	2.50	0.18	0.10	0.01
DF 0014	Plums, dried (prunes)	PP	0.54	0.61	0.33	0.35	0.19	0.10	0.05	0.35	0.19	0.49	0.26	0.13	0.07
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.34	13.03	4.43	16.29	5.54	8.29	2.82	12.95	4.40	5.35	1.82	0.10	0.03
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.75	1.31	0.98	5.50	4.13	0.10	0.08	2.57	1.93	0.82	0.62	2.15	1.61
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.21	6.33	1.33	11.22	2.36	5.21	1.09	9.38	1.97	4.55	0.96	0.78	0.16
JF 0269	Grape juice (from wine grapes)	PP	0.11	0.56	0.06	1.96	0.22	0.10	0.01	2.24	0.25	2.27	0.25	0.34	0.04
-	Graps must (from wine-grapes)	PP	0.32	0.16	0.05	0.10	0.03	0.10	0.03	0.12	0.04	0.11	0.04	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.21	88.93	18.68	62.41	13.11	1.84	0.39	25.07	5.26	61.17	12.85	5.84	1.23
FB 0265	Cranberry, raw	RAC	0.012	0.10	0.00	0.10	0.00	0.10	0.00	1.22	0.01	0.11	0.00	NC	-
FB 0275	Strawberry, raw	RAC	0.455	4.49	2.04	5.66	2.58	0.10	0.05	6.63	3.02	5.75	2.62	0.10	0.05
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 0355	Pomegranate, raw, (incl processed)	RAC	0.01	7.91	0.08	9.72	0.10	7.67	0.08	5.26	0.05	9.04	0.09	14.43	0.14
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
-	Onions, dry, raw	RAC	0.02	19.69	0.39	29.83	0.60	24.64	0.49	31.35	0.63	9.72	0.19	12.59	0.25
-	Onions, green, raw	RAC	1.3	1.55	2.02	0.74	0.96	1.05	1.37	3.74	4.86	0.94	1.22	6.45	8.39
VB 0040	Group of Brassica vegetables (except Brassica leafy vegetables), raw	RAC	0.56	20.71	11.60	39.81	22.29	25.06	14.03	37.93	21.24	18.12	10.15	16.74	9.37
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.065	7.14	0.46	16.92	1.10	37.58	2.44	15.16	0.99	4.42	0.29	12.67	0.82
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.01	20.68	0.21	25.00	0.25	85.72	0.86	34.31	0.34	11.54	0.12	23.32	0.23
VO 0448	Tomato, raw	RAC	0.08	32.13	2.57	51.27	4.10	34.92	2.79	73.37	5.87	15.15	1.21	8.88	0.71
-	Tomato, canned (& peeled)	PP	0.004	7.57	0.03	2.66	0.01	0.30	0.00	0.97	0.00	7.31	0.03	0.41	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.07	4.96	0.35	3.20	0.22	0.15	0.01	1.61	0.11	6.88	0.48	0.52	0.04
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.014	0.80	0.01	0.10	0.00	0.10	0.00	0.61	0.01	0.40	0.01	0.10	0.00

**CYANTRANILIPROLE (263)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		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) (Capsicum spp. Only)	RAC	0.08	6.39	0.51	15.53	1.24	19.09	1.53	10.36	0.83	8.29	0.66	4.53	0.36
-	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
VO 2046	Subgroup of eggplants	RAC	0.08	1.01	0.08	1.69	0.14	21.37	1.71	3.00	0.24	1.40	0.11	NC	-
VL 0053	Group of Leafy vegetables, raw	RAC	4.7	18.83	88.50	21.85	102.70	121.23	569.78	43.09	202.52	18.18	85.45	18.32	86.10
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.29	5.07	1.47	0.83	0.24	0.17	0.05	3.70	1.07	NC	-	NC	-
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.07	2.42	0.17	6.09	0.43	4.33	0.30	2.09	0.15	18.99	1.33	0.17	0.01
VP 2063	Subgroup of succulent peas without pods	RAC	0.07	10.72	0.75	1.99	0.14	2.72	0.19	4.26	0.30	4.23	0.30	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.01	1.51	0.02	1.50	0.02	1.90	0.02	5.11	0.05	1.36	0.01	23.43	0.23
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.033	106.33	3.51	117.78	3.89	42.12	1.39	195.70	6.46	222.52	7.34	80.47	2.66
VR 2070	Subgroup of Root vegetables, raw	RAC	0.01	64.22	0.64	65.78	0.66	49.73	0.50	57.68	0.58	113.82	1.14	37.27	0.37
VR 0573	Arrowroot, raw	RAC	0.01	0.10	0.00	0.10	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	0.10	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	0.10	0.00	NC	-	0.22	0.00	NC	-	0.78	0.01
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.02	225.03	4.50	234.24	4.68	71.48	1.43	177.55	3.55	234.55	4.69	37.71	0.75
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	-	0.10	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	-	0.10	0.00	0.71	0.01	NC	-	17.57	0.18
VR 2072	Subgroup of Aquatic root and tuber vegetables	RAC	0.01	NC	-	NC	-	3.42	0.03	NC	-	NC	-	NC	-
VS 0624	Celery	RAC	2	7.68	15.36	2.85	5.70	NC	-	3.34	6.68	16.83	33.66	4.04	8.08
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0.01	20.96	0.21	16.04	0.16	339.67	3.40	75.51	0.76	16.86	0.17	86.13	0.86
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	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 (incl oil)	RAC	0.077	32.68	2.52	19.91	1.53	7.83	0.60	15.69	1.21	NC	-	NC	-
SO 0691	Cotton seed, raw (incl oil)	RAC	0.16	10.71	1.71	4.23	0.68	7.19	1.15	7.54	1.21	5.66	0.91	2.38	0.38



CYANTRANILIPROLE (263)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.03 mg/kg bw							
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 0702	Sunflower seed, raw (incl oil)	RAC	0.067	23.40	1.57	29.33	1.97	1.24	0.08	13.85	0.93	6.48	0.43	6.91	0.46
SB 0716	Coffee beans 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
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.041	112.02	4.59	120.71	4.95	63.46	2.60	88.99	3.65	96.24	3.95	41.02	1.68
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.1	28.01	2.80	30.18	3.02	15.86	1.59	22.25	2.22	24.06	2.41	10.25	1.03
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.1	6.44	0.64	15.51	1.55	3.79	0.38	8.29	0.83	18.44	1.84	8.00	0.80
MO 0105	Edible offal (mammalian), raw	RAC	0.38	15.17	5.76	5.19	1.97	6.30	2.39	6.78	2.58	3.32	1.26	3.17	1.20
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.21	388.92	81.67	335.88	70.53	49.15	10.32	331.25	69.56	468.56	98.40	245.45	51.54
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.0039	66.38	0.26	48.47	0.19	21.58	0.08	78.41	0.31	48.04	0.19	76.01	0.30
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.0083	7.38	0.06	5.39	0.04	2.40	0.02	8.71	0.07	5.34	0.04	8.45	0.07
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0083	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	0.0321	0.33	0.01	0.72	0.02	0.27	0.01	0.35	0.01	0.80	0.03	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.0426	25.84	1.10	29.53	1.26	28.05	1.19	33.19	1.41	36.44	1.55	8.89	0.38
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
Total intake (µg//person)=				279.5		283.7		637.5		373.5		296.7		206.2	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (µg//person)=				1800		1800		1650		1800		1800		1800	
%ADI=				15.5%		15.8%		38.6%		20.7%		16.5%		11.5%	
Rounded %ADI=				20%		20%		40%		20%		20%		10%	

CYANTRANILIPROLE (263)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.03 mg/kg bw					
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		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	0.041	21.16	0.87	2.94	0.12	58.52	2.40	0.44	0.02	5.13	0.21
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.16	68.85	11.02	10.93	1.75	70.82	11.33	189.78	30.36	19.56	3.13

**CYANTRANILIPROLE (263)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		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
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.05	0.10	0.01	0.10	0.01	7.19	0.36	0.10	0.01	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	0.93	0.10	0.09	0.10	0.09	5.96	5.54	0.10	0.09	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.07	0.10	0.01	0.10	0.01	15.56	1.09	0.10	0.01	NC	-
DF 0014	Plums, dried (prunes)	PP	0.54	0.10	0.05	0.10	0.05	0.37	0.20	0.10	0.05	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.34	0.10	0.03	0.10	0.03	10.76	3.66	0.10	0.03	NC	-
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.75	0.82	0.62	4.05	3.04	5.94	4.46	0.43	0.32	2.66	2.00
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.21	0.14	0.03	0.36	0.08	15.22	3.20	0.10	0.02	0.10	0.02
JF 0269	Grape juice (from wine grapes)	PP	0.11	0.10	0.01	0.10	0.01	0.41	0.05	0.10	0.01	NC	-
-	Graps must (from wine-grapes)	PP	0.32	0.10	0.03	0.10	0.03	0.11	0.04	0.10	0.03	0.19	0.06
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.21	0.31	0.07	0.23	0.05	60.43	12.69	0.52	0.11	31.91	6.70
FB 0265	Cranberry, raw	RAC	0.012	NC	-	NC	-	0.10	0.00	NC	-	NC	-
FB 0275	Strawberry, raw	RAC	0.455	0.10	0.05	0.10	0.05	3.35	1.52	0.10	0.05	0.10	0.05
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	0.10	0.00	20.12	0.20
FI 0355	Pomegranate, raw, (incl processed)	RAC	0.01	5.49	0.05	27.17	0.27	NC	-	2.89	0.03	17.87	0.18
VA 0381	Garlic, raw	RAC	0.02	0.82	0.02	2.06	0.04	3.79	0.08	0.10	0.00	0.29	0.01
-	Onions, dry, raw	RAC	0.02	9.01	0.18	20.24	0.40	30.90	0.62	9.61	0.19	2.11	0.04
-	Onions, green, raw	RAC	1.3	1.43	1.86	0.10	0.13	0.20	0.26	NC	-	6.30	8.19
VB 0040	Group of Brassica vegetables (except Brassica leafy vegetables), raw	RAC	0.56	5.46	3.06	4.28	2.40	58.72	32.88	0.10	0.06	NC	-
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.065	0.92	0.06	3.20	0.21	13.55	0.88	1.91	0.12	0.10	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 0448	Tomato, raw	RAC	0.08	12.99	1.04	4.79	0.38	58.40	4.67	0.92	0.07	0.10	0.01
-	Tomato, canned (& peeled)	PP	0.004	0.10	0.00	0.10	0.00	2.42	0.01	0.10	0.00	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.07	0.58	0.04	0.22	0.02	2.21	0.15	0.24	0.02	3.10	0.22
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.014	0.10	0.00	0.10	0.00	0.42	0.01	0.10	0.00	0.10	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers) (Capsicum spp. Only)	RAC	0.08	8.97	0.72	14.13	1.13	25.14	2.01	0.91	0.07	NC	-
-	Peppers, chili, dried	PP	0.7	0.58	0.41	1.27	0.89	1.21	0.85	0.12	0.08	NC	-
VO 2046	Subgroup of eggplants	RAC	0.08	1.31	0.10	8.26	0.66	3.95	0.32	0.10	0.01	NC	-
VL 0053	Group of Leafy vegetables, raw	RAC	4.7	12.42	58.37	8.75	41.13	7.53	35.39	7.07	33.23	14.11	66.32
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.29	NC	-	NC	-	NC	-	NC	-	NC	-

**CYANTRANILIPROLE (263)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		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
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.07	0.37	0.03	3.14	0.22	4.88	0.34	0.10	0.01	NC	-
VP 2063	Subgroup of succulent peas without pods	RAC	0.07	0.21	0.01	0.10	0.01	5.51	0.39	0.10	0.01	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.01	7.11	0.07	2.33	0.02	3.76	0.04	44.70	0.45	3.27	0.03
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.033	15.80	0.52	14.29	0.47	104.36	3.44	17.11	0.56	35.20	1.16
VR 2070	Subgroup of Root vegetables, raw	RAC	0.01	31.84	0.32	23.38	0.23	68.28	0.68	17.52	0.18	71.01	0.71
VR 0573	Arrowroot, raw	RAC	0.01	13.83	0.14	18.24	0.18	0.10	0.00	0.10	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	0.10	0.00	0.10	0.00	20.14	0.20
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.02	23.96	0.48	13.56	0.27	213.41	4.27	104.35	2.09	8.56	0.17
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	-
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.01	NC	-	NC	-	0.10	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	0.10	0.00	5.65	0.06	30.85	0.31
VR 2072	Subgroup of Aquatic root and tuber vegetables	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
VS 0624	Celery	RAC	2	3.66	7.32	2.65	5.30	4.84	9.68	2.47	4.94	4.94	9.88
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0.01	52.55	0.53	286.02	2.86	18.64	0.19	19.67	0.20	75.09	0.75
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	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 (incl oil)	RAC	0.077	0.19	0.01	0.10	0.01	12.07	0.93	0.10	0.01	NC	-
SO 0691	Cotton seed, raw (incl oil)	RAC	0.16	8.14	1.30	0.32	0.05	2.84	0.45	2.69	0.43	0.97	0.16
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.067	0.94	0.06	0.22	0.01	32.01	2.14	12.12	0.81	0.48	0.03
SB 0716	Coffee beans 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
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.041	23.34	0.96	40.71	1.67	97.15	3.98	18.06	0.74	57.71	2.37
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.1	5.84	0.58	10.18	1.02	24.29	2.43	4.52	0.45	14.43	1.44
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.1	1.05	0.11	1.14	0.11	18.69	1.87	0.94	0.09	3.12	0.31
MO 0105	Edible offal (mammalian), raw	RAC	0.38	4.64	1.76	1.97	0.75	10.01	3.80	3.27	1.24	3.98	1.51

CYANTRANILIPROLE (263)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		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
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.21	108.75	22.84	70.31	14.77	436.11	91.58	61.55	12.93	79.09	16.61
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.0039	3.53	0.01	10.83	0.04	51.36	0.20	4.53	0.02	50.00	0.20
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.0083	0.39	0.00	1.20	0.01	5.71	0.05	0.50	0.00	5.56	0.05
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0083	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.0321	0.10	0.00	0.70	0.02	0.97	0.03	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.0426	3.84	0.16	4.41	0.19	27.25	1.16	1.13	0.05	7.39	0.31
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (µg//person)=				118.4		84.5		252.9		95.3		130.2	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (µg//person)=				1800		1800		1800		1800		1800	
%ADI=				6.6%		4.7%		14.0%		5.3%		7.2%	
Rounded %ADI=				7%		5%		10%		5%		7%	

## CYAZOFAMID (281)

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									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FB 0269	Grapes, raw (incl juice, excl must, excl dried, excl wine)	RAC	0.06	12.86	0.77	9.49	0.57	0.10	0.01	17.25	1.04	3.99	0.24	54.48	3.27
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.013	0.51	0.01	0.51	0.01	0.10	0.00	1.27	0.02	0.12	0.00	2.07	0.03
-	Graps must (from wine-grapes)	PP	0.035	0.33	0.01	0.13	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
FB 1236	Wine grapes, raw (incl must, juice, wine)	RAC	0.03	14.11	0.42	26.83	0.80	2.85	0.09	18.95	0.57	8.84	0.27	60.01	1.80
VA 2031	Subgroup of bulb onions	RAC	0.0615	31.65	1.95	43.28	2.66	3.68	0.23	38.48	2.37	20.46	1.26	47.29	2.91
VA 2032	Subgroup of Green Onions	RAC	1.5	2.64	3.96	3.09	4.64	1.05	1.58	2.89	4.34	0.61	0.92	5.24	7.86
VB 0040	Group of Brassica vegetables (except Brassica leafy vegetables), raw	RAC	0.31	6.43	1.99	40.26	12.48	0.80	0.25	9.94	3.08	12.07	3.74	17.73	5.50
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.04	53.14	2.13	86.21	3.45	6.28	0.25	92.76	3.71	15.64	0.63	155.30	6.21
VO 0448	Tomato, raw	RAC	0.06	41.73	2.50	75.65	4.54	10.66	0.64	82.87	4.97	24.75	1.49	200.93	12.06
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.043	2.34	0.10	1.33	0.06	1.57	0.07	4.24	0.18	0.34	0.01	2.83	0.12
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.27	6.93	1.87	10.97	2.96	8.83	2.38	9.13	2.47	6.65	1.80	20.01	5.40
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.072	4.49	0.32	6.44	0.46	7.21	0.52	5.68	0.41	9.52	0.69	8.92	0.64
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.06	5.58	0.33	4.31	0.26	0.89	0.05	9.31	0.56	13.64	0.82	20.12	1.21
VL 0053	Group of Leafy vegetables, raw	RAC	3.2	8.47	27.10	22.36	71.55	7.74	24.77	25.51	81.63	45.77	146.46	21.22	67.90
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	3.7	2.63	9.73	9.27	34.30	1.86	6.88	5.82	21.53	19.53	72.26	4.90	18.13
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.125	0.68	0.09	NC	-	NC	-	0.39	0.05	0.22	0.03	0.49	0.06
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.025	1.56	0.04	0.60	0.02	0.49	0.01	1.18	0.03	0.90	0.02	7.79	0.19
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
DH 1100	Hops, dry	RAC	3.6	0.10	0.36	0.10	0.36	0.10	0.36	0.10	0.36	NC	-	0.10	0.36
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (µg/person)=				54.3		142.3		38.2		127.9		231.2		134.9	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (µg/person)=				12000		12000		12000		12000		12000		12000	
%ADI=				0.5%		1.2%		0.3%		1.1%		1.9%		1.1%	
Rounded %ADI=				0%		1%		0%		1%		2%		1%	

## CYAZOFAMID (281)

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 (incl juice, excl must, excl dried, excl wine)	RAC	0.06	7.03	0.42	13.65	0.82	5.23	0.31	12.15	0.73	7.35	0.44	1.21	0.07
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.013	3.09	0.04	1.51	0.02	0.10	0.00	1.38	0.02	4.26	0.06	0.42	0.01
-	Graps must (from wine-grapes)	PP	0.035	0.16	0.01	0.10	0.00	0.10	0.00	0.12	0.00	0.11	0.00	NC	-
FB 1236	Wine grapes, raw (incl must, juice, wine)	RAC	0.03	129.34	3.88	99.46	2.98	7.76	0.23	46.71	1.40	91.48	2.74	9.23	0.28
VA 2031	Subgroup of bulb onions	RAC	0.0615	20.67	1.27	31.32	1.93	37.52	2.31	35.08	2.16	11.77	0.72	13.74	0.85
VA 2032	Subgroup of Green Onions	RAC	1.5	5.57	8.36	5.15	7.73	1.77	2.66	4.28	6.42	17.34	26.01	6.48	9.72
VB 0040	Group of Brassica vegetables (except Brassica leafy vegetables), raw	RAC	0.31	20.71	6.42	39.81	12.34	25.06	7.77	37.93	11.76	18.12	5.62	16.74	5.19
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.04	27.81	1.11	41.93	1.68	123.30	4.93	49.47	1.98	15.95	0.64	35.99	1.44
VO 0448	Tomato, raw	RAC	0.06	32.13	1.93	51.27	3.08	34.92	2.10	73.37	4.40	15.15	0.91	8.88	0.53
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.043	4.96	0.21	3.20	0.14	0.15	0.01	1.61	0.07	6.88	0.30	0.52	0.02
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.27	6.36	1.72	15.46	4.17	10.74	2.90	7.28	1.97	8.21	2.22	3.58	0.97
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.072	0.82	0.06	1.53	0.11	10.85	0.78	4.59	0.33	1.84	0.13	2.00	0.14
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.06	1.01	0.06	1.69	0.10	21.37	1.28	3.00	0.18	1.40	0.08	NC	-
VL 0053	Group of Leafy vegetables, raw	RAC	3.2	18.83	60.26	21.85	69.92	121.23	387.94	43.09	137.89	18.18	58.18	18.32	58.62
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	3.7	0.10	0.37	NC	-	26.78	99.09	5.00	18.50	0.58	2.15	5.68	21.02
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.125	5.07	0.63	0.83	0.10	0.17	0.02	3.70	0.46	NC	-	NC	-
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.025	2.21	0.06	5.25	0.13	4.17	0.10	1.61	0.04	16.95	0.42	0.17	0.00
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
DH 1100	Hops, dry	RAC	3.6	NC	-	NC	-	0.10	0.36	0.10	0.36	NC	-	NC	-
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (µg//person)=				89.0		107.6		513.5		190.4		103.0		99.2	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (µg//person)=				12000		12000		11000		12000		12000		12000	
%ADI=				0.7%		0.9%		4.7%		1.6%		0.9%		0.8%	
Rounded %ADI=				1%		1%		5%		2%		1%		1%	

## CYAZOFAMID (281)

## 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 (incl juice, excl must, excl dried, excl wine)	RAC	0.06	0.15	0.01	0.38	0.02	15.73	0.94	0.10	0.01	0.10	0.01
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.013	0.10	0.00	0.13	0.00	1.06	0.01	0.10	0.00	0.10	0.00
-	Graps must (from wine-grapes)	PP	0.035	0.10	0.00	0.10	0.00	0.11	0.00	0.10	0.00	0.19	0.01
FB 1236	Wine grapes, raw (incl must, juice, wine)	RAC	0.03	0.58	0.02	0.70	0.02	98.85	2.97	0.73	0.02	44.12	1.32
VA 2031	Subgroup of bulb onions	RAC	0.0615	9.83	0.60	22.30	1.37	34.69	2.13	9.65	0.59	2.39	0.15
VA 2032	Subgroup of Green Onions	RAC	1.5	1.45	2.18	1.50	2.25	1.42	2.13	0.10	0.15	6.30	9.45
VB 0040	Group of Brassica vegetables (except Brassica leafy vegetables), raw	RAC	0.31	5.46	1.69	4.28	1.33	58.72	18.20	0.10	0.03	NC	-
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.04	5.96	0.24	9.74	0.39	51.82	2.07	13.61	0.54	0.10	0.00
VO 0448	Tomato, raw	RAC	0.06	12.99	0.78	4.79	0.29	58.40	3.50	0.92	0.06	0.10	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.043	0.58	0.02	0.22	0.01	2.21	0.10	0.24	0.01	3.10	0.13
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.27	7.55	2.04	12.48	3.37	24.78	6.69	0.87	0.23	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.072	5.49	0.40	10.57	0.76	8.84	0.64	0.91	0.07	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.06	1.31	0.08	8.26	0.50	3.95	0.24	0.10	0.01	NC	-
VL 0053	Group of Leafy vegetables, raw	RAC	3.2	12.42	39.74	8.75	28.00	7.53	24.10	7.07	22.62	14.11	45.15
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	3.7	3.58	13.25	2.64	9.77	NC	-	1.83	6.77	3.65	13.51
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.125	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.025	0.30	0.01	3.13	0.08	4.11	0.10	0.10	0.00	NC	-
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
DH 1100	Hops, dry	RAC	3.6	NC	-	NC	-	0.10	0.36	NC	-	NC	-
-	-	-	-	-	-	-	-	-	-	-	-	-	-

Total intake (µg/person)=	61.3	48.3	66.3	32.2	69.8
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (µg/person)=	12000	12000	12000	12000	12000
%ADI=	0.5%	0.4%	0.6%	0.3%	0.6%
Rounded %ADI=	1%	0%	1%	0%	1%

DIQUAT (031)				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 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	34.91	0.00	16.51	0.00	17.23	0.00	104.48	0.00	35.57	0.00	98.49	0.00
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0	19.79	0.00	38.25	0.00	17.96	0.00	32.56	0.00	8.08	0.00	64.45	0.00
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0	11.60	0.00	23.79	0.00	0.25	0.00	11.84	0.00	2.41	0.00	33.44	0.00
FB 0275	Strawberry, raw	RAC	0	0.70	0.00	2.01	0.00	0.10	0.00	1.36	0.00	0.37	0.00	2.53	0.00
FT 0292	Cashew apple, raw	RAC	0	NC	-	0.10	0.00	0.62	0.00	NC	-	1.77	0.00	NC	-
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0	5.23	0.00	6.94	0.00	99.45	0.00	32.47	0.00	48.30	0.00	24.70	0.00
VO 0050	Group of Fruiting vegetables other than cucurbits, raw, (incl processed commodities)	RAC	0	70.72	0.00	103.53	0.00	37.61	0.00	129.38	0.00	61.87	0.00	265.39	0.00
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.05	2.39	0.12	1.61	0.08	10.47	0.52	1.84	0.09	12.90	0.65	7.44	0.37
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.05	1.27	0.06	0.10	0.01	0.12	0.01	2.49	0.12	0.23	0.01	5.54	0.28
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.05	0.10	0.01	NC	-	1.74	0.09	0.10	0.01	0.10	0.01	0.10	0.01
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.05	0.63	0.03	1.09	0.05	0.40	0.02	1.40	0.07	1.68	0.08	0.48	0.02
OR 0541	Soya oil, refined	PP	0.00275	12.99	0.04	10.43	0.03	3.63	0.01	13.10	0.04	10.70	0.03	13.10	0.04
-	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	0.05	1.70	0.09	0.10	0.01	3.00	0.15	1.80	0.09	1.64	0.08	1.33	0.07
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.17	1.62	0.28	3.22	0.55	0.92	0.16	1.50	0.26	2.90	0.49	0.17	0.03
VD 0524	Chick-pea (dry) (Cicer spp), raw	RAC	0.24	5.34	1.28	0.13	0.03	0.10	0.02	4.69	1.13	7.24	1.74	5.52	1.32
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.17	2.12	0.36	0.10	0.02	0.10	0.02	3.21	0.55	1.60	0.27	4.90	0.83
VD 0537	Pigeon pea (dry) (Cajanus spp), raw	RAC	0.17	NC	-	NC	-	0.10	0.02	0.10	0.02	3.38	0.57	NC	-
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.05	59.74	2.99	316.14	15.81	9.78	0.49	60.26	3.01	54.12	2.71	119.82	5.99
GC 0650	Rye, raw (incl flour)	RAC	0.505	0.13	0.07	19.38	9.79	0.10	0.05	0.12	0.06	0.10	0.05	2.15	1.09
GC 0653	Triticale, raw (incl flour)	RAC	0.505	NC	-	NC	-	NC	-	0.10	0.05	0.39	0.20	NC	-



DIQUAT (031)				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 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 pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	1.55	19.91	30.86	31.16	48.30	5.04	7.81	3.10	4.81	9.77	15.14	4.31	6.68
TN 0295	Cashew nuts, nutmeat	RAC	0	0.10	0.00	0.10	0.00	0.24	0.00	0.47	0.00	0.32	0.00	0.10	0.00
SO 0495	Rape seed, raw	RAC	0.49	0.10	0.05	NC	-	NC	-	0.10	0.05	0.75	0.37	0.10	0.05
OR 0495	Rape seed oil, edible	PP	0.0098	0.35	0.00	0.44	0.00	0.19	0.00	0.97	0.01	3.28	0.03	0.77	0.01
SO 0702	Sunflower seed, raw	RAC	0.11	0.10	0.01	0.33	0.04	0.10	0.01	0.24	0.03	0.10	0.01	0.10	0.01
OR 0702	Sunflower seed oil, edible	PP	0.066	2.97	0.20	14.42	0.95	0.43	0.03	3.46	0.23	2.20	0.15	5.53	0.36
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0	1.36	0.00	3.59	0.00	1.44	0.00	5.18	0.00	2.02	0.00	1.70	0.00
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)=				36.4		75.7		9.4		10.6		22.6		17.2	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (µg//person)=				360		360		360		360		360		360	
%ADI=				10.1%		21.0%		2.6%		2.9%		6.3%		4.8%	
Rounded %ADI=				10%		20%		3%		3%		6%		5%	

DIQUAT (031)				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 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	114.42	0.00	62.91	0.00	26.97	0.00	96.72	0.00	96.22	0.00	563.19	0.00
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0	71.38	0.00	81.73	0.00	42.91	0.00	58.89	0.00	103.85	0.00	12.48	0.00

**DIQUAT (031)**

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 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 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0	19.98	0.00	24.87	0.00	14.41	0.00	19.54	0.00	10.78	0.00	0.50	0.00
FB 0275	Strawberry, raw	RAC	0	4.49	0.00	5.66	0.00	0.10	0.00	6.63	0.00	5.75	0.00	0.10	0.00
FT 0292	Cashew apple, raw	RAC	0	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0	25.76	0.00	23.65	0.00	23.83	0.00	24.37	0.00	19.43	0.00	101.55	0.00
VO 0050	Group of Fruiting vegetables other than cucurbits, raw, (incl processed commodities)	RAC	0	72.92	0.00	86.99	0.00	79.04	0.00	97.13	0.00	65.96	0.00	17.98	0.00
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.05	1.51	0.08	1.50	0.08	1.90	0.10	5.11	0.26	1.36	0.07	23.43	1.17
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.05	0.10	0.01	0.10	0.01	1.16	0.06	0.40	0.02	NC	-	0.10	0.01
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.05	NC	-	NC	-	0.16	0.01	0.10	0.01	NC	-	NC	-
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.05	0.47	0.02	0.77	0.04	9.12	0.46	8.05	0.40	0.10	0.01	6.06	0.30
OR 0541	Soya oil, refined	PP	0.00275	19.06	0.05	21.06	0.06	5.94	0.02	33.78	0.09	40.05	0.11	13.39	0.04
-	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	0.05	0.10	0.01	NC	-	0.57	0.03	0.11	0.01	0.16	0.01	0.94	0.05
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.17	3.80	0.65	1.25	0.21	0.90	0.15	2.33	0.40	2.70	0.46	3.83	0.65
VD 0524	Chick-pea (dry) (Cicer spp), raw	RAC	0.24	0.27	0.06	1.33	0.32	0.32	0.08	0.15	0.04	0.10	0.02	0.10	0.02
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.17	0.95	0.16	1.18	0.20	0.40	0.07	0.96	0.16	0.71	0.12	1.28	0.22
VD 0537	Pigeon pea (dry) (Cajanus spp), raw	RAC	0.17	NC	-	NC	-	0.20	0.03	NC	-	NC	-	NC	-
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.05	225.03	11.25	234.24	11.71	71.48	3.57	177.55	8.88	234.55	11.73	37.71	1.89
GC 0650	Rye, raw (incl flour)	RAC	0.505	3.21	1.62	35.38	17.87	0.21	0.11	6.50	3.28	1.49	0.75	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	0.505	0.10	0.05	0.17	0.09	0.29	0.15	0.10	0.05	NC	-	NC	-
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	1.55	36.18	56.08	53.45	82.85	9.39	14.55	35.25	54.64	46.68	72.35	15.92	24.68
TN 0295	Cashew nuts, nutmeat	RAC	0	0.59	0.00	0.23	0.00	0.18	0.00	0.52	0.00	1.75	0.00	2.78	0.00
SO 0495	Rape seed, raw	RAC	0.49	NC	-	NC	-	0.10	0.05	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.0098	12.52	0.12	7.63	0.07	3.00	0.03	6.01	0.06	NC	-	NC	-
SO 0702	Sunflower seed, raw	RAC	0.11	0.10	0.01	1.32	0.15	0.10	0.01	1.17	0.13	NC	-	0.10	0.01
OR 0702	Sunflower seed oil, edible	PP	0.066	9.50	0.63	11.37	0.75	0.49	0.03	5.15	0.34	2.63	0.17	2.80	0.18

DIQUAT (031)		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 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
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0	10.90	0.00	12.44	0.00	0.77	0.00	9.48	0.00	22.07	0.00	8.15	0.00
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)=				70.8		114.4		19.5		68.8		85.8		29.2	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (µg/person)=				360		360		330		360		360		360	
%ADI=				19.7%		31.8%		5.9%		19.1%		23.8%		8.1%	
Rounded %ADI=				20%		30%		6%		20%		20%		8%	

DIQUAT (031)		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: 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	21.16	0.00	2.94	0.00	58.52	0.00	0.44	0.00	5.13	0.00		
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0	68.89	0.00	11.06	0.00	80.62	0.00	189.82	0.00	19.56	0.00		
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0	0.10	0.00	0.10	0.00	33.36	0.00	0.10	0.00	NC	-		
FB 0275	Strawberry, raw	RAC	0	0.10	0.00	0.10	0.00	3.35	0.00	0.10	0.00	0.10	0.00		
FT 0292	Cashew apple, raw	RAC	0	0.87	0.00	NC	-	NC	-	NC	-	NC	-		
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0	44.80	0.00	118.17	0.00	25.25	0.00	454.49	0.00	310.23	0.00		
VO 0050	Group of Fruiting vegetables other than cucurbits, raw, (incl processed commodities)	RAC	0	36.09	0.00	37.19	0.00	109.09	0.00	3.78	0.00	12.50	0.00		
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.05	7.11	0.36	2.33	0.12	3.76	0.19	44.70	2.24	3.27	0.16		

**DIQUAT (031)**

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: µg/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.05	3.70	0.19	0.10	0.01	0.17	0.01	0.10	0.01	NC	-
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.05	12.77	0.64	0.99	0.05	0.10	0.01	4.33	0.22	NC	-
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.05	2.89	0.14	0.21	0.01	0.48	0.02	3.16	0.16	0.26	0.01
OR 0541	Soya oil, refined	PP	0.00275	2.32	0.01	2.54	0.01	18.70	0.05	2.51	0.01	6.29	0.02
-	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	0.05	2.54	0.13	1.77	0.09	0.10	0.01	0.10	0.01	3.99	0.20
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.17	1.53	0.26	2.52	0.43	3.52	0.60	3.56	0.61	0.74	0.13
VD 0524	Chick-pea (dry) (Cicer spp), raw	RAC	0.24	1.09	0.26	1.56	0.37	0.33	0.08	0.18	0.04	0.47	0.11
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.17	0.67	0.11	7.26	1.23	0.37	0.06	0.10	0.02	NC	-
VD 0537	Pigeon pea (dry) (Cajanus spp), raw	RAC	0.17	1.14	0.19	0.10	0.02	NC	-	5.53	0.94	NC	-
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.05	23.96	1.20	13.56	0.68	213.41	10.67	104.35	5.22	8.56	0.43
GC 0650	Rye, raw (incl flour)	RAC	0.505	0.10	0.05	0.10	0.05	13.95	7.04	0.10	0.05	0.88	0.44
GC 0653	Triticale, raw (incl flour)	RAC	0.505	0.10	0.05	NC	-	NC	-	NC	-	NC	-
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	1.55	11.58	17.95	2.33	3.61	46.71	72.40	3.72	5.77	16.26	25.20
TN 0295	Cashew nuts, nutmeat	RAC	0	0.91	0.00	0.14	0.00	0.11	0.00	0.10	0.00	NC	-
SO 0495	Rape seed, raw	RAC	0.49	NC	-	0.10	0.05	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.0098	0.10	0.00	0.10	0.00	4.62	0.05	0.10	0.00	NC	-
SO 0702	Sunflower seed, raw	RAC	0.11	0.10	0.01	0.10	0.01	0.10	0.01	2.23	0.25	NC	-
OR 0702	Sunflower seed oil, edible	PP	0.066	0.37	0.02	0.10	0.01	12.98	0.86	4.01	0.26	0.20	0.01
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0	0.95	0.00	1.32	0.00	11.64	0.00	2.96	0.00	14.73	0.00
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

DIQUAT (031)				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: µg/person							
					G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
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)=					21.6		6.7		92.1		15.8		26.7	
Bodyweight per region (kg bw) =					60		60		60		60		60	
ADI (µg/person)=					360		360		360		360		360	
%ADI=					6.0%		1.9%		25.6%		4.4%		7.4%	
Rounded %ADI=					6%		2%		30%		4%		7%	

ETHIPROLE (304)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.005 mg/kg bw							
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
CM 0649 (GC 0649)	Rice, husked, dry ( incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.14	1.26	0.18	1.58	0.22	31.05	4.35	5.43	0.76	0.90	0.13	2.18	0.31
CM 1205	Rice polished, dry	PP	0.04	34.21	1.37	10.39	0.42	41.72	1.67	82.38	3.30	150.24	6.01	70.47	2.82
SB 0716	Coffee beans, raw (i.e. green coffee)	RAC	0.0245	0.96	0.02	0.16	0.00	0.91	0.02	0.27	0.01	1.37	0.03	0.46	0.01
SM 0716	Coffee beans, roasted	PP	0.044	0.19	0.01	0.91	0.04	0.16	0.01	2.50	0.11	0.39	0.02	0.40	0.02
-	Coffee beans, instant coffee (incl essences and concentrates)	PP	0.048	0.10	0.00	0.94	0.05	0.10	0.00	0.70	0.03	0.10	0.00	0.29	0.01
-	Coffee beans, substitutes, containing coffee	PP	0.048	0.10	0.00	0.10	0.00	0.16	0.01	0.17	0.01	0.10	0.00	0.10	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.021	24.96	0.52	57.95	1.22	16.70	0.35	38.38	0.81	26.46	0.56	29.00	0.61
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.094	6.24	0.59	14.49	1.36	4.18	0.39	9.60	0.90	6.62	0.62	7.25	0.68
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.094	3.29	0.31	6.14	0.58	0.82	0.08	1.57	0.15	2.23	0.21	1.07	0.10
MO 0105	Edible offal (mammalian), raw	RAC	0.076	4.79	0.36	9.68	0.74	2.97	0.23	5.49	0.42	3.84	0.29	5.03	0.38
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.011	289.65	3.19	485.88	5.34	26.92	0.30	239.03	2.63	199.91	2.20	180.53	1.99
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.02	13.17	0.26	26.78	0.54	7.24	0.14	116.71	2.33	22.54	0.45	32.09	0.64

ETHIPROLE (304)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.005 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
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.037	1.46	0.05	2.98	0.11	0.80	0.03	12.97	0.48	2.50	0.09	3.57	0.13
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.037	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	0.031	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.17	0.24	0.01	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.03	7.84	0.24	23.08	0.69	2.88	0.09	14.89	0.45	9.81	0.29	14.83	0.44
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (µg//person)=				7.1		11.3		7.7		12.5		10.9		8.2	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (µg//person)=				300		300		300		300		300		300	
%ADI=				2.4%		3.8%		2.6%		4.2%		3.6%		2.7%	
Rounded %ADI=				2%		4%		3%		4%		4%		3%	

## ETHIPROLE (304)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.005 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
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.14	3.70	0.52	2.11	0.30	1.51	0.21	1.75	0.25	0.29	0.04	5.12	0.72
CM 1205	Rice polished, dry	PP	0.04	13.38	0.54	10.80	0.43	262.08	10.48	57.16	2.29	12.83	0.51	62.78	2.51
SB 0716	Coffee beans, raw (i.e. green coffee)	RAC	0.0245	0.60	0.01	NC	-	0.62	0.02	1.71	0.04	NC	-	3.51	0.09
SM 0716	Coffee beans, roasted	PP	0.044	7.02	0.31	9.75	0.43	0.10	0.00	5.09	0.22	13.38	0.59	0.77	0.03
-	Coffee beans, instant coffee (incl essences and concentrates)	PP	0.048	0.75	0.04	0.30	0.01	0.10	0.00	0.67	0.03	2.43	0.12	1.43	0.07
-	Coffee beans, substitutes, containing coffee	PP	0.048	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.15	0.01
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.021	112.02	2.35	120.71	2.53	63.46	1.33	88.99	1.87	96.24	2.02	41.02	0.86
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.094	28.01	2.63	30.18	2.84	15.86	1.49	22.25	2.09	24.06	2.26	10.25	0.96
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.094	6.44	0.61	15.51	1.46	3.79	0.36	8.29	0.78	18.44	1.73	8.00	0.75
MO 0105	Edible offal (mammalian), raw	RAC	0.076	15.17	1.15	5.19	0.39	6.30	0.48	6.78	0.52	3.32	0.25	3.17	0.24
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.011	388.92	4.28	335.88	3.69	49.15	0.54	331.25	3.64	468.56	5.15	245.45	2.70
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.02	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	0.037	7.38	0.27	5.39	0.20	2.40	0.09	8.71	0.32	5.34	0.20	8.45	0.31
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.037	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.03	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.031	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	0.03	25.84	0.78	29.53	0.89	28.05	0.84	33.19	1.00	36.44	1.09	8.89	0.27
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (µg/person)=				14.8		14.2		16.3		14.6		15.0		11.0	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (µg/person)=				300		300		275		300		300		300	
%ADI=				4.9%		4.7%		5.9%		4.9%		5.0%		3.7%	
Rounded %ADI=				5%		5%		6%		5%		5%		4%	

**ETHIPROLE (304)**

## International Estimated Daily Intake (IEDI)

ADI = 0 - 0.005 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
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.14	13.58	1.90	4.29	0.60	2.17	0.30	0.10	0.01	8.84	1.24
CM 1205	Rice polished, dry	PP	0.04	30.20	1.21	218.34	8.73	12.77	0.51	15.24	0.61	51.35	2.05
SB 0716	Coffee beans, raw (i.e. green coffee)	RAC	0.0245	0.83	0.02	0.69	0.02	1.09	0.03	2.91	0.07	0.82	0.02
SM 0716	Coffee beans, roasted	PP	0.044	0.10	0.00	0.41	0.02	7.50	0.33	0.10	0.00	0.10	0.00
-	Coffee beans, instant coffee (incl essences and concentrates)	PP	0.048	0.10	0.00	0.10	0.00	0.60	0.03	0.10	0.00	5.53	0.27
-	Coffee beans, substitutes, containing coffee	PP	0.048	0.10	0.00	0.10	0.00	0.13	0.01	0.10	0.00	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.021	23.34	0.49	40.71	0.85	97.15	2.04	18.06	0.38	57.71	1.21
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.094	5.84	0.55	10.18	0.96	24.29	2.28	4.52	0.42	14.43	1.36
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.094	1.05	0.10	1.14	0.11	18.69	1.76	0.94	0.09	3.12	0.29
MO 0105	Edible offal (mammalian), raw	RAC	0.076	4.64	0.35	1.97	0.15	10.01	0.76	3.27	0.25	3.98	0.30
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.011	108.75	1.20	70.31	0.77	436.11	4.80	61.55	0.68	79.09	0.87
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.02	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	0.037	0.39	0.01	1.20	0.04	5.71	0.21	0.50	0.02	5.56	0.21
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.037	NC	-	NC	-	0.32	0.01	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.031	0.10	0.00	0.70	0.02	0.97	0.03	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.03	3.84	0.12	4.41	0.13	27.25	0.82	1.13	0.03	7.39	0.22

Total intake (µg//person)=	6.0	12.6	14.9	2.7	9.0
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (µg//person)=	300	300	300	300	300
%ADI=	2.0%	4.2%	5.0%	0.9%	3.0%
Rounded %ADI=	2%	4%	5%	1%	3%



## FENPICOXAMID (305)

## 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
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
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-

Total intake (µg//person)=	0.1	0.1	1.0	0.3	0.5	0.2
Bodyweight per region (kg bw) =	60	60	60	60	60	60
ADI (µg//person)=	3000	3000	3000	3000	3000	3000
%ADI=	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Rounded %ADI=	0%	0%	0%	0%	0%	0%

## FENPICOXAMID (305)

## 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
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
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-

Total intake (µg//person)=	0.3	0.2	0.2	0.2	0.2	1.0
Bodyweight per region (kg bw) =	60	60	55	60	60	60
ADI (µg//person)=	3000	3000	2750	3000	3000	3000
%ADI=	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Rounded %ADI=	0%	0%	0%	0%	0%	0%

## FENPICOXAMID (305)

## 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
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
-	-	-		-	-	-	-	-	-	-	-	-	-

Total intake (µg//person)=	0.4	1.2	0.3	4.5	3.1
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (µg//person)=	3000	3000	3000	3000	3000
%ADI=	0.0%	0.0%	0.0%	0.2%	0.1%
Rounded %ADI=	0%	0%	0%	0%	0%

FLUDIOXONIL (211)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.4 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	0.41	32.25	13.22	11.67	4.78	16.70	6.85	76.01	31.16	33.90	13.90	92.97	38.12
JF 0001	Group of Citrus fruit, juice	PP	0.64	1.30	0.83	2.37	1.52	0.22	0.14	13.88	8.88	0.75	0.48	2.63	1.68
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	2.1	19.35	40.64	34.06	71.53	17.87	37.53	25.74	54.05	7.69	16.15	56.85	119.39
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.17	0.32	0.05	3.07	0.52	0.10	0.02	5.00	0.85	0.29	0.05	5.57	0.95
FS 0012	Group of Stone fruits, raw	RAC	0.8	10.82	8.66	22.73	18.18	0.24	0.19	10.46	8.37	2.23	1.78	31.91	25.53
DF 0014	Plums, dried (prunes)	PP	0.96	0.10	0.10	0.10	0.10	0.10	0.10	0.18	0.17	0.10	0.10	0.10	0.10
FB 0264	Blackberries, raw	RAC	1	0.35	0.35	0.11	0.11	0.10	0.10	0.10	0.10	0.10	0.10	1.23	1.23
FB 0266	Dewberries, incl boysen- & loganberry, raw	RAC	1	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10
FB 0272	Raspberries, red, black, raw	RAC	1	0.10	0.10	0.93	0.93	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10
FB 0020	Blueberries, raw	RAC	0.6	0.10	0.06	0.10	0.06	0.10	0.06	0.10	0.06	0.10	0.06	0.10	0.06
FB 0021	Currants, Black, Red, White, raw	RAC	0.62	0.10	0.06	0.74	0.46	0.10	0.06	0.10	0.06	0.10	0.06	0.10	0.06
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.28	13.02	3.65	9.25	2.59	0.10	0.03	16.91	4.73	3.70	1.04	54.44	15.24
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.31	0.51	0.16	0.51	0.16	0.10	0.03	1.27	0.39	0.12	0.04	2.07	0.64
JF 0269	Grape juice (from wine grapes)	PP	0.26	0.14	0.04	0.29	0.08	0.10	0.03	0.30	0.08	0.24	0.06	0.10	0.03
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.01	0.67	0.01	12.53	0.13	2.01	0.02	1.21	0.01	3.53	0.04	4.01	0.04
FB 0275	Strawberry, raw	RAC	0.27	0.70	0.19	2.01	0.54	0.10	0.03	1.36	0.37	0.37	0.10	2.53	0.68
FT 0336	Guava, raw	RAC	0.125	0.47	0.06	0.10	0.01	0.48	0.06	0.49	0.06	4.42	0.55	0.10	0.01
FI 0326	Avocado, raw	RAC	0.05	0.13	0.01	0.10	0.01	2.05	0.10	2.54	0.13	2.34	0.12	0.12	0.01
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.02	10.48	0.21	0.10	0.00	7.24	0.14	6.87	0.14	19.98	0.40	6.25	0.13
FI 0355	Pomegranate, raw, (incl processed)	RAC	1.75	3.40	5.95	2.10	3.68	2.65	4.64	10.89	19.06	NC	-	6.67	11.67
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	2	0.61	1.22	1.56	3.12	7.89	15.78	9.36	18.72	8.76	17.52	1.30	2.60
FI 0341	Kiwifruit, raw	RAC	7.2	0.10	0.72	0.36	2.59	0.10	0.72	1.17	8.42	0.10	0.72	0.69	4.97
VA 2031	Subgroup of bulb onions	RAC	0.04	31.65	1.27	43.28	1.73	3.68	0.15	38.48	1.54	20.46	0.82	47.29	1.89
VA 2032	Subgroup of Green Onions	RAC	0.14	2.64	0.37	3.09	0.43	1.05	0.15	2.89	0.40	0.61	0.09	5.24	0.73
VB 0400	Broccoli, raw	RAC	0.23	0.88	0.20	0.17	0.04	0.10	0.02	1.25	0.29	3.00	0.69	1.09	0.25
VB 0041	Cabbages, head, raw	RAC	0.24	2.73	0.66	27.92	6.70	0.55	0.13	4.47	1.07	4.27	1.02	10.25	2.46
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.065	53.14	3.45	86.21	5.60	6.28	0.41	92.76	6.03	15.64	1.02	155.30	10.09
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.66	42.04	27.75	76.13	50.25	10.69	7.06	84.59	55.83	24.92	16.45	203.27	134.16

## FLUDIOXONIL (211)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 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
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.924	2.34	2.16	1.33	1.23	1.57	1.45	4.24	3.92	0.34	0.31	2.83	2.61
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.145	0.29	0.04	0.29	0.04	0.10	0.01	0.38	0.06	0.10	0.01	0.14	0.02
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers) (Capsicum spp. Only)	RAC	0.18	8.48	1.53	13.74	2.47	10.13	1.82	11.29	2.03	9.52	1.71	26.36	4.74
-	Peppers, chili, dried	PP	1.2	0.42	0.50	0.53	0.64	0.84	1.01	0.50	0.60	0.95	1.14	0.37	0.44
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.06	5.58	0.33	4.31	0.26	0.89	0.05	9.31	0.56	13.64	0.82	20.12	1.21
VL 0483	Lettuce, leaf, raw	RAC	8.3	0.53	4.40	0.36	2.99	0.16	1.33	6.21	51.54	1.90	15.77	6.05	50.22
VL 0502	Spinach, raw	RAC	5.8	0.74	4.29	0.22	1.28	0.10	0.58	0.91	5.28	0.10	0.58	2.92	16.94
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	1.2	2.63	3.16	9.27	11.12	1.86	2.23	5.82	6.98	19.53	23.44	4.90	5.88
VL 0473	Watercress, raw	RAC	1.2	1.21	1.45	2.15	2.58	1.33	1.60	3.24	3.89	11.36	13.63	1.56	1.87
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.04	0.68	0.03	NC	-	NC	-	0.39	0.02	0.22	0.01	0.49	0.02
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.02	1.56	0.03	0.60	0.01	0.49	0.01	1.18	0.02	0.90	0.02	7.79	0.16
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.02	1.97	0.04	0.51	0.01	0.10	0.00	0.79	0.02	3.68	0.07	3.80	0.08
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
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.02	1.62	0.03	3.22	0.06	0.92	0.02	1.50	0.03	2.90	0.06	0.17	0.00
VD 0524	Chick-pea (dry) (Cicer spp), raw	RAC	0.11	5.34	0.59	0.13	0.01	0.10	0.01	4.69	0.52	7.24	0.80	5.52	0.61
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.11	2.12	0.23	0.10	0.01	0.10	0.01	3.21	0.35	1.60	0.18	4.90	0.54
VR 0577	Carrots, raw	RAC	0.19	9.51	1.81	30.78	5.85	0.37	0.07	8.75	1.66	2.80	0.53	6.10	1.16
VR 0494	Radish roots, raw	RAC	0.06	2.31	0.14	4.09	0.25	2.53	0.15	6.15	0.37	5.88	0.35	2.97	0.18
VR 0589	Potato, raw	RAC	1.5	59.07	88.61	313.97	470.96	9.23	13.85	48.16	72.24	52.38	78.57	117.43	176.15
VR 0508	Sweet potato, raw (incl dried)	RAC	3.5	0.18	0.63	0.18	0.63	42.16	147.56	1.61	5.64	3.06	10.71	6.67	23.35
VR 0600	Yams, raw (incl dried)	RAC	3.5	0.10	0.35	NC	-	90.40	316.40	6.45	22.58	0.74	2.59	0.65	2.28
VS 0624	Celery	RAC	4.55	2.14	9.74	3.79	17.24	2.35	10.69	5.69	25.89	0.10	0.46	2.75	12.51
GC 0080	Group of Cereal grains, raw, (incl processed) (incl sweet corn)	RAC	0.02	484.43	9.69	464.63	9.29	262.36	5.25	486.81	9.74	469.62	9.39	614.04	12.28
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 0675	Pistachio nut, nutmeat	RAC	0.05	0.41	0.02	0.10	0.01	0.10	0.01	0.85	0.04	0.10	0.01	1.08	0.05
SO 0495	Rape seed, raw (incl oil)	RAC	0.02	0.93	0.02	1.16	0.02	0.49	0.01	2.53	0.05	9.32	0.19	2.02	0.04

**FLUDIOXONIL (211)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 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
SO 0691	Cotton seed, raw (incl oil)	RAC	0.05	20.53	1.03	9.80	0.49	6.42	0.32	4.73	0.24	7.14	0.36	18.68	0.93
HH 0720	Herbs, raw (incl dried)	RAC	2.65	1.69	4.48	1.91	5.06	1.18	3.13	3.35	8.88	0.55	1.46	1.64	4.35
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	0.003	6.24	0.02	14.49	0.04	4.18	0.01	9.60	0.03	6.62	0.02	7.25	0.02
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.003	3.29	0.01	6.14	0.02	0.82	0.00	1.57	0.00	2.23	0.01	1.07	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.02	4.79	0.10	9.68	0.19	2.97	0.06	5.49	0.11	3.84	0.08	5.03	0.10
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.008	289.65	2.32	485.88	3.89	26.92	0.22	239.03	1.91	199.91	1.60	180.53	1.44
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	0.028	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.15	0.24	0.01	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	7.84	0.08	23.08	0.23	2.88	0.03	14.89	0.15	9.81	0.10	14.83	0.15
Total intake (µg//person)=				249.0		714.1		583.5		447.9		239.9		694.6	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (µg//person)=				24000		24000		24000		24000		24000		24000	
%ADI=				1.0%		3.0%		2.4%		1.9%		1.0%		2.9%	
Rounded %ADI=				1%		3%		2%		2%		1%		3%	

**FLUDIOXONIL (211)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 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	0.41	38.66	15.85	54.93	22.52	26.36	10.81	51.46	21.10	51.06	20.93	466.36	191.21
JF 0001	Group of Citrus fruit, juice	PP	0.64	36.84	23.58	3.75	2.40	0.30	0.19	21.62	13.84	21.82	13.96	46.67	29.87
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	2.1	51.09	107.29	65.40	137.34	42.71	89.69	45.29	95.11	62.51	131.27	7.74	16.25
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.17	14.88	2.53	11.98	2.04	0.15	0.03	9.98	1.70	30.32	5.15	3.47	0.59
FS 0012	Group of Stone fruits, raw	RAC	0.8	15.97	12.78	22.86	18.29	14.26	11.41	17.39	13.91	8.09	6.47	0.11	0.09
DF 0014	Plums, dried (prunes)	PP	0.96	0.61	0.59	0.35	0.34	0.10	0.10	0.35	0.34	0.49	0.47	0.13	0.12
FB 0264	Blackberries, raw	RAC	1	0.10	0.10	0.52	0.52	0.14	0.14	0.24	0.24	NC	-	0.10	0.10

## FLUDIOXONIL (211)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 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 0266	Dewberries, incl boysen- & loganberry, raw	RAC	1	0.10	0.10	NC	-	0.10	0.10	0.10	0.10	NC	-	0.10	0.10
FB 0272	Raspberries, red, black, raw	RAC	1	0.47	0.47	0.91	0.91	0.10	0.10	0.99	0.99	1.14	1.14	NC	-
FB 0020	Blueberries, raw	RAC	0.6	0.10	0.06	0.23	0.14	0.10	0.06	0.83	0.50	0.33	0.20	NC	-
FB 0021	Currants, Black, Red, White, raw	RAC	0.62	0.48	0.30	4.23	2.62	NC	-	1.51	0.94	0.49	0.30	NC	-
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.28	6.48	1.81	11.31	3.17	5.21	1.46	9.50	2.66	4.66	1.30	0.78	0.22
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.31	3.09	0.96	1.51	0.47	0.10	0.03	1.38	0.43	4.26	1.32	0.42	0.13
JF 0269	Grape juice (from wine grapes)	PP	0.26	0.56	0.15	1.96	0.51	0.10	0.03	2.24	0.58	2.27	0.59	0.34	0.09
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.01	88.93	0.89	62.41	0.62	1.84	0.02	25.07	0.25	61.17	0.61	5.84	0.06
FB 0275	Strawberry, raw	RAC	0.27	4.49	1.21	5.66	1.53	0.10	0.03	6.63	1.79	5.75	1.55	0.10	0.03
FT 0336	Guava, raw	RAC	0.125	0.10	0.01	NC	-	0.42	0.05	NC	-	NC	-	NC	-
FI 0326	Avocado, raw	RAC	0.05	2.65	0.13	0.87	0.04	0.46	0.02	1.64	0.08	1.30	0.07	0.96	0.05
FI 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 0355	Pomegranate, raw, (incl processed)	RAC	1.75	7.91	13.84	9.72	17.01	7.67	13.42	5.26	9.21	9.04	15.82	14.43	25.25
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	2	13.13	26.26	11.13	22.26	6.94	13.88	14.36	28.72	36.74	73.48	18.81	37.62
FI 0341	Kiwifruit, raw	RAC	7.2	2.46	17.71	3.62	26.06	0.10	0.72	1.48	10.66	7.43	53.50	0.10	0.72
VA 2031	Subgroup of bulb onions	RAC	0.04	20.67	0.83	31.32	1.25	37.52	1.50	35.08	1.40	11.77	0.47	13.74	0.55
VA 2032	Subgroup of Green Onions	RAC	0.14	5.57	0.78	5.15	0.72	1.77	0.25	4.28	0.60	17.34	2.43	6.48	0.91
VB 0400	Broccoli, raw	RAC	0.23	4.24	0.98	1.76	0.40	NC	-	0.51	0.12	3.79	0.87	0.26	0.06
VB 0041	Cabbages, head, raw	RAC	0.24	8.97	2.15	27.12	6.51	1.44	0.35	24.96	5.99	4.55	1.09	11.23	2.70
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.065	27.81	1.81	41.93	2.73	123.30	8.01	49.47	3.22	15.95	1.04	35.99	2.34
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.66	43.88	28.96	55.41	36.57	35.38	23.35	74.88	49.42	26.50	17.49	9.51	6.28
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.924	4.96	4.58	3.20	2.96	0.15	0.14	1.61	1.49	6.88	6.36	0.52	0.48
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.145	0.80	0.12	0.10	0.01	0.10	0.01	0.61	0.09	0.40	0.06	0.10	0.01
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chili peppers) (Capsicum spp. Only)	RAC	0.18	6.39	1.15	15.53	2.80	19.09	3.44	10.36	1.86	8.29	1.49	4.53	0.82
-	Peppers, chili, dried	PP	1.2	0.11	0.13	0.21	0.25	0.36	0.43	0.21	0.25	0.25	0.30	0.15	0.18
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.06	1.01	0.06	1.69	0.10	21.37	1.28	3.00	0.18	1.40	0.08	NC	-
VL 0483	Lettuce, leaf, raw	RAC	8.3	14.50	120.35	11.76	97.61	13.14	109.06	19.50	161.85	4.81	39.92	2.23	18.51
VL 0502	Spinach, raw	RAC	5.8	2.20	12.76	1.76	10.21	13.38	77.60	2.94	17.05	5.53	32.07	0.10	0.58
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	1.2	0.10	0.12	NC	-	26.78	32.14	5.00	6.00	0.58	0.70	5.68	6.82

FLUDIOXONIL (211)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.4 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
VL 0473	Watercress, raw	RAC	1.2	0.35	0.42	3.13	3.76	0.32	0.38	NC	-	NC	-	2.30	2.76
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.04	5.07	0.20	0.83	0.03	0.17	0.01	3.70	0.15	NC	-	NC	-
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.02	2.21	0.04	5.25	0.11	4.17	0.08	1.61	0.03	16.95	0.34	0.17	0.00
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.02	10.72	0.21	1.99	0.04	2.72	0.05	4.26	0.09	4.23	0.08	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
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.02	3.80	0.08	1.25	0.03	0.90	0.02	2.33	0.05	2.70	0.05	3.83	0.08
VD 0524	Chick-pea (dry) (Cicer spp), raw	RAC	0.11	0.27	0.03	1.33	0.15	0.32	0.04	0.15	0.02	0.10	0.01	0.10	0.01
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.11	0.95	0.10	1.18	0.13	0.40	0.04	0.96	0.11	0.71	0.08	1.28	0.14
VR 0577	Carrots, raw	RAC	0.19	26.26	4.99	27.13	5.15	10.07	1.91	16.49	3.13	44.69	8.49	8.75	1.66
VR 0494	Radish roots, raw	RAC	0.06	3.83	0.23	11.99	0.72	NC	-	5.26	0.32	2.19	0.13	4.37	0.26
VR 0589	Potato, raw	RAC	1.5	202.90	304.35	215.82	323.73	69.98	104.97	166.61	249.92	214.41	321.62	25.32	37.98
VR 0508	Sweet potato, raw (incl dried)	RAC	3.5	0.93	3.26	0.32	1.12	64.65	226.28	5.37	18.80	0.30	1.05	3.13	10.96
VR 0600	Yams, raw (incl dried)	RAC	3.5	NC	-	NC	-	0.10	0.35	0.71	2.49	NC	-	17.57	61.50
VS 0624	Celery	RAC	4.55	7.68	34.94	2.85	12.97	NC	-	3.34	15.20	16.83	76.58	4.04	18.38
GC 0080	Group of Cereal grains, raw, (incl processed) (incl sweet corn)	RAC	0.02	345.63	6.91	386.16	7.72	514.33	10.29	402.72	8.05	295.30	5.91	359.97	7.20
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 0675	Pistachio nut, nutmeat	RAC	0.05	0.35	0.02	0.48	0.02	0.10	0.01	0.39	0.02	0.23	0.01	0.10	0.01
SO 0495	Rape seed, raw (incl oil)	RAC	0.02	32.68	0.65	19.91	0.40	7.83	0.16	15.69	0.31	NC	-	NC	-
SO 0691	Cotton seed, raw (incl oil)	RAC	0.05	10.71	0.54	4.23	0.21	7.19	0.36	7.54	0.38	5.66	0.28	2.38	0.12
HH 0720	Herbs, raw (incl dried)	RAC	2.65	2.61	6.92	2.31	6.12	8.89	23.56	3.92	10.39	1.16	3.07	2.06	5.46
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.01	112.02	1.12	120.71	1.21	63.46	0.63	88.99	0.89	96.24	0.96	41.02	0.41
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.003	28.01	0.08	30.18	0.09	15.86	0.05	22.25	0.07	24.06	0.07	10.25	0.03
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.003	6.44	0.02	15.51	0.05	3.79	0.01	8.29	0.02	18.44	0.06	8.00	0.02
MO0105	Edible offal (mammalian), raw	RAC	0.02	15.17	0.30	5.19	0.10	6.30	0.13	6.78	0.14	3.32	0.07	3.17	0.06
ML0106	Milks, raw or skimmed (incl dairy products)	RAC	0.008	388.92	3.11	335.88	2.69	49.15	0.39	331.25	2.65	468.56	3.75	245.45	1.96

FLUDIOXONIL (211)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.4 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
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	0.028	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	0.01	25.84	0.26	29.53	0.30	28.05	0.28	33.19	0.33	36.44	0.36	8.89	0.09	
Total intake (µg//person)=					771.5		789.0		770.6		768.5		857.9		493.9	
Bodyweight per region (kg bw) =					60		60		55		60		60		60	
ADI (µg//person)=					24000		24000		22000		24000		24000		24000	
%ADI=					3.2%		3.3%		3.5%		3.2%		3.6%		2.1%	
Rounded %ADI=					3%		3%		4%		3%		4%		2%	

FLUDIOXONIL (211)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.4 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	0.41	20.93	8.58	2.35	0.96	30.71	12.59	0.15	0.06	4.45	1.82	
JF 0001	Group of Citrus fruit, juice	PP	0.64	0.11	0.07	0.29	0.19	13.55	8.67	0.14	0.09	0.33	0.21	
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	2.1	68.85	144.59	10.93	22.95	70.82	148.72	189.78	398.54	19.56	41.08	
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.17	0.10	0.02	0.10	0.02	7.19	1.22	0.10	0.02	NC	-	
FS 0012	Group of Stone fruits, raw	RAC	0.8	0.10	0.08	0.10	0.08	31.44	25.15	0.10	0.08	NC	-	
DF 0014	Plums, dried (prunes)	PP	0.96	0.10	0.10	0.10	0.10	0.37	0.36	0.10	0.10	NC	-	
FB 0264	Blackberries, raw	RAC	1	0.10	0.10	7.29	7.29	0.25	0.25	0.10	0.10	NC	-	
FB 0266	Dewberries, incl boysen- & loganberry, raw	RAC	1	0.10	0.10	0.10	0.10	NC	-	0.10	0.10	NC	-	
FB 0272	Raspberries, red, black, raw	RAC	1	0.10	0.10	0.10	0.10	2.04	2.04	0.10	0.10	NC	-	
FB 0020	Blueberries, raw	RAC	0.6	NC	-	NC	-	0.20	0.12	NC	-	NC	-	
FB 0021	Currants, Black, Red, White, raw	RAC	0.62	0.10	0.06	NC	-	0.74	0.46	NC	-	NC	-	
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.28	0.14	0.04	0.36	0.10	15.33	4.29	0.10	0.03	0.28	0.08	
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.31	0.10	0.03	0.13	0.04	1.06	0.33	0.10	0.03	0.10	0.03	
JF 0269	Grape juice (from wine grapes)	PP	0.26	0.10	0.03	0.10	0.03	0.41	0.11	0.10	0.03	NC	-	
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.01	0.31	0.00	0.23	0.00	60.43	0.60	0.52	0.01	31.91	0.32	
FB 0275	Strawberry, raw	RAC	0.27	0.10	0.03	0.10	0.03	3.35	0.90	0.10	0.03	0.10	0.03	

## FLUDIOXONIL (211)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 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
FT 0336	Guava, raw	RAC	0.125	0.10	0.01	0.10	0.01	NC	-	0.14	0.02	3.11	0.39
FI 0326	Avocado, raw	RAC	0.05	1.12	0.06	0.10	0.01	0.84	0.04	0.10	0.01	6.60	0.33
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	0.10	0.00	20.12	0.40
FI 0355	Pomegranate, raw, (incl processed)	RAC	1.75	5.49	9.61	27.17	47.55	NC	-	2.89	5.06	17.87	31.27
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	2	8.51	17.02	6.27	12.54	6.89	13.78	0.18	0.36	24.94	49.88
FI 0341	Kiwifruit, raw	RAC	7.2	0.10	0.72	0.10	0.72	2.00	14.40	0.10	0.72	NC	-
VA 2031	Subgroup of bulb onions	RAC	0.04	9.83	0.39	22.30	0.89	34.69	1.39	9.65	0.39	2.39	0.10
VA 2032	Subgroup of Green Onions	RAC	0.14	1.45	0.20	1.50	0.21	1.42	0.20	0.10	0.01	6.30	0.88
VB 0400	Broccoli, raw	RAC	0.23	0.10	0.02	0.10	0.02	2.13	0.49	0.10	0.02	NC	-
VB 0041	Cabbages, head, raw	RAC	0.24	3.82	0.92	2.99	0.72	49.16	11.80	0.10	0.02	NC	-
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.065	5.96	0.39	9.74	0.63	51.82	3.37	13.61	0.88	0.10	0.01
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.66	13.10	8.65	4.90	3.23	62.16	41.03	1.04	0.69	0.10	0.07
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.924	0.58	0.54	0.22	0.20	2.21	2.04	0.24	0.22	3.10	2.86
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.145	0.10	0.01	0.10	0.01	0.42	0.06	0.10	0.01	0.10	0.01
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chili peppers) (Capsicum spp. Only)	RAC	0.18	8.97	1.61	14.13	2.54	25.14	4.53	0.91	0.16	NC	-
-	Peppers, chili, dried	PP	1.2	0.58	0.70	1.27	1.52	1.21	1.45	0.12	0.14	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.06	1.31	0.08	8.26	0.50	3.95	0.24	0.10	0.01	NC	-
VL 0483	Lettuce, leaf, raw	RAC	8.3	0.29	2.41	0.10	0.83	6.71	55.69	0.10	0.83	NC	-
VL 0502	Spinach, raw	RAC	5.8	0.17	0.99	0.10	0.58	0.81	4.70	0.10	0.58	NC	-
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	1.2	3.58	4.30	2.64	3.17	NC	-	1.83	2.20	3.65	4.38
VL 0473	Watercress, raw	RAC	1.2	2.08	2.50	1.50	1.80	0.10	0.12	1.41	1.69	2.81	3.37
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.04	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.02	0.30	0.01	3.13	0.06	4.11	0.08	0.10	0.00	NC	-
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.02	0.21	0.00	0.10	0.00	5.51	0.11	0.10	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
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.02	1.53	0.03	2.52	0.05	3.52	0.07	3.56	0.07	0.74	0.01
VD 0524	Chick-pea (dry) (Cicer spp), raw	RAC	0.11	1.09	0.12	1.56	0.17	0.33	0.04	0.18	0.02	0.47	0.05
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.11	0.67	0.07	7.26	0.80	0.37	0.04	0.10	0.01	NC	-



## FLUDIOXONIL (211)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 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 0577	Carrots, raw	RAC	0.19	2.07	0.39	3.00	0.57	25.29	4.81	0.10	0.02	NC	-
VR 0494	Radish roots, raw	RAC	0.06	3.96	0.24	2.86	0.17	3.30	0.20	2.67	0.16	5.34	0.32
VR 0589	Potato, raw	RAC	1.5	22.45	33.68	10.47	15.71	193.10	289.65	98.00	147.00	8.03	12.05
VR 0508	Sweet potato, raw (incl dried)	RAC	3.5	28.83	100.91	61.55	215.43	0.15	0.53	221.94	776.79	NC	-
VR 0600	Yams, raw (incl dried)	RAC	3.5	70.93	248.26	30.62	107.17	0.10	0.35	5.65	19.78	30.85	107.98
VS 0624	Celery	RAC	4.55	3.66	16.65	2.65	12.06	4.84	22.02	2.47	11.24	4.94	22.48
GC 0080	Group of Cereal grains, raw, (incl processed) (incl sweet corn)	RAC	0.02	407.04	8.14	417.04	8.34	402.79	8.06	195.30	3.91	263.26	5.27
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	0.10	0.00	0.17	0.00
TN 0675	Pistachio nut, nutmeat	RAC	0.05	0.10	0.01	0.10	0.01	0.15	0.01	0.10	0.01	NC	-
SO 0495	Rape seed, raw (incl oil)	RAC	0.02	0.19	0.00	0.10	0.00	12.07	0.24	0.10	0.00	NC	-
SO 0691	Cotton seed, raw (incl oil)	RAC	0.05	8.14	0.41	0.32	0.02	2.84	0.14	2.69	0.13	0.97	0.05
HH 0720	Herbs, raw (incl dried)	RAC	2.65	1.85	4.90	1.67	4.43	2.80	7.42	1.24	3.29	2.75	7.29
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	0.003	5.84	0.02	10.18	0.03	24.29	0.07	4.52	0.01	14.43	0.04
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.003	1.05	0.00	1.14	0.00	18.69	0.06	0.94	0.00	3.12	0.01
MO 0105	Edible offal (mammalian), raw	RAC	0.02	4.64	0.09	1.97	0.04	10.01	0.20	3.27	0.07	3.98	0.08
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.008	108.75	0.87	70.31	0.56	436.11	3.49	61.55	0.49	79.09	0.63
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	0.028	0.10	0.00	0.70	0.02	0.97	0.03	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	3.84	0.04	4.41	0.04	27.25	0.27	1.13	0.01	7.39	0.07

Total intake (µg//person)=	620.8	476.3	701.3	1378.5	294.9
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (µg//person)=	24000	24000	24000	24000	24000
%ADI=	2.6%	2.0%	2.9%	5.7%	1.2%
Rounded %ADI=	3%	2%	3%	6%	1%

**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
FC 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	0.33	32.25	10.64	11.67	3.85	16.70	5.51	76.01	25.08	33.90	11.19	92.97	30.68
JF 0001	Group of Citrus fruit, juice	PP	0.015	1.30	0.02	2.37	0.04	0.22	0.00	13.88	0.21	0.75	0.01	2.63	0.04
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	0.10	0.01	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	0.10	0.08	0.61	0.46	0.10	0.08	6.64	5.01
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.44	2.67	1.17	8.77	3.86	0.10	0.04	3.03	1.33	0.70	0.31	4.34	1.91
DF 0014	Plums, dried (prunes)	PP	1.2	0.10	0.12	0.10	0.12	0.10	0.12	0.18	0.22	0.10	0.12	0.10	0.12
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	0.10	0.13	0.10	0.13	0.10	0.13	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	0.10	0.13	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	0.10	0.13	1.51	1.96
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.47	12.68	5.96	9.12	4.29	0.10	0.05	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	0.10	0.20	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	0.10	0.02	0.30	0.05	0.24	0.04	0.10	0.02
-	Graps must (from wine-grapes)	PP	0.11	0.33	0.04	0.13	0.01	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01
-	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	0.10	0.13	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	0.10	0.01	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	0.10	0.01	3.05	0.16	0.80	0.04	7.28	0.39	1.00	0.05
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	0.10	0.02	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	0.10	0.02	0.73	0.16	NC	-	1.67	0.37
VB 0405	Kohlrabi, raw	RAC	0.22	0.10	0.02	0.89	0.20	0.10	0.02	0.14	0.03	NC	-	0.33	0.07
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	0.10	0.00	1.11	0.01	0.11	0.00	1.50	0.02

## 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
-	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	0.10	0.00	0.38	0.00	0.10	0.00	0.14	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers) (Capsicum spp. Only)	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
-	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
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	0.10	0.68	0.91	6.19	0.10	0.68	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 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	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	0.10	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
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	0.58	0.01	0.10	0.00	0.37	0.00	0.10	0.00	1.65	0.02	0.30	0.00
-	Soya paste (i.e. miso)	PP	0.005	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.005	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	0.005	0.10	0.00	0.10	0.00	0.10	0.00	0.34	0.00	0.10	0.00	0.10	0.00
-	Soya flour	PP	0.005	0.10	0.00	0.86	0.00	0.10	0.00	1.02	0.01	0.10	0.00	0.15	0.00
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.04	1.62	0.06	3.22	0.13	0.92	0.04	1.50	0.06	2.90	0.12	0.17	0.01
VD 0524	Chick-pea (dry) (Cicer spp), raw	RAC	0.04	5.34	0.21	0.13	0.01	0.10	0.00	4.69	0.19	7.24	0.29	5.52	0.22
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.04	2.12	0.08	0.10	0.00	0.10	0.00	3.21	0.13	1.60	0.06	4.90	0.20
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	-	0.10	0.00	0.66	0.03	0.47	0.02	88.94	3.56
VR 0573	Arrowroot, raw	RAC	0.01	1.53	0.02	0.10	0.00	0.93	0.01	1.33	0.01	0.47	0.00	0.10	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									
				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 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.01	0.10	0.00	0.10	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	0.10	0.00	0.96	0.01	1.36	0.01	0.48	0.00	0.10	0.00
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.035	59.74	2.09	316.14	11.06	9.78	0.34	60.26	2.11	54.12	1.89	119.82	4.19
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	-	0.10	0.00	0.26	0.00	1.27	0.01
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.01	0.10	0.00	NC	-	25.12	0.25	0.10	0.00	0.10	0.00	0.97	0.01
VR 0600	Yams, raw (incl dried)	RAC	0.01	0.10	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	0.10	0.16	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	0.10	0.01	2.15	0.18
GC 0653	Triticale, raw (incl flour)	RAC	0.085	NC	-	NC	-	NC	-	0.10	0.01	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	0.10	0.00	1.12	0.02	NC	-	0.10	0.00	0.56	0.01	NC	-
CF 1210	Wheat, germ	PP	0.1	NC	-	NC	-	0.10	0.01	0.10	0.01	0.14	0.01	0.10	0.01
CP 1212	Wheat, wholemeal bread	PP	0.054	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01
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
GC 0640	Barley, raw	RAC	0.535	2.49	1.33	NC	-	0.10	0.05	0.10	0.05	0.18	0.10	0.38	0.20
-	Barley, pot&pearled	PP	0.086	7.12	0.61	7.34	0.63	0.10	0.01	0.10	0.01	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	0.10	0.01	0.10	0.01	0.48	0.04	0.10	0.01
-	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	0.10	0.00	1.04	0.01	0.18	0.00	0.33	0.00	0.10	0.00	0.10	0.00
-	Barley Malt Extract	PP	0.0054	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.535	0.10	0.05	7.05	3.77	0.10	0.05	1.71	0.91	0.96	0.51	0.10	0.05
CM 0649 (GC 0649)	Rice, husked, dry ( incl oil, incl beverages, incl starch, excl polished, excl flour)	REP	0.55	1.20	0.66	1.30	0.72	31.05	17.08	4.79	2.63	0.61	0.34	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	0.10	0.01	0.22	0.02	0.10	0.01	0.50	0.04	0.22	0.02	0.10	0.01
-	Rice, Fermented Beverages (rice wine, sake)	PP	0.11	NC	-	NC	-	NC	-	NC	-	0.10	0.01	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									
				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 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.2	4.34	0.87	0.10	0.02	16.25	3.25	15.82	3.16	10.97	2.19	2.92	0.58
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
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	0.10	0.00	NC	-	0.10	0.00	2.29	0.00	0.10	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	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	Mustard seeds, raw (incl flour, incl oil)	RAC	0.09	0.10	0.01	0.10	0.01	0.10	0.01	0.31	0.03	0.10	0.01	0.10	0.01
SO 0305	Olives for oil production, raw (incl oil)	RAC	0.09	12.61	1.13	1.35	0.12	0.27	0.02	8.04	0.72	0.58	0.05	21.80	1.96
SO 0495	Rape seed, raw	RAC	0.09	0.10	0.01	NC	-	NC	-	0.10	0.01	0.75	0.07	0.10	0.01
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 0693	Linseed, raw (incl oil)	RAC	0.09	0.10	0.01	NC	-	NC	-	0.10	0.01	0.13	0.01	NC	-
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	0.10	0.00	0.10	0.00	0.10	0.00	0.19	0.01	0.10	0.00	0.10	0.00
SO 0698	Poppy seed, raw (incl oil)	RAC	0.09	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01
SO 0699	Safflower seed, raw (incl oil)	RAC	0.09	0.10	0.01	0.20	0.02	0.10	0.01	0.10	0.01	0.29	0.03	0.10	0.01
SO 0700	Sesame seed, raw (incl oil)	RAC	0.09	1.22	0.11	0.10	0.01	0.54	0.05	4.23	0.38	0.82	0.07	2.77	0.25
SO 0701	Shea nut (karite nuts), nutmeat, raw (incl butter)	RAC	0.09	NC	-	NC	-	0.34	0.03	NC	-	NC	-	NC	-
SO 0702	Sunflower seed, raw	RAC	0.055	0.10	0.01	0.33	0.02	0.10	0.01	0.24	0.01	0.10	0.01	0.10	0.01
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
-	Castor bean, raw (incl oil)	RAC	0.09	NC	-	0.10	0.01	NC	-	NC	-	NC	-	0.10	0.01
-	Cucurbitaceae seeds, raw (melonseeds, pumpkin seeds, watermelon seeds)	RAC	0.09	0.10	0.01	NC	-	1.08	0.10	0.38	0.03	0.10	0.01	0.25	0.02
-	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

**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
SB 0716	Coffee beans 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
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
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)=				95.5		141.6		71.3		143.2		101.3		214.9	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (µg//person)=				1200		1200		1200		1200		1200		1200	
%ADI=				8.0%		11.8%		5.9%		11.9%		8.4%		17.9%	
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 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	0.33	38.66	12.76	54.93	18.13	26.36	8.70	51.46	16.98	51.06	16.85	466.36	153.90
JF 0001	Group of Citrus fruit, juice	PP	0.015	36.84	0.55	3.75	0.06	0.30	0.00	21.62	0.32	21.82	0.33	46.67	0.70
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	0.10	0.08	2.93	2.21	1.50	1.13	NC	-
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.44	5.55	2.44	4.37	1.92	6.08	2.68	3.66	1.61	3.93	1.73	0.46	0.20

**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
DF 0014	Plums, dried (prunes)	PP	1.2	0.61	0.73	0.35	0.42	0.10	0.12	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	0.10	0.05
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	0.10	0.13
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	1.3	1.31	1.70	5.50	7.15	0.10	0.13	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	0.10	0.13	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	0.10	0.20	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	0.10	0.02	2.24	0.36	2.27	0.36	0.34	0.05
-	Graps must (from wine-grapes)	PP	0.11	0.16	0.02	0.10	0.01	0.10	0.01	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	0.10	0.13	7.85	10.21	5.86	7.62	0.10	0.13
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
VB 0405	Kohlrabi, raw	RAC	0.22	NC	-	3.25	0.72	NC	-	NC	-	0.10	0.02	0.36	0.08
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	0.10	0.00	0.10	0.00	0.61	0.01	0.40	0.01	0.10	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers) (Capsicum spp. Only)	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
-	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
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	-

## 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 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
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	0.10	0.68
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 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	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
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	0.10	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	0.005	NC	-	NC	-	NC	-	1.87	0.01	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.005	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	0.005	0.45	0.00	0.29	0.00	2.93	0.01	4.35	0.02	0.10	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 0072	Peas (dry) (Pisum spp), raw	RAC	0.04	3.80	0.15	1.25	0.05	0.90	0.04	2.33	0.09	2.70	0.11	3.83	0.15
VD 0524	Chick-pea (dry) (Cicer spp), raw	RAC	0.04	0.27	0.01	1.33	0.05	0.32	0.01	0.15	0.01	0.10	0.00	0.10	0.00
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.04	0.95	0.04	1.18	0.05	0.40	0.02	0.96	0.04	0.71	0.03	1.28	0.05
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	0.10	0.01	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	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	NC	-	NC	-
VR 0573	Arrowroot, raw	RAC	0.01	0.10	0.00	0.10	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	0.10	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	0.10	0.00	NC	-	0.22	0.00	NC	-	0.78	0.01
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.035	225.03	7.88	234.24	8.20	71.48	2.50	177.55	6.21	234.55	8.21	37.71	1.32
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	-	0.10	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	-	0.10	0.00	0.71	0.01	NC	-	17.57	0.18



**FLUXAPYROXAD (256)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.02 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets 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 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	0.10	0.01	0.17	0.01	0.29	0.02	0.10	0.01	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	-	0.10	0.00	0.83	0.01	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.1	0.97	0.10	0.10	0.01	0.10	0.01	0.10	0.01	NC	-	0.10	0.01
CP 1212	Wheat, wholemeal bread	PP	0.054	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01
CP 1211	Wheat, white bread	PP	0.01	1.30	0.01	0.46	0.00	0.10	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
GC 0640	Barley, raw	RAC	0.535	0.10	0.05	NC	-	0.10	0.05	1.36	0.73	NC	-	NC	-
-	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	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01	0.68	0.05	0.10	0.01
-	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	-	0.10	0.00	0.10	0.00	NC	-	2.14	0.01
-	Barley Malt Extract	PP	0.0054	0.37	0.00	0.10	0.00	0.10	0.00	0.10	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 oil, incl beverages, incl starch, excl polished, excl flour)	REP	0.55	2.43	1.34	1.62	0.89	0.58	0.32	1.69	0.93	NC	-	5.03	2.77
CM1205	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	0.10	0.01	0.23	0.02	0.10	0.01
-	Rice, Fermented Beverages (rice wine, sake)	PP	0.11	NC	-	NC	-	0.10	0.01	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 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
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	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

**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 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 0090	Mustard seeds, raw (incl flour, incl oil)	RAC	0.09	0.30	0.03	0.48	0.04	0.33	0.03	0.63	0.06	1.03	0.09	0.40	0.04
SO 0305	Olives for oil production, raw (incl oil)	RAC	0.09	17.78	1.60	48.67	4.38	0.10	0.01	22.50	2.03	14.09	1.27	2.46	0.22
SO 0495	Rape seed, raw	RAC	0.09	NC	-	NC	-	0.10	0.01	NC	-	NC	-	NC	-
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 0693	Linseed, raw (incl oil)	RAC	0.09	NC	-	NC	-	0.10	0.01	0.10	0.01	NC	-	NC	-
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	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.15	0.00	0.75	0.02
SO 0698	Poppy seed, raw (incl oil)	RAC	0.09	0.10	0.01	0.25	0.02	0.10	0.01	0.10	0.01	NC	-	NC	-
SO 0699	Safflower seed, raw (incl oil)	RAC	0.09	0.10	0.01	0.10	0.01	0.10	0.01	0.16	0.01	NC	-	NC	-
SO 0700	Sesame seed, raw (incl oil)	RAC	0.09	0.61	0.05	0.10	0.01	1.53	0.14	0.85	0.08	0.10	0.01	0.14	0.01
SO 0701	Shea nut (karite nuts), nutmeat, raw (incl butter)	RAC	0.09	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
SO 0702	Sunflower seed, raw	RAC	0.055	0.10	0.01	1.32	0.07	0.10	0.01	1.17	0.06	NC	-	0.10	0.01
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
-	Castor bean, raw (incl oil)	RAC	0.09	NC	-	NC	-	0.10	0.01	NC	-	NC	-	NC	-
-	Cucurbitaceae seeds, raw (melonseeds, pumpkin seeds, watermelon seeds)	RAC	0.09	NC	-	NC	-	0.10	0.01	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	0.10	0.01	0.10	0.01	0.17	0.02	0.22	0.02	NC	-	0.32	0.03
SB 0716	Coffee beans 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
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

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	
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)=					185.0		195.0		240.1		195.1		208.8		232.5	
Bodyweight per region (kg bw) =					60		60		55		60		60		60	
ADI (µg//person)=					1200		1200		1100		1200		1200		1200	
%ADI=					15.4%		16.3%		21.8%		16.3%		17.4%		19.4%	
Rounded %ADI=					20%		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 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	0.33	20.93	6.91	2.35	0.78	30.71	10.13	0.15	0.05	4.45	1.47
JF 0001	Group of Citrus fruit, juice	PP	0.015	0.11	0.00	0.29	0.00	13.55	0.20	0.14	0.00	0.33	0.00
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	0.10	0.01	0.10	0.01	7.19	0.36	0.10	0.01	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	0.755	0.10	0.08	0.10	0.08	5.96	4.50	0.10	0.08	NC	-
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.44	0.10	0.04	0.10	0.04	16.65	7.33	0.10	0.04	NC	-
DF 0014	Plums, dried (prunes)	PP	1.2	0.10	0.12	0.10	0.12	0.37	0.44	0.10	0.12	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.465	0.10	0.05	0.10	0.05	10.76	5.00	0.10	0.05	NC	-
FB 2005	Subgroup of Caneberries, raw	RAC	1.3	0.10	0.13	7.30	9.49	2.29	2.98	0.10	0.13	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	0.10	0.05	0.10	0.05
DF 0269	Grapes, dried (= currants, raisins and sultanais) (from table-grapes)	PP	2	0.10	0.20	0.13	0.26	1.06	2.12	0.10	0.20	0.10	0.20
JF 0269	Grape juice (from wine grapes)	PP	0.16	0.10	0.02	0.10	0.02	0.41	0.07	0.10	0.02	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
-	Graps must (from wine-grapes)	PP	0.11	0.10	0.01	0.10	0.01	0.11	0.01	0.10	0.01	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	0.10	0.13	0.10	0.13	3.37	4.38	0.10	0.13	0.10	0.13
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	0.10	0.01	20.12	2.92
FI 0350	Papaya, raw	RAC	0.054	6.47	0.35	0.25	0.01	0.19	0.01	0.10	0.01	26.42	1.43
VA 0381	Garlic, raw	RAC	0.23	0.82	0.19	2.06	0.47	3.79	0.87	0.10	0.02	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	0.10	0.02	0.10	0.02	4.86	1.07	0.10	0.02	NC	-
VB 0402	Brussels sprouts, raw	RAC	0.22	0.88	0.19	0.69	0.15	2.89	0.64	0.10	0.02	NC	-
VB 0041	Cabbages, head, raw	RAC	0.04	3.82	0.15	2.99	0.12	49.16	1.97	0.10	0.00	NC	-
VB 0467	Chinese cabbage, type pe-tsai, raw	RAC	0.22	0.62	0.14	0.49	0.11	NC	-	0.10	0.02	NC	-
VB 0405	Kohlrabi, raw	RAC	0.22	0.12	0.03	0.10	0.02	1.81	0.40	0.10	0.02	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	0.10	0.01
VO 0448	Tomato, raw	RAC	0.07	12.99	0.91	4.79	0.34	58.40	4.09	0.92	0.06	0.10	0.01
-	Tomato, canned (& peeled)	PP	0.013	0.10	0.00	0.10	0.00	2.42	0.03	0.10	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	0.10	0.00	0.10	0.00	0.42	0.01	0.10	0.00	0.10	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers) (Capsicum spp. Only)	RAC	0.07	8.97	0.63	14.13	0.99	25.14	1.76	0.91	0.06	NC	-
-	Peppers, chili, dried	PP	0.7	0.58	0.41	1.27	0.89	1.21	0.85	0.12	0.08	NC	-
VO 2046	Subgroup of eggplants	RAC	0.07	1.31	0.09	8.26	0.58	3.95	0.28	0.10	0.01	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.51	0.29	0.15	0.10	0.05	6.71	3.42	0.10	0.05	NC	-
VL 0502	Spinach, raw	RAC	6.8	0.17	1.16	0.10	0.68	0.81	5.51	0.10	0.68	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 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	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	0.10	0.00	NC	-
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.03	0.21	0.01	0.10	0.00	5.51	0.17	0.10	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

**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
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	2.76	0.03	0.10	0.00	0.33	0.00	3.16	0.03	NC	-
-	Soya paste (i.e. miso)	PP	0.005	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.005	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	0.005	0.10	0.00	0.13	0.00	0.17	0.00	0.10	0.00	0.56	0.00
-	Soya flour	PP	0.005	0.11	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.04	1.53	0.06	2.52	0.10	3.52	0.14	3.56	0.14	0.74	0.03
VD 0524	Chick-pea (dry) (Cicer spp), raw	RAC	0.04	1.09	0.04	1.56	0.06	0.33	0.01	0.18	0.01	0.47	0.02
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.04	0.67	0.03	7.26	0.29	0.37	0.01	0.10	0.00	NC	-
VR 0577	Carrots, raw	RAC	0.06	2.07	0.12	3.00	0.18	25.29	1.52	0.10	0.01	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	0.10	0.00	0.10	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	0.10	0.00	0.10	0.00	20.14	0.20
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.035	23.96	0.84	13.56	0.47	213.41	7.47	104.35	3.65	8.56	0.30
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	-
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.01	NC	-	NC	-	0.10	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	0.10	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	0.10	0.01	0.10	0.01	13.95	1.19	0.10	0.01	0.88	0.07
GC 0653	Triticale, raw (incl flour)	RAC	0.085	0.10	0.01	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	0.10	0.00	NC	-	NC	-	NC	-	0.97	0.01
CF 1210	Wheat, germ	PP	0.1	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.054	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01
CP 1211	Wheat, white bread	PP	0.01	0.43	0.00	0.41	0.00	1.56	0.02	0.11	0.00	0.10	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

**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
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
GC 0640	Barley, raw	RAC	0.535	0.10	0.05	0.10	0.05	0.16	0.09	NC	-	NC	-
-	Barley, pot&pearled	PP	0.086	5.46	0.47	0.10	0.01	1.44	0.12	0.10	0.01	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	0.08	0.10	0.01	NC	-	0.32	0.03	0.10	0.01	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	0.10	0.00	0.11	0.00	0.67	0.00	0.10	0.00	4.61	0.02
-	Barley Malt Extract	PP	0.0054	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.535	0.37	0.20	0.10	0.05	2.79	1.49	0.10	0.05	NC	-
CM 0649 (GC 0649)	Rice, husked, dry ( incl oil, incl beverages, incl starch, excl polished, excl flour)	REP	0.55	13.54	7.45	4.12	2.27	1.96	1.08	0.10	0.06	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	0.10	0.01	0.13	0.01	0.16	0.01	0.10	0.01	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 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
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	0.10	0.00	0.10	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	0.10	0.00	0.17	0.00
TN 0085	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 0090	Mustard seeds, raw (incl flour, incl oil)	RAC	0.09	0.10	0.01	0.19	0.02	0.32	0.03	0.10	0.01	0.10	0.01
SO 0305	Olives for oil production, raw (incl oil)	RAC	0.09	0.18	0.02	0.11	0.01	11.00	0.99	0.10	0.01	0.49	0.04
SO 0495	Rape seed, raw	RAC	0.09	NC	-	0.10	0.01	NC	-	NC	-	NC	-
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 0693	Linseed, raw (incl oil)	RAC	0.09	0.10	0.01	NC	-	0.10	0.01	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	0.10	0.00	0.10	0.00	0.10	0.00	NC	-	NC	-
SO 0698	Poppy seed, raw (incl oil)	RAC	0.09	0.10	0.01	0.10	0.01	0.11	0.01	NC	-	NC	-
SO 0699	Safflower seed, raw (incl oil)	RAC	0.09	0.10	0.01	NC	-	NC	-	NC	-	NC	-
SO 0700	Sesame seed, raw (incl oil)	RAC	0.09	2.34	0.21	0.66	0.06	0.26	0.02	9.84	0.89	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
SO 0701	Shea nut (karite nuts), nutmeat, raw (incl butter)	RAC	0.09	0.95	0.09	NC	-	NC	-	NC	-	NC	-
SO 0702	Sunflower seed, raw	RAC	0.055	0.10	0.01	0.10	0.01	0.10	0.01	2.23	0.12	NC	-
OR 0702	Sunflower seed oil, edible	PP	0.004	0.37	0.00	0.10	0.00	12.98	0.05	4.01	0.02	0.20	0.00
-	Castor bean, raw (incl oil)	RAC	0.09	NC	-	NC	-	NC	-	NC	-	NC	-
-	Cucurbitaceae seeds, raw (melonseeds, pumpkin seeds, watermelon seeds)	RAC	0.09	1.81	0.16	NC	-	0.10	0.01	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 beans 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
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	-
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)=	104.1	84.1	177.8	121.3	93.6
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (µg//person)=	1200	1200	1200	1200	1200
%ADI=	8.7%	7.0%	14.8%	10.1%	7.8%
Rounded %ADI=	9%	7%	10%	10%	8%

IMAZALIL (110)			International Estimated Daily Intake (IEDI)				ADI = 0 - 0.03 mg/kg bw								
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
Subgroup of Lemons and limes, raw (incl lemon juice, excl kumquat commodities)		RAC	0.18	2.46	0.44	2.18	0.39	0.74	0.13	10.99	1.98	7.09	1.28	14.51	2.61
Kumquats, raw (incl juice)		RAC	5	2.36	11.80	0.27	1.35	3.19	15.95	14.44	72.20	1.66	8.30	1.71	8.55
Subgroup of Oranges, sweet, sour, raw		RAC	0.09	20.66	1.86	5.23	0.47	11.90	1.07	37.90	3.41	21.16	1.90	56.46	5.08
Subgroup of Oranges, juice (single strength, incl. concentrated)		PP	0.01	1.27	0.01	2.20	0.02	0.10	0.00	11.81	0.12	0.46	0.00	1.69	0.02
Banana, raw (incl raw plantains)		RAC	0.05	4.90	0.25	6.94	0.35	99.37	4.97	32.44	1.62	48.24	2.41	24.67	1.23
Tomato, raw (incl juice, incl paste, incl canned)		RAC	0.13	51.75	6.73	81.80	10.63	16.99	2.21	102.02	13.26	26.32	3.42	214.77	27.92
Potato, raw		RAC	2.2	59.07	129.95	313.97	690.73	9.23	20.31	48.16	105.95	52.38	115.24	117.43	258.35
Triticale, raw (incl flour)		RAC	0	NC	-	NC	-	NC	-	0.10	0.00	0.39	0.00	NC	-
Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)		RAC	0	381.15	0.00	341.55	0.00	38.35	0.00	281.89	0.00	172.83	0.00	434.07	0.00
Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)		RAC	0	19.91	0.00	31.16	0.00	5.04	0.00	3.10	0.00	9.77	0.00	4.31	0.00
MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle		RAC	0.04	24.96	1.00	57.95	2.32	16.70	0.67	38.38	1.54	26.46	1.06	29.00	1.16
MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat		RAC	0.04	6.24	0.25	14.49	0.58	4.18	0.17	9.60	0.38	6.62	0.26	7.25	0.29
Mammalian fats, raw, excl milk fats (incl rendered fats)		RAC	0.04	3.29	0.13	6.14	0.25	0.82	0.03	1.57	0.06	2.23	0.09	1.07	0.04
Edible offal (mammalian), raw		RAC	0.34	4.79	1.63	9.68	3.29	2.97	1.01	5.49	1.87	3.84	1.31	5.03	1.71
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
Poultry meat, raw (incl prepared) - 90% as muscle		RAC	0.04	13.17	0.53	26.78	1.07	7.24	0.29	116.71	4.67	22.54	0.90	32.09	1.28
Poultry meat, raw (incl prepared) - 10% as fat		RAC	0.04	1.46	0.06	2.98	0.12	0.80	0.03	12.97	0.52	2.50	0.10	3.57	0.14
Poultry fat, raw (incl rendered)		RAC	0.04	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
Poultry edible offal, raw (incl prepared)		RAC	0.04	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.21	0.24	0.01	0.10	0.00
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)=				154.8		712.0		46.9		208.1		136.5		308.7	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (µg//person)=				1800		1800		1800		1800		1800		1800	
%ADI=				8.6%		39.6%		2.6%		11.6%		7.6%		17.1%	
Rounded %ADI=				9%		40%		3%		10%		8%		20%	



IMAZALIL (110)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.03 mg/kg bw								
Codex Code		Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		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, excl kumquat commodities)	RAC	0.18	5.45	0.98	9.83	1.77	0.92	0.17	10.85	1.95	5.27	0.95	5.23	0.94	
FC 0303	Kumquats, raw (incl juice)	RAC	5	4.67	23.35	5.86	29.30	1.96	9.80	1.45	7.25	17.05	85.25	1.37	6.85	
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.09	15.68	1.41	24.00	2.16	6.80	0.61	29.09	2.62	15.39	1.39	160.47	14.44	
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.01	33.31	0.33	1.78	0.02	0.28	0.00	18.97	0.19	14.01	0.14	13.36	0.13	
FI 0327	Banana, raw (incl raw plantains)	RAC	0.05	25.61	1.28	23.59	1.18	23.58	1.18	24.26	1.21	18.88	0.94	101.55	5.08	
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.13	64.74	8.42	68.31	8.88	36.05	4.69	82.09	10.67	54.50	7.09	11.69	1.52	
VR 0589	Potato, raw	RAC	2.2	202.90	446.38	215.82	474.80	69.98	153.96	166.61	366.54	214.41	471.70	25.32	55.70	
GC 0653	Triticale, raw (incl flour)	RAC	0	0.10	0.00	0.17	0.00	0.29	0.00	0.10	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	253.07	0.00	244.73	0.00	134.44	0.00	235.10	0.00	216.39	0.00	167.40	0.00	
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0	36.18	0.00	53.45	0.00	9.39	0.00	35.25	0.00	46.68	0.00	15.92	0.00	
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.04	112.02	4.48	120.71	4.83	63.46	2.54	88.99	3.56	96.24	3.85	41.02	1.64	
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.04	28.01	1.12	30.18	1.21	15.86	0.63	22.25	0.89	24.06	0.96	10.25	0.41	
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.04	6.44	0.26	15.51	0.62	3.79	0.15	8.29	0.33	18.44	0.74	8.00	0.32	
MO 0105	Edible offal (mammalian), raw	RAC	0.34	15.17	5.16	5.19	1.76	6.30	2.14	6.78	2.31	3.32	1.13	3.17	1.08	
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	0.04	66.38	2.66	48.47	1.94	21.58	0.86	78.41	3.14	48.04	1.92	76.01	3.04	
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.04	7.38	0.30	5.39	0.22	2.40	0.10	8.71	0.35	5.34	0.21	8.45	0.34	
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.04	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.03	NC	-	
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.04	0.33	0.01	0.72	0.03	0.27	0.01	0.35	0.01	0.80	0.03	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)=					496.7		529.3		177.4		401.7		577.1		91.7	
Bodyweight per region (kg bw) =					60		60		55		60		60		60	
ADI (µg//person)=					1800		1800		1650		1800		1800		1800	
%ADI=					27.6%		29.4%		10.8%		22.3%		32.1%		5.1%	
Rounded %ADI=					30%		30%		10%		20%		30%		5%	

IMAZALIL (110)				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
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice, excl kumquat commodities)	RAC	0.18	0.62	0.11	0.74	0.13	4.44	0.80	0.10	0.02	NC	-
FC 0303	Kumquats, raw (incl juice)	RAC	5	18.35	91.75	0.23	1.15	1.78	8.90	0.10	0.50	3.35	16.75
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.09	1.18	0.11	1.11	0.10	14.28	1.29	0.10	0.01	1.08	0.10
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.01	0.10	0.00	0.26	0.00	12.61	0.13	0.14	0.00	0.33	0.00
FI 0327	Banana, raw (incl raw plantains)	RAC	0.05	44.76	2.24	118.16	5.91	25.19	1.26	454.49	22.72	310.23	15.51
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.13	15.50	2.02	5.78	0.75	71.52	9.30	2.00	0.26	12.50	1.63
VR 0589	Potato, raw	RAC	2.2	22.45	49.39	10.47	23.03	193.10	424.82	98.00	215.60	8.03	17.67
GC 0653	Triticale, raw (incl flour)	RAC	0	0.10	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	57.20	0.00	110.47	0.00	272.62	0.00	25.82	0.00	132.04	0.00
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0	11.58	0.00	2.33	0.00	46.71	0.00	3.72	0.00	16.26	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.04	23.34	0.93	40.71	1.63	97.15	3.89	18.06	0.72	57.71	2.31
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.04	5.84	0.23	10.18	0.41	24.29	0.97	4.52	0.18	14.43	0.58
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.04	1.05	0.04	1.14	0.05	18.69	0.75	0.94	0.04	3.12	0.12
MO 0105	Edible offal (mammalian), raw	RAC	0.34	4.64	1.58	1.97	0.67	10.01	3.40	3.27	1.11	3.98	1.35
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	0.04	3.53	0.14	10.83	0.43	51.36	2.05	4.53	0.18	50.00	2.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.04	0.39	0.02	1.20	0.05	5.71	0.23	0.50	0.02	5.56	0.22
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.04	NC	-	NC	-	0.32	0.01	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.04	0.10	0.00	0.70	0.03	0.97	0.04	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)=				148.6		34.4		458.4		241.4		58.4	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (µg/person)=				1800		1800		1800		1800		1800	
%ADI=				8.3%		1.9%		25.5%		13.4%		3.2%	
Rounded %ADI=				8%		2%		30%		10%		3%	

## ISOFETAMID (290)

## 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 juice, incl apple cider)	RAC	0.135	19.79	2.67	38.25	5.16	17.96	2.42	32.56	4.40	8.08	1.09	64.45	8.70
FS 0013	Subgroup of Cherries, raw	RAC	1.1	0.92	1.01	9.15	10.07	0.10	0.11	0.61	0.67	0.10	0.11	6.64	7.30
FS 0014	Subgroup of Plums, raw	RAC	0.175	2.40	0.42	8.60	1.51	0.10	0.02	2.52	0.44	0.58	0.10	4.16	0.73
DF 0014	Plums, dried (prunes)	PP	0.56	0.10	0.06	0.10	0.06	0.10	0.06	0.18	0.10	0.10	0.06	0.10	0.06
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.76	8.01	6.09	5.87	4.46	0.18	0.14	8.19	6.22	1.64	1.25	22.46	17.07
FB 2005	Subgroup of Caneberries, raw	RAC	0.68	0.42	0.29	1.05	0.71	0.10	0.07	0.10	0.07	0.10	0.07	1.24	0.84
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.31	0.53	0.16	1.31	0.41	0.40	0.12	1.66	0.51	0.10	0.03	0.99	0.31
FB 2008	Subgroup of Small fruit vine climbing, raw (incl processed)	RAC	0.73	16.25	11.86	28.96	21.14	2.87	2.10	24.22	17.68	9.33	6.81	68.64	50.11
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.7	0.51	0.87	0.51	0.87	0.10	0.17	1.27	2.16	0.12	0.20	2.07	3.52
JF 0269	Grape juice (from wine grapes)	PP	0.095	0.14	0.01	0.29	0.03	0.10	0.01	0.30	0.03	0.24	0.02	0.10	0.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.28	0.67	0.19	12.53	3.51	2.01	0.56	1.21	0.34	3.53	0.99	4.01	1.12
FB 2009	Subgroup of Low growing berries, raw	RAC	0.49	0.71	0.35	2.02	0.99	0.10	0.05	1.39	0.68	0.37	0.18	2.53	1.24
VL 0483	Lettuce, leaf, raw	RAC	0.115	0.53	0.06	0.36	0.04	0.16	0.02	6.21	0.71	1.90	0.22	6.05	0.70
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.096	0.68	0.07	NC	-	NC	-	0.39	0.04	0.22	0.02	0.49	0.05
<b>014B</b>	<b>Peas with pods</b>	-	0.096	-	-	-	-	-	-	-	-	-	-	-	-
VD 2065	Subgroup of dry beans, raw (incl processed)	RAC	0.01	78.20	0.78	60.68	0.61	35.89	0.36	80.34	0.80	75.90	0.76	87.62	0.88
VD 2066	Subgroup of dry peas, raw	RAC	0.01	9.09	0.09	3.35	0.03	1.06	0.01	9.48	0.09	15.11	0.15	10.58	0.11
TN 0660	Almonds, nutmeat	RAC	0.01	1.38	0.01	0.10	0.00	0.10	0.00	1.00	0.01	0.10	0.00	0.81	0.01
SO 0495	Rape seed, raw	RAC	0.01	0.10	0.00	NC	-	NC	-	0.10	0.00	0.75	0.01	0.10	0.00
OR 0495	Rape seed oil, edible	PP	0.02	0.35	0.01	0.44	0.01	0.19	0.00	0.97	0.02	3.28	0.07	0.77	0.02
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	0.012	6.24	0.07	14.49	0.17	4.18	0.05	9.60	0.12	6.62	0.08	7.25	0.09
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.012	3.29	0.04	6.14	0.07	0.82	0.01	1.57	0.02	2.23	0.03	1.07	0.01
MO 0105	Edible offal (mammalian), raw	RAC	0.058	4.79	0.28	9.68	0.56	2.97	0.17	5.49	0.32	3.84	0.22	5.03	0.29
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.003	289.65	0.87	485.88	1.46	26.92	0.08	239.03	0.72	199.91	0.60	180.53	0.54
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



ISOFETAMID (290)				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
VD 2065	Subgroup of dry beans, raw (incl processed)	RAC	0.01	107.87	1.08	119.29	1.19	45.91	0.46	201.31	2.01	224.04	2.24	104.90	1.05
VD 2066	Subgroup of dry peas, raw	RAC	0.01	5.01	0.05	3.76	0.04	1.82	0.02	3.44	0.03	3.49	0.03	5.15	0.05
TN 0660	Almonds, nutmeat	RAC	0.01	0.81	0.01	2.21	0.02	0.10	0.00	1.02	0.01	1.47	0.01	NC	-
SO 0495	Rape seed, raw	RAC	0.01	NC	-	NC	-	0.10	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.02	12.52	0.25	7.63	0.15	3.00	0.06	6.01	0.12	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.01	112.02	1.12	120.71	1.21	63.46	0.63	88.99	0.89	96.24	0.96	41.02	0.41
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.012	28.01	0.34	30.18	0.36	15.86	0.19	22.25	0.27	24.06	0.29	10.25	0.12
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.012	6.44	0.08	15.51	0.19	3.79	0.05	8.29	0.10	18.44	0.22	8.00	0.10
MO 0105	Edible offal (mammalian), raw	RAC	0.058	15.17	0.88	5.19	0.30	6.30	0.37	6.78	0.39	3.32	0.19	3.17	0.18
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.003	388.92	1.17	335.88	1.01	49.15	0.15	331.25	0.99	468.56	1.41	245.45	0.74
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)=				166.2		137.6		23.4		82.4		134.6		15.9	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (µg/person)=				3000		3000		2750		3000		3000		3000	
%ADI=				5.5%		4.6%		0.8%		2.7%		4.5%		0.5%	
Rounded %ADI=				6%		5%		1%		3%		4%		1%	

ISOFETAMID (290)				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		
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.135	68.89	9.30	11.06	1.49	80.62	10.88	189.82	25.63	19.56	2.64		
FS 0013	Subgroup of Cherries, raw	RAC	1.1	0.10	0.11	0.10	0.11	5.96	6.56	0.10	0.11	NC	-		
FS 0014	Subgroup of Plums, raw	RAC	0.175	0.10	0.02	0.10	0.02	15.56	2.72	0.10	0.02	NC	-		
DF 0014	Plums, dried (prunes)	PP	0.56	0.10	0.06	0.10	0.06	0.37	0.21	0.10	0.06	NC	-		

## ISOFETAMID (290)

## 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
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.76	0.10	0.08	0.10	0.08	10.76	8.18	0.10	0.08	NC	-
FB 2005	Subgroup of Caneberries, raw	RAC	0.68	0.10	0.07	7.30	4.96	2.29	1.56	0.10	0.07	NC	-
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.31	0.82	0.25	4.05	1.26	5.94	1.84	0.43	0.13	2.66	0.82
FB 2008	Subgroup of Small fruit vine climbing, raw (incl processed)	RAC	0.73	0.60	0.44	1.26	0.92	103.25	75.37	0.74	0.54	44.23	32.29
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.7	0.10	0.17	0.13	0.22	1.06	1.80	0.10	0.17	0.10	0.17
JF 0269	Grape juice (from wine grapes)	PP	0.095	0.10	0.01	0.10	0.01	0.41	0.04	0.10	0.01	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.28	0.31	0.09	0.23	0.06	60.43	16.92	0.52	0.15	31.91	8.93
FB 2009	Subgroup of Low growing berries, raw	RAC	0.49	0.10	0.05	0.10	0.05	3.37	1.65	0.10	0.05	0.10	0.05
VL 0483	Lettuce, leaf, raw	RAC	0.115	0.29	0.03	0.10	0.01	6.71	0.77	0.10	0.01	NC	-
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.096	NC	-	NC	-	NC	-	NC	-	NC	-
<b>014B</b>	<b>Peas with pods</b>	-	0.096	-	-	-	-	-	-	-	-	-	-
VD 2065	Subgroup of dry beans, raw (incl processed)	RAC	0.01	41.93	0.42	19.42	0.19	108.31	1.08	66.18	0.66	42.47	0.42
VD 2066	Subgroup of dry peas, raw	RAC	0.01	4.43	0.04	11.36	0.11	4.22	0.04	9.36	0.09	1.21	0.01
TN 0660	Almonds, nutmeat	RAC	0.01	0.10	0.00	0.10	0.00	0.61	0.01	0.10	0.00	NC	-
SO 0495	Rape seed, raw	RAC	0.01	NC	-	0.10	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.02	0.10	0.00	0.10	0.00	4.62	0.09	0.10	0.00	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	0.012	5.84	0.07	10.18	0.12	24.29	0.29	4.52	0.05	14.43	0.17
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.012	1.05	0.01	1.14	0.01	18.69	0.22	0.94	0.01	3.12	0.04
MO 0105	Edible offal (mammalian), raw	RAC	0.058	4.64	0.27	1.97	0.11	10.01	0.58	3.27	0.19	3.98	0.23
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.003	108.75	0.33	70.31	0.21	436.11	1.31	61.55	0.18	79.09	0.24
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)=				12.0		10.4		133.1		28.4		46.6	
Bodyweight per region (kg bw) =				60		60		60		60		60	

**ISOFETAMID (290)**

## 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
		ADI (µg//person)=			3000		3000		3000		3000		3000
		%ADI=			0.4%		0.3%		4.4%		0.9%		1.6%
		Rounded %ADI=			0%		0%		4%		1%		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
-	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	0.10	0.02	0.74	0.16	0.10	0.02	0.10	0.02	0.10	0.02	0.10	0.02
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.365	12.68	4.63	9.12	3.33	0.10	0.04	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	0.10	0.06	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	0.10	0.02	0.30	0.05	0.24	0.04	0.10	0.02
-	Graps must (from wine-grapes)	PP	0.11	0.33	0.04	0.13	0.01	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01
-	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	0.10	0.01	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	0.10	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	0.10	0.32	0.28	0.90	0.10	0.32	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	RAC	0.045	1.43	0.06	2.61	0.12	1.05	0.05	2.01	0.09	2.59	0.12	6.24	0.28
VR 0574	Beetroot, raw	RAC	0	3.42	0.00	6.06	0.00	3.75	0.00	9.11	0.00	NC	-	4.39	0.00
VR 0596	Sugar beet, raw (incl sugar)	RAC	0	0.13	0.00	NC	-	0.10	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 nuts, nutmeat	RAC	0.1	0.10	0.01	0.10	0.01	0.10	0.01	0.14	0.01	0.10	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	0.10	0.01	7.63	0.76

**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
-	Olive oil (virgin and residue oil)	PP	0.34	2.17	0.74	0.13	0.04	0.10	0.03	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
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)=				22.0		29.0		2.6		26.9		8.9		65.2	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (µg/person)=				18000		18000		18000		18000		18000		18000	
%ADI=				0.1%		0.2%		0.0%		0.1%		0.0%		0.4%	
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 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
-	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	0.10	0.04
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	0.10	0.06	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	0.10	0.02	2.24	0.40	2.27	0.41	0.34	0.06
-	Graps must (from wine-grapes)	PP	0.11	0.16	0.02	0.10	0.01	0.10	0.01	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	0.10	0.01	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
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



## 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 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	0.10	0.32
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	RAC	0.045	NC	-	NC	-	8.25	0.37	3.03	0.14	NC	-	0.91	0.04
VR 0574	Beetroot, raw	RAC	0	9.91	0.00	6.34	0.00	NC	-	9.65	0.00	19.11	0.00	6.47	0.00
VR 0596	Sugar beet, raw (incl sugar)	RAC	0	0.10	0.00	NC	-	0.10	0.00	0.10	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 nuts, 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	0.10	0.01	0.10	0.01	0.57	0.06	0.10	0.01	NC	-
-	Olive oil (virgin and residue oil)	PP	0.34	3.40	1.16	9.49	3.23	0.10	0.03	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)=	40.0	46.8	24.5	26.2	73.4	10.0
Bodyweight per region (kg bw) =	60	60	55	60	60	60
ADI (µg//person)=	18000	18000	16500	18000	18000	18000
%ADI=	0.2%	0.3%	0.1%	0.1%	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
-	Peaches and nectarines, raw	RAC	0.37	0.10	0.04	0.10	0.04	7.47	2.76	0.10	0.04	NC	-
FB 0021	Currants, Black, Red, White, raw	RAC	0.21	0.10	0.02	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	0.10	0.04	0.10	0.04
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.58	0.10	0.06	0.13	0.08	1.06	0.61	0.10	0.06	0.10	0.06
JF 0269	Grape juice (from wine grapes)	PP	0.18	0.10	0.02	0.10	0.02	0.41	0.07	0.10	0.02	NC	-
-	Graps must (from wine-grapes)	PP	0.11	0.10	0.01	0.10	0.01	0.11	0.01	0.10	0.01	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	0.10	0.01	0.10	0.01	1.75	0.18	0.10	0.01	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	0.10	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	0.10	0.00	0.29	0.01
VA 0384	Leek, raw	RAC	3.2	0.10	0.32	1.44	4.61	1.22	3.90	0.10	0.32	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	0.10	0.01
VO 0445	Peppers, sweet, raw	RAC	0.045	1.24	0.06	1.27	0.06	NC	-	0.10	0.00	NC	-
VR 0574	Beetroot, raw	RAC	0	5.86	0.00	4.23	0.00	9.46	0.00	3.96	0.00	7.91	0.00
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 nuts, nutmeat	RAC	0.1	0.15	0.02	0.22	0.02	0.31	0.03	0.10	0.01	0.10	0.01
SO 0305	Olives for oil production, raw	RAC	0.1	NC	-	NC	-	0.10	0.01	NC	-	NC	-
-	Olive oil (virgin and residue oil)	PP	0.34	0.10	0.03	0.10	0.03	2.14	0.73	0.10	0.03	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
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
-	-	-	-	-	-	-	-	-	-	-	-	-	-

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
	Total intake (µg//person)=				3.2		8.7		32.9		2.7		7.0
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg//person)=				18000		18000		18000		18000		18000
	%ADI=				0.0%		0.0%		0.2%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%

LUFENURON (286)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.02 mg/kg bw							
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	0.1	2.42	0.24	2.15	0.22	0.43	0.04	10.74	1.07	6.59	0.66	14.06	1.41
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.09	20.66	1.86	5.23	0.47	11.90	1.07	37.90	3.41	21.16	1.90	56.46	5.08
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.01	1.27	0.01	2.20	0.02	0.10	0.00	11.81	0.12	0.46	0.00	1.69	0.02
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.29	19.35	5.61	34.06	9.88	17.87	5.18	25.74	7.46	7.69	2.23	56.85	16.49
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.06	0.32	0.02	3.07	0.18	0.10	0.01	5.00	0.30	0.29	0.02	5.57	0.33
VC 0424	Cucumber, raw	RAC	0.02	8.01	0.16	30.66	0.61	1.45	0.03	19.84	0.40	0.27	0.01	34.92	0.70
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.02	8.90	0.18	8.64	0.17	0.80	0.02	17.90	0.36	2.80	0.06	29.17	0.58
VO 0448	Tomato, raw	RAC	0.08	41.73	3.34	75.65	6.05	10.66	0.85	82.87	6.63	24.75	1.98	200.93	16.07
-	Tomato, canned (& peeled)	PP	0.014	0.20	0.00	0.31	0.00	0.10	0.00	1.11	0.02	0.11	0.00	1.50	0.02
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.078	2.34	0.18	1.33	0.10	1.57	0.12	4.24	0.33	0.34	0.03	2.83	0.22
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.014	0.29	0.00	0.29	0.00	0.10	0.00	0.38	0.01	0.10	0.00	0.14	0.00
VO 0445	Peppers, sweet, raw	RAC	0.15	1.43	0.21	2.61	0.39	1.05	0.16	2.01	0.30	2.59	0.39	6.24	0.94
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0	72.79	0.00	59.05	0.00	20.55	0.00	74.20	0.00	61.12	0.00	73.24	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 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
SB 0716	Coffee beans 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

**LUFENURON (286)**

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
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.04	24.96	1.00	57.95	2.32	16.70	0.67	38.38	1.54	26.46	1.06	29.00	1.16
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	1.07	6.24	6.68	14.49	15.50	4.18	4.47	9.60	10.27	6.62	7.08	7.25	7.76
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	1.07	3.29	3.52	6.14	6.57	0.82	0.88	1.57	1.68	2.23	2.39	1.07	1.14
MO 0105	Edible offal (mammalian), raw	RAC	0.09	4.79	0.43	9.68	0.87	2.97	0.27	5.49	0.49	3.84	0.35	5.03	0.45
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.117	289.65	33.89	485.88	56.85	26.92	3.15	239.03	27.97	199.91	23.39	180.53	21.12
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.0006	13.17	0.01	26.78	0.02	7.24	0.00	116.71	0.07	22.54	0.01	32.09	0.02
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.027	1.46	0.04	2.98	0.08	0.80	0.02	12.97	0.35	2.50	0.07	3.57	0.10
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.027	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	0.004	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.02	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	7.84	0.08	23.08	0.23	2.88	0.03	14.89	0.15	9.81	0.10	14.83	0.15
Total intake (µg//person)=				58.4		104.2		18.2		64.1		42.9		75.7	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (µg//person)=				1200		1200		1200		1200		1200		1200	
%ADI=				4.9%		8.7%		1.5%		5.3%		3.6%		6.3%	
Rounded %ADI=				5%		9%		2%		5%		4%		6%	

**LUFENURON (286)**

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 (excl kumquat commodities)	RAC	0.1	3.78	0.38	8.84	0.88	0.92	0.09	6.71	0.67	4.09	0.41	4.57	0.46
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.09	15.68	1.41	24.00	2.16	6.80	0.61	29.09	2.62	15.39	1.39	160.47	14.44
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.01	33.31	0.33	1.78	0.02	0.28	0.00	18.97	0.19	14.01	0.14	13.36	0.13
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.29	51.09	14.82	65.40	18.97	42.71	12.39	45.29	13.13	62.51	18.13	7.74	2.24
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.06	14.88	0.89	11.98	0.72	0.15	0.01	9.98	0.60	30.32	1.82	3.47	0.21
VC 0424	Cucumber, raw	RAC	0.02	6.72	0.13	11.03	0.22	32.10	0.64	15.10	0.30	4.05	0.08	9.57	0.19
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.02	9.20	0.18	11.95	0.24	14.63	0.29	8.99	0.18	7.86	0.16	2.46	0.05

## LUFENURON (286)

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
VO 0448	Tomato, raw	RAC	0.08	32.13	2.57	51.27	4.10	34.92	2.79	73.37	5.87	15.15	1.21	8.88	0.71
-	Tomato, canned (& peeled)	PP	0.014	7.57	0.11	2.66	0.04	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	0.078	4.96	0.39	3.20	0.25	0.15	0.01	1.61	0.13	6.88	0.54	0.52	0.04
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.014	0.80	0.01	0.10	0.00	0.10	0.00	0.61	0.01	0.40	0.01	0.10	0.00
VO 0445	Peppers, sweet, raw	RAC	0.15	NC	-	NC	-	8.25	1.24	3.03	0.45	NC	-	0.91	0.14
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0	106.33	0.00	117.78	0.00	42.12	0.00	195.70	0.00	222.52	0.00	80.47	0.00
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 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
SB 0716	Coffee beans 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
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.04	112.02	4.48	120.71	4.83	63.46	2.54	88.99	3.56	96.24	3.85	41.02	1.64
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	1.07	28.01	29.97	30.18	32.29	15.86	16.97	22.25	23.81	24.06	25.74	10.25	10.97
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	1.07	6.44	6.89	15.51	16.60	3.79	4.06	8.29	8.87	18.44	19.73	8.00	8.56
MO 0105	Edible offal (mammalian), raw	RAC	0.09	15.17	1.37	5.19	0.47	6.30	0.57	6.78	0.61	3.32	0.30	3.17	0.29
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.117	388.92	45.50	335.88	39.30	49.15	5.75	331.25	38.76	468.56	54.82	245.45	28.72
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.0006	66.38	0.04	48.47	0.03	21.58	0.01	78.41	0.05	48.04	0.03	76.01	0.05
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.027	7.38	0.20	5.39	0.15	2.40	0.06	8.71	0.24	5.34	0.14	8.45	0.23
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.027	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	0.004	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	0.01	25.84	0.26	29.53	0.30	28.05	0.28	33.19	0.33	36.44	0.36	8.89	0.09

Total intake (µg//person)=	112.5	124.3	49.3	102.7	131.6	70.3
Bodyweight per region (kg bw) =	60	60	55	60	60	60
ADI (µg//person)=	1200	1200	1100	1200	1200	1200
%ADI=	9.4%	10.4%	4.5%	8.6%	11.0%	5.9%
Rounded %ADI=	9%	10%	4%	9%	10%	6%

## LUFENURON (286)

## 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 (excl kumquat commodities)	RAC	0.1	0.61	0.06	0.73	0.07	4.01	0.40	0.10	0.01	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.09	1.18	0.11	1.11	0.10	14.28	1.29	0.10	0.01	1.08	0.10
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.01	0.10	0.00	0.26	0.00	12.61	0.13	0.14	0.00	0.33	0.00
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.29	68.85	19.97	10.93	3.17	70.82	20.54	189.78	55.04	19.56	5.67
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.06	0.10	0.01	0.10	0.01	7.19	0.43	0.10	0.01	NC	-
VC 0424	Cucumber, raw	RAC	0.02	0.68	0.01	1.81	0.04	10.40	0.21	0.10	0.00	0.10	0.00
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.02	0.19	0.00	0.10	0.00	4.98	0.10	0.10	0.00	NC	-
VO 0448	Tomato, raw	RAC	0.08	12.99	1.04	4.79	0.38	58.40	4.67	0.92	0.07	0.10	0.01
-	Tomato, canned (& peeled)	PP	0.014	0.10	0.00	0.10	0.00	2.42	0.03	0.10	0.00	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.078	0.58	0.05	0.22	0.02	2.21	0.17	0.24	0.02	3.10	0.24
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.014	0.10	0.00	0.10	0.00	0.42	0.01	0.10	0.00	0.10	0.00
VO 0445	Peppers, sweet, raw	RAC	0.15	1.24	0.19	1.27	0.19	NC	-	0.10	0.02	NC	-
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0	15.80	0.00	14.29	0.00	104.36	0.00	17.11	0.00	35.20	0.00
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 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
SB 0716	Coffee beans 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
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.04	23.34	0.93	40.71	1.63	97.15	3.89	18.06	0.72	57.71	2.31
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	1.07	5.84	6.24	10.18	10.89	24.29	25.99	4.52	4.83	14.43	15.44
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	1.07	1.05	1.12	1.14	1.22	18.69	20.00	0.94	1.01	3.12	3.34
MO 0105	Edible offal (mammalian), raw	RAC	0.09	4.64	0.42	1.97	0.18	10.01	0.90	3.27	0.29	3.98	0.36
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.117	108.75	12.72	70.31	8.23	436.11	51.02	61.55	7.20	79.09	9.25
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.0006	3.53	0.00	10.83	0.01	51.36	0.03	4.53	0.00	50.00	0.03
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.027	0.39	0.01	1.20	0.03	5.71	0.15	0.50	0.01	5.56	0.15
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.027	NC	-	NC	-	0.32	0.01	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.004	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-

**LUFENURON (286)**

## 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
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	3.84	0.04	4.41	0.04	27.25	0.27	1.13	0.01	7.39	0.07
Total intake (µg//person)=				#NAME?		26.5		132.9		71.1		37.6	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (µg//person)=				1200		1200		1200		1200		1200	
%ADI=				#NAME?		2.2%		11.1%		5.9%		3.1%	
Rounded %ADI=				#NAME?		2%		10%		6%		3%	

**MANDIPROPAMID (231)**

## 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									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.43	13.02	5.60	9.25	3.98	0.10	0.04	16.91	7.27	3.70	1.59	54.44	23.41
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.68	0.51	0.86	0.51	0.86	0.10	0.17	1.27	2.13	0.12	0.20	2.07	3.48
JF 0269	Grape juice (from wine grapes)	PP	0.14	0.14	0.02	0.29	0.04	0.10	0.01	0.30	0.04	0.24	0.03	0.10	0.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.366	0.67	0.25	12.53	4.59	2.01	0.74	1.21	0.44	3.53	1.29	4.01	1.47
-	Onions, dry, raw	RAC	0.01	29.36	0.29	37.50	0.38	3.56	0.04	34.78	0.35	18.81	0.19	43.38	0.43
-	Onions, green, raw	RAC	0.48	2.45	1.18	1.49	0.72	1.02	0.49	2.60	1.25	0.60	0.29	2.03	0.97
VB 0400	Broccoli, raw	RAC	0.435	0.88	0.38	0.17	0.07	0.10	0.04	1.25	0.54	3.00	1.31	1.09	0.47
VB 0041	Cabbages, head, raw	RAC	0.01	2.73	0.03	27.92	0.28	0.55	0.01	4.47	0.04	4.27	0.04	10.25	0.10
VC 0424	Cucumber, raw	RAC	0.02	8.01	0.16	30.66	0.61	1.45	0.03	19.84	0.40	0.27	0.01	34.92	0.70
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini), raw	RAC	0.04	0.78	0.03	2.06	0.08	0.30	0.01	1.61	0.06	2.25	0.09	2.36	0.09
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.115	8.90	1.02	8.64	0.99	0.80	0.09	17.90	2.06	2.80	0.32	29.17	3.35
VO 0448	Tomato, raw (incl paste, excl juice, excl canned)	RAC	0.06	51.07	3.06	80.96	4.86	16.96	1.02	99.83	5.99	26.09	1.57	212.26	12.74
-	Tomato, canned (& peeled)	PP	0.022	0.20	0.00	0.31	0.01	0.10	0.00	1.11	0.02	0.11	0.00	1.50	0.03
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.059	0.29	0.02	0.29	0.02	0.10	0.01	0.38	0.02	0.10	0.01	0.14	0.01
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.84	6.93	5.82	10.97	9.21	8.83	7.42	9.13	7.67	6.65	5.59	20.01	16.81
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.12	4.49	0.54	6.44	0.77	7.21	0.87	5.68	0.68	9.52	1.14	8.92	1.07
VL 0053	Group of Leafy vegetables, raw	RAC	5.65	8.47	47.86	22.36	126.33	7.74	43.73	25.51	144.13	45.77	258.60	21.22	119.89
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.22	0.68	0.15	NC	-	NC	-	0.39	0.09	0.22	0.05	0.49	0.11

MANDIPROPAMID (231)				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									
				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 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.0185	59.74	1.11	316.14	5.85	9.78	0.18	60.26	1.11	54.12	1.00	119.82	2.22
VS 0624	Celery	RAC	2.7	2.14	5.78	3.79	10.23	2.35	6.35	5.69	15.36	0.10	0.27	2.75	7.43
-	Barley beer	PP	0.057	4.87	0.28	93.78	5.35	24.28	1.38	12.76	0.73	39.28	2.24	18.15	1.03
-	Millet beer	PP	0.057	NC	-	NC	-	3.86	0.22	NC	-	NC	-	NC	-
-	Sorghum beer	PP	0.057	NC	-	NC	-	17.56	1.00	NC	-	NC	-	NC	-
-	Maize beer	PP	0.057	NC	-	NC	-	4.61	0.26	NC	-	NC	-	NC	-
SB 0715	Cocoa beans, raw (incl roasted)	RAC	0.01	0.10	0.00	0.30	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
-	Cocoa paste	PP	0.01	0.10	0.00	0.16	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
DM 0715	Cocoa powder	PP	0.005	0.11	0.00	0.10	0.00	0.19	0.00	0.79	0.00	0.27	0.00	0.34	0.00
DM 1215	Cocoa butter	PP	0.005	0.10	0.00	0.28	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
-	Cocoa products NES	PP	0.01	0.59	0.01	3.39	0.03	0.31	0.00	3.33	0.03	0.13	0.00	0.43	0.00
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)=				74.4		175.3		64.1		190.4		275.8		195.8	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (µg//person)=				12000		12000		12000		12000		12000		12000	
%ADI=				0.6%		1.5%		0.5%		1.6%		2.3%		1.6%	
Rounded %ADI=				1%		1%		1%		2%		2%		2%	



**MANDIPROPAMID (231)**

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 (incl must, excl dried, excl juice, excl wine)	RAC	0.43	6.48	2.79	11.31	4.86	5.21	2.24	9.50	4.09	4.66	2.00	0.78	0.34
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.68	3.09	5.19	1.51	2.54	0.10	0.17	1.38	2.32	4.26	7.16	0.42	0.71
JF 0269	Grape juice (from wine grapes)	PP	0.14	0.56	0.08	1.96	0.27	0.10	0.01	2.24	0.31	2.27	0.32	0.34	0.05
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.366	88.93	32.55	62.41	22.84	1.84	0.67	25.07	9.18	61.17	22.39	5.84	2.14
-	Onions, dry, raw	RAC	0.01	19.69	0.20	29.83	0.30	24.64	0.25	31.35	0.31	9.72	0.10	12.59	0.13
-	Onions, green, raw	RAC	0.48	1.55	0.74	0.74	0.36	1.05	0.50	3.74	1.80	0.94	0.45	6.45	3.10
VB 0400	Broccoli, raw	RAC	0.435	4.24	1.84	1.76	0.77	NC	-	0.51	0.22	3.79	1.65	0.26	0.11
VB 0041	Cabbages, head, raw	RAC	0.01	8.97	0.09	27.12	0.27	1.44	0.01	24.96	0.25	4.55	0.05	11.23	0.11
VC 0424	Cucumber, raw	RAC	0.02	6.72	0.13	11.03	0.22	32.10	0.64	15.10	0.30	4.05	0.08	9.57	0.19
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.04	NC	-	NC	-	5.48	0.22	NC	-	NC	-	1.03	0.04
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.115	9.20	1.06	11.95	1.37	14.63	1.68	8.99	1.03	7.86	0.90	2.46	0.28
VO 0448	Tomato, raw (incl paste, excl juice, excl canned)	RAC	0.06	51.98	3.12	64.09	3.85	35.52	2.13	79.82	4.79	42.65	2.56	10.96	0.66
-	Tomato, canned (& peeled)	PP	0.022	7.57	0.17	2.66	0.06	0.30	0.01	0.97	0.02	7.31	0.16	0.41	0.01
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.059	0.80	0.05	0.10	0.01	0.10	0.01	0.61	0.04	0.40	0.02	0.10	0.01
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.84	6.36	5.34	15.46	12.99	10.74	9.02	7.28	6.12	8.21	6.90	3.58	3.01
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.12	0.82	0.10	1.53	0.18	10.85	1.30	4.59	0.55	1.84	0.22	2.00	0.24
VL 0053	Group of Leafy vegetables, raw	RAC	5.65	18.83	106.39	21.85	123.45	121.23	684.95	43.09	243.46	18.18	102.72	18.32	103.51
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.22	5.07	1.12	0.83	0.18	0.17	0.04	3.70	0.81	NC	-	NC	-
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.0185	225.03	4.16	234.24	4.33	71.48	1.32	177.55	3.28	234.55	4.34	37.71	0.70
VS 0624	Celery	RAC	2.7	7.68	20.74	2.85	7.70	NC	-	3.34	9.02	16.83	45.44	4.04	10.91
-	Barley beer	PP	0.057	180.21	10.27	259.46	14.79	45.91	2.62	172.36	9.82	234.42	13.36	65.30	3.72
-	Millet beer	PP	0.057	NC	-	NC	-	0.10	0.01	NC	-	NC	-	NC	-
-	Sorghum beer	PP	0.057	NC	-	NC	-	0.10	0.01	NC	-	NC	-	NC	-
-	Maize beer	PP	0.057	NC	-	NC	-	NC	-	1.99	0.11	NC	-	NC	-
SB 0715	Cocoa beans, raw (incl roasted)	RAC	0.01	NC	-	NC	-	0.10	0.00	0.26	0.00	NC	-	1.41	0.01
-	Cocoa paste	PP	0.01	NC	-	NC	-	0.10	0.00	0.10	0.00	NC	-	NC	-
DM 0715	Cocoa powder	PP	0.005	2.78	0.01	1.82	0.01	0.20	0.00	1.66	0.01	0.10	0.00	0.74	0.00

MANDIPROPAMID (231)				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	
DM 1215	Cocoa butter	PP	0.005	0.98	0.00	0.59	0.00	0.10	0.00	0.10	0.00	1.05	0.01	NC	-	
-	Cocoa products NES	PP	0.01	3.79	0.04	3.18	0.03	0.10	0.00	2.10	0.02	0.17	0.00	3.13	0.03	
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)=					196.2		201.4		707.8		297.9		210.8		130.0	
Bodyweight per region (kg bw) =					60		60		55		60		60		60	
ADI (µg//person)=					12000		12000		11000		12000		12000		12000	
%ADI=					1.6%		1.7%		6.4%		2.5%		1.8%		1.1%	
Rounded %ADI=					2%		2%		6%		2%		2%		1%	

MANDIPROPAMID (231)				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 (incl must, excl dried, excl juice, excl wine)	RAC	0.43	0.14	0.06	0.36	0.15	15.33	6.59	0.10	0.04	0.28	0.12
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.68	0.10	0.17	0.13	0.22	1.06	1.78	0.10	0.17	0.10	0.17
JF 0269	Grape juice (from wine grapes)	PP	0.14	0.10	0.01	0.10	0.01	0.41	0.06	0.10	0.01	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.366	0.31	0.11	0.23	0.08	60.43	22.12	0.52	0.19	31.91	11.68
-	Onions, dry, raw	RAC	0.01	9.01	0.09	20.24	0.20	30.90	0.31	9.61	0.10	2.11	0.02
-	Onions, green, raw	RAC	0.48	1.43	0.69	0.10	0.05	0.20	0.10	NC	-	6.30	3.02
VB 0400	Broccoli, raw	RAC	0.435	0.10	0.04	0.10	0.04	2.13	0.93	0.10	0.04	NC	-
VB 0041	Cabbages, head, raw	RAC	0.01	3.82	0.04	2.99	0.03	49.16	0.49	0.10	0.00	NC	-
VC 0424	Cucumber, raw	RAC	0.02	0.68	0.01	1.81	0.04	10.40	0.21	0.10	0.00	0.10	0.00

**MANDIPROPAMID (231)**

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
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.04	0.10	0.00	1.01	0.04	NC	-	1.91	0.08	NC	-
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.115	0.19	0.02	0.10	0.01	4.98	0.57	0.10	0.01	NC	-
VO 0448	Tomato, raw (incl paste, excl juice, excl canned)	RAC	0.06	15.33	0.92	5.65	0.34	67.23	4.03	1.88	0.11	12.48	0.75
-	Tomato, canned (& peeled)	PP	0.022	0.10	0.00	0.10	0.00	2.42	0.05	0.10	0.00	NC	-
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.059	0.10	0.01	0.10	0.01	0.42	0.02	0.10	0.01	0.10	0.01
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.84	7.55	6.34	12.48	10.48	24.78	20.82	0.87	0.73	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.12	5.49	0.66	10.57	1.27	8.84	1.06	0.91	0.11	NC	-
VL 0053	Group of Leafy vegetables, raw	RAC	5.65	12.42	70.17	8.75	49.44	7.53	42.54	7.07	39.95	14.11	79.72
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.22	NC	-	NC	-	NC	-	NC	-	NC	-
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.0185	23.96	0.44	13.56	0.25	213.41	3.95	104.35	1.93	8.56	0.16
VS 0624	Celery	RAC	2.7	3.66	9.88	2.65	7.16	4.84	13.07	2.47	6.67	4.94	13.34
-	Barley beer	PP	0.057	16.25	0.93	11.36	0.65	225.21	12.84	19.49	1.11	52.17	2.97
-	Millet beer	PP	0.057	5.80	0.33	NC	-	NC	-	22.96	1.31	NC	-
-	Sorghum beer	PP	0.057	24.90	1.42	NC	-	NC	-	70.33	4.01	NC	-
-	Maize beer	PP	0.057	1.03	0.06	NC	-	NC	-	40.94	2.33	NC	-
SB 0715	Cocoa beans, raw (incl roasted)	RAC	0.01	0.10	0.00	0.53	0.01	0.33	0.00	0.10	0.00	NC	-
-	Cocoa paste	PP	0.01	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	NC	-
DM 0715	Cocoa powder	PP	0.005	0.10	0.00	0.20	0.00	1.17	0.01	0.10	0.00	1.80	0.01
DM 1215	Cocoa butter	PP	0.005	0.10	0.00	0.10	0.00	0.38	0.00	0.10	0.00	NC	-
-	Cocoa products NES	PP	0.01	0.10	0.00	0.17	0.00	4.41	0.04	0.10	0.00	0.51	0.01
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)=				92.4		70.5		131.6		58.9		112.0	
Bodyweight per region (kg bw) =				60		60		60		60		60	

**MANDIPROPAMID (231)**

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		
					12000		12000		12000		12000		12000		12000
					0.8%		0.6%		1.1%		0.5%		0.9%		
					1%		1%		1%		0%		1%		

ADI (µg/person)=

12000

12000

12000

12000

12000

%ADI=

0.8%

0.6%

1.1%

0.5%

0.9%

Rounded %ADI=

1%

1%

1%

0%

1%

**NORFLURAZON (308)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.005 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
VL 2050	Subgroup of Leafy greens	RAC	0.053	3.93	0.21	5.28	0.28	3.07	0.16	14.53	0.77	8.25	0.44	12.75	0.68
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	0.096	2.63	0.25	9.27	0.89	1.86	0.18	5.82	0.56	19.53	1.87	4.90	0.47
VR 2070	Subgroup of Root vegetables, raw	RAC	0.04	24.72	0.99	57.71	2.31	17.01	0.68	49.58	1.98	9.33	0.37	114.41	4.58
GC 2086	Subgroup of wheat, similar grains and pseudocereals without husks, raw (including processed)	RAC	0.04	381.29	15.25	360.94	14.44	38.45	1.54	282.01	11.28	173.32	6.93	436.22	17.45
GC 2088	Subgroup of rice cereals	REP	0.1	45.40	4.54	14.99	1.50	84.88	8.49	111.73	11.17	194.75	19.48	93.12	9.31
GC 2089	Subgroup of Sorghum Grain and Millet	RAC	0.04	5.80	0.23	2.32	0.09	23.09	0.92	16.72	0.67	27.14	1.09	2.92	0.12
GC 2091	Subgroup of Maize Cereals	RAC	0.04	29.81	1.19	44.77	1.79	108.95	4.36	52.37	2.09	60.28	2.41	75.69	3.03
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.0012	24.96	0.03	57.95	0.07	16.70	0.02	38.38	0.05	26.46	0.03	29.00	0.03
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.00043	6.24	0.00	14.49	0.01	4.18	0.00	9.60	0.00	6.62	0.00	7.25	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.00043	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	0.065	4.79	0.31	9.68	0.63	2.97	0.19	5.49	0.36	3.84	0.25	5.03	0.33
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0014	289.65	0.41	485.88	0.68	26.92	0.04	239.03	0.33	199.91	0.28	180.53	0.25
	Total intake (µg/person)=				23.4		22.7		16.6		29.3		33.2		36.2
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				300		300		300		300		300		300
	%ADI=				7.8%		7.6%		5.5%		9.8%		11.1%		12.1%
	Rounded %ADI=				8%		8%		6%		10%		10%		10%

NORFLURAZON (308)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.005 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 2050	Subgroup of Leafy greens	RAC	0.053	18.38	0.97	18.73	0.99	82.36	4.37	25.32	1.34	17.60	0.93	7.37	0.39
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	0.096	0.10	0.01	NC	-	26.78	2.57	5.00	0.48	0.58	0.06	5.68	0.55
VR 2070	Subgroup of Root vegetables, raw	RAC	0.04	64.22	2.57	65.78	2.63	49.73	1.99	57.68	2.31	113.82	4.55	37.27	1.49
GC 2086	Subgroup of wheat, similar grains and pseudocereals without husks, raw (including processed)	RAC	0.04	256.28	10.25	280.29	11.21	134.94	5.40	241.61	9.66	217.88	8.72	167.40	6.70
GC 2088	Subgroup of rice cereals	REP	0.1	20.96	2.10	16.04	1.60	339.67	33.97	75.51	7.55	16.86	1.69	86.13	8.61
GC 2089	Subgroup of Sorghum Grain and Millet	RAC	0.04	0.10	0.00	0.16	0.01	3.19	0.13	1.85	0.07	NC	-	7.12	0.28
GC 2091	Subgroup of Maize Cereals	RAC	0.04	18.51	0.74	26.18	1.05	26.04	1.04	39.99	1.60	7.36	0.29	64.58	2.58
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.0012	112.02	0.13	120.71	0.14	63.46	0.08	88.99	0.11	96.24	0.12	41.02	0.05
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.00043	28.01	0.01	30.18	0.01	15.86	0.01	22.25	0.01	24.06	0.01	10.25	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.00043	6.44	0.00	15.51	0.01	3.79	0.00	8.29	0.00	18.44	0.01	8.00	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.065	15.17	0.99	5.19	0.34	6.30	0.41	6.78	0.44	3.32	0.22	3.17	0.21
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0014	388.92	0.54	335.88	0.47	49.15	0.07	331.25	0.46	468.56	0.66	245.45	0.34
Total intake (µg//person)=				18.3		18.5		50.0		24.0		17.2		21.2	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (µg//person)=				300		300		275		300		300		300	
%ADI=				6.1%		6.2%		18.2%		8.0%		5.7%		7.1%	
Rounded %ADI=				6%		6%		20%		8%		6%		7%	

NORFLURAZON (308)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.005 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	G17 diet	G17 intake
VL 2050	Subgroup of Leafy greens	RAC	0.053	4.99	0.26	3.29	0.17	7.53	0.40	3.05	0.16	6.09	0.32		
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	0.096	3.58	0.34	2.64	0.25	NC	-	1.83	0.18	3.65	0.35		
VR 2070	Subgroup of Root vegetables, raw	RAC	0.04	31.84	1.27	23.38	0.94	68.28	2.73	17.52	0.70	71.01	2.84		
GC 2086	Subgroup of wheat, similar grains and pseudocereals without husks, raw (including processed)	RAC	0.04	57.23	2.29	110.47	4.42	286.57	11.46	25.82	1.03	132.92	5.32		

**NORFLURAZON (308)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.005 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 2088	Subgroup of rice cereals	REP	0.1	52.55	5.26	286.02	28.60	18.64	1.86	19.67	1.97	75.09	7.51
GC 2089	Subgroup of Sorghum Grain and Millet	RAC	0.04	150.90	6.04	2.80	0.11	NC	-	68.93	2.76	NC	-
GC 2091	Subgroup of Maize Cereals	RAC	0.04	116.66	4.67	10.52	0.42	38.46	1.54	76.60	3.06	34.44	1.38
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.0012	23.34	0.03	40.71	0.05	97.15	0.12	18.06	0.02	57.71	0.07
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.00043	5.84	0.00	10.18	0.00	24.29	0.01	4.52	0.00	14.43	0.01
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.00043	1.05	0.00	1.14	0.00	18.69	0.01	0.94	0.00	3.12	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.065	4.64	0.30	1.97	0.13	10.01	0.65	3.27	0.21	3.98	0.26
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0014	108.75	0.15	70.31	0.10	436.11	0.61	61.55	0.09	79.09	0.11
Total intake (µg/person)=				20.6		35.2		19.4		10.2		18.2	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (µg/person)=				300		300		300		300		300	
%ADI=				6.9%		11.7%		6.5%		3.4%		6.1%	
Rounded %ADI=				7%		10%		6%		3%		6%	

**OXATHIPIPROLIN (291)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug//person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0001	Group of Citrus fruit, raw (excl kumquat commodities)	RAC	0.056	29.89	1.67	11.40	0.64	13.51	0.76	61.57	3.45	32.24	1.81	91.26	5.11
JF 0001	Group of Citrus fruit, juice	PP	0.032	1.30	0.04	2.37	0.08	0.22	0.01	13.88	0.44	0.75	0.02	2.63	0.08
FC 0303	Kumquats, raw (incl juice)	RAC	0.057	2.36	0.13	0.27	0.02	3.19	0.18	14.44	0.82	1.66	0.09	1.71	0.10
FB 2005	Subgroup of Caneberries, raw	RAC	0.056	0.42	0.02	1.05	0.06	0.10	0.01	0.10	0.01	0.10	0.01	1.24	0.07
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.21	12.68	2.66	9.12	1.92	0.10	0.02	16.88	3.54	3.70	0.78	54.42	11.43
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.29	0.51	0.15	0.51	0.15	0.10	0.03	1.27	0.37	0.12	0.03	2.07	0.60
JF 0269	Grape juice (from wine grapes)	PP	0.034	0.14	0.00	0.29	0.01	0.10	0.00	0.30	0.01	0.24	0.01	0.10	0.00
-	Graps must (from wine-grapes)	PP	0.13	0.33	0.04	0.13	0.02	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.029	0.67	0.02	12.53	0.36	2.01	0.06	1.21	0.04	3.53	0.10	4.01	0.12
FB 0275	Strawberry, raw	RAC	0.08	0.70	0.06	2.01	0.16	0.10	0.01	1.36	0.11	0.37	0.03	2.53	0.20
VA 0381	Garlic, raw	RAC	0.066	2.29	0.15	5.78	0.38	0.11	0.01	3.69	0.24	1.65	0.11	3.91	0.26

OXATHIAPIPROLIN (291)				International Estimated Daily Intake (IEDI)				ADI = 0 - 4 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as 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
-	Onions, dry, raw	RAC	0.066	29.36	1.94	37.50	2.48	3.56	0.23	34.78	2.30	18.81	1.24	43.38	2.86
VA 0384	Leek, raw	RAC	0.656	0.18	0.12	1.59	1.04	0.10	0.07	0.28	0.18	0.10	0.07	3.21	2.11
-	Onions, green, raw	RAC	0.656	2.45	1.61	1.49	0.98	1.02	0.67	2.60	1.71	0.60	0.39	2.03	1.33
VB 0400	Broccoli, raw	RAC	0.276	0.88	0.24	0.17	0.05	0.10	0.03	1.25	0.35	3.00	0.83	1.09	0.30
VB 0404	Cauliflower, raw	RAC	0.136	1.65	0.22	0.32	0.04	0.10	0.01	2.33	0.32	4.79	0.65	2.03	0.28
VB 0402	Brussels sprouts, raw	RAC	0.056	0.63	0.04	6.41	0.36	0.13	0.01	1.03	0.06	NC	-	2.35	0.13
VB 0041	Cabbages, head, raw	RAC	0.196	2.73	0.54	27.92	5.47	0.55	0.11	4.47	0.88	4.27	0.84	10.25	2.01
VB 0467	Chinese cabbage, type pe-tsai, raw	RAC	0.056	0.45	0.03	4.56	0.26	0.10	0.01	0.73	0.04	NC	-	1.67	0.09
VB 2016	Subgroup of Stem Brassicas, raw	RAC	0.056	0.10	0.01	0.89	0.05	0.10	0.01	0.14	0.01	NC	-	0.33	0.02
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.03	53.14	1.59	86.21	2.59	6.28	0.19	92.76	2.78	15.64	0.47	155.30	4.66
VO 0448	Tomato, raw	RAC	0.04	41.73	1.67	75.65	3.03	10.66	0.43	82.87	3.31	24.75	0.99	200.93	8.04
-	Tomato, canned (& peeled)	PP	0.0016	0.20	0.00	0.31	0.00	0.10	0.00	1.11	0.00	0.11	0.00	1.50	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.044	2.34	0.10	1.33	0.06	1.57	0.07	4.24	0.19	0.34	0.01	2.83	0.12
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.006	0.29	0.00	0.29	0.00	0.10	0.00	0.38	0.00	0.10	0.00	0.14	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.04	1.97	0.08	NC	-	3.68	0.15	3.24	0.13	5.72	0.23	1.57	0.06
VO 0444	Peppers, chili, raw	RAC	0.04	3.99	0.16	7.30	0.29	2.93	0.12	5.62	0.22	NC	-	17.44	0.70
-	Peppers, chili, dried	PP	0.4	0.42	0.17	0.53	0.21	0.84	0.34	0.50	0.20	0.95	0.38	0.37	0.15
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.04	4.49	0.18	6.44	0.26	7.21	0.29	5.68	0.23	9.52	0.38	8.92	0.36
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.04	5.58	0.22	4.31	0.17	0.89	0.04	9.31	0.37	13.64	0.55	20.12	0.80
VL 0460	Amaranth leaves, raw (i.e. Bledo)	RAC	0.33	1.09	0.36	1.94	0.64	1.20	0.40	2.91	0.96	NC	-	1.41	0.47
VL 0464	Chard, raw (i.e. Beet leaves; Silver beet)	RAC	0.33	0.40	0.13	0.70	0.23	0.44	0.15	1.06	0.35	4.66	1.54	0.51	0.17
VL 0465	Chervil, raw	RAC	0.33	0.19	0.06	0.34	0.11	0.21	0.07	0.52	0.17	NC	-	0.25	0.08
VL 2752	Chrysanthemum, edible leaved	RAC	0.33	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03	NC	-	0.10	0.03
VL 0470	Corn salad (Lambs lettuce)	RAC	0.33	0.64	0.21	1.13	0.37	0.70	0.23	1.70	0.56	NC	-	0.82	0.27
VL 0474	Dandelion, raw (i.e. Laiteron, Pissenlit)	RAC	0.33	0.13	0.04	0.23	0.08	0.14	0.05	0.34	0.11	1.44	0.48	0.16	0.05
VL 0476	Endive, raw (i.e. scarole)	RAC	0.33	0.10	0.03	0.10	0.03	0.10	0.03	0.40	0.13	0.10	0.03	0.39	0.13
VL 0483	Lettuce, leaf, raw	RAC	2.2	0.53	1.17	0.36	0.79	0.16	0.35	6.21	13.66	1.90	4.18	6.05	13.31
VL 2765	Perilla leaves (Sesame leaves)	RAC	0.33	0.15	0.05	0.27	0.09	0.17	0.06	0.40	0.13	NC	-	0.19	0.06
VL 0492	Purslane, raw	RAC	0.33	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03	NC	-	0.10	0.03
VL 0502	Spinach, raw	RAC	3.7	0.74	2.74	0.22	0.81	0.10	0.37	0.91	3.37	0.10	0.37	2.92	10.80
VL 0503	Spinach, Indian, raw (i.e. vine spinach)	RAC	0.33	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03	0.16	0.05	0.10	0.03
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	3.28	2.63	8.63	9.27	30.41	1.86	6.10	5.82	19.09	19.53	64.06	4.90	16.07

**OXATHIPIPROLIN (291)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as 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
VL 2052	Subgroup of Leaves of Root and Tuber Vegetables	RAC	0.065	0.18	0.01	0.31	0.02	0.84	0.05	0.47	0.03	2.06	0.13	0.23	0.01
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.12	0.68	0.08	NC	-	NC	-	0.39	0.05	0.22	0.03	0.49	0.06
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.12	5.07	0.61	1.02	0.12	0.49	0.06	1.78	0.21	1.19	0.14	8.57	1.03
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.09	1.97	0.18	0.51	0.05	0.10	0.01	0.79	0.07	3.68	0.33	3.80	0.34
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.12	2.39	0.29	1.61	0.19	10.47	1.26	1.84	0.22	12.90	1.55	7.44	0.89
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.12	1.27	0.15	0.10	0.01	0.12	0.01	2.49	0.30	0.23	0.03	5.54	0.66
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.12	0.10	0.01	NC	-	1.74	0.21	0.10	0.01	0.10	0.01	0.10	0.01
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.176	72.79	12.81	59.05	10.39	20.55	3.62	74.20	13.06	61.12	10.76	73.24	12.89
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.12	1.70	0.20	0.10	0.01	3.00	0.36	1.80	0.22	1.64	0.20	1.33	0.16
VD 2066	Subgroup of dry peas, raw	RAC	0.12	9.09	1.09	3.35	0.40	1.06	0.13	9.48	1.14	15.11	1.81	10.58	1.27
VD 2067	Subgroup of dry underground pulses, raw	RAC	0.12	NC	-	NC	-	0.20	0.02	NC	-	NC	-	NC	-
VR 2070	Subgroup of Root vegetables, raw	RAC	0.06	24.72	1.48	57.71	3.46	17.01	1.02	49.58	2.97	9.33	0.56	114.41	6.86
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0.116	63.11	7.32	316.33	36.69	651.91	75.62	72.06	8.36	84.88	9.85	132.70	15.39
VS 2080	Subgroup of stems and petioles	RAC	0.056	3.11	0.17	5.52	0.31	3.42	0.19	8.29	0.46	0.10	0.01	4.00	0.22
VS 2081	Subgroup of young shoots	RAC	0.681	1.84	1.25	3.25	2.21	2.01	1.37	4.90	3.34	0.10	0.07	2.56	1.74
VS 2082	Subgroup of other stalk and stem vegetables	RAC	0.056	1.09	0.06	0.70	0.04	0.44	0.02	1.37	0.08	2.53	0.14	1.72	0.10
GC 2086	Subgroup of wheat, similar grains and pseudocereals without husks, raw (including processed)	RAC	0.056	381.29	21.35	360.94	20.21	38.45	2.15	282.01	15.79	173.32	9.71	436.22	24.43
GC 2087	Subgroup of barley, similar grains, and pseudocereals with husks, raw (including processed)	RAC	0.056	19.96	1.12	38.62	2.16	5.13	0.29	4.81	0.27	10.80	0.60	4.44	0.25



**OXATHIPIPROLIN (291)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as 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 2088	Subgroup of rice cereals	REP	0.056	45.40	2.54	14.99	0.84	84.88	4.75	111.73	6.26	194.75	10.91	93.12	5.21
GC 2089	Subgroup of Sorghum Grain and Millet	RAC	0.056	5.80	0.32	2.32	0.13	23.09	1.29	16.72	0.94	27.14	1.52	2.92	0.16
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	<b>0.112</b>	29.81	3.34	44.77	5.01	108.95	12.20	52.37	5.87	60.28	6.75	75.69	8.48
-	Cereals, NES, raw (including processed) : canagua, quihuicha, Job's tears and wild rice	RAC	0.056	2.04	0.11	2.99	0.17	1.86	0.10	19.17	1.07	3.33	0.19	1.66	0.09
GC 2090	Subgroup of Sweet Corns	RAC	<b>0.112</b>	0.14	0.02	0.94	0.11	5.70	0.64	2.61	0.29	1.94	0.22	0.22	0.02
SO 0090	Mustard seeds, raw (incl flour, incl oil)	RAC	0.062	0.10	0.01	0.10	0.01	0.10	0.01	0.31	0.02	0.10	0.01	0.10	0.01
SO 0495	Rape seed, raw (incl oil)	RAC	0.062	0.93	0.06	1.16	0.07	0.49	0.03	2.53	0.16	9.32	0.58	2.02	0.13
SO 0691	Cotton seed, raw (incl oil)	RAC	0.062	20.53	1.27	9.80	0.61	6.42	0.40	4.73	0.29	7.14	0.44	18.68	1.16
SO 0693	Linseed, raw (incl oil)	RAC	0.062	0.10	0.01	NC	-	NC	-	0.10	0.01	0.13	0.01	NC	-
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.062	1.30	0.08	1.23	0.08	12.62	0.78	2.87	0.18	6.59	0.41	2.67	0.17
SO 0698	Poppy seed, raw (incl oil)	RAC	<b>0.102</b>	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01
SO 0699	Safflower seed, raw (incl oil)	RAC	0.062	0.10	0.01	0.20	0.01	0.10	0.01	0.10	0.01	0.29	0.02	0.10	0.01
SO 0700	Sesame seed, raw (incl oil)	RAC	0.062	1.22	0.08	0.10	0.01	0.54	0.03	4.23	0.26	0.82	0.05	2.77	0.17
SO 0701	Shea nut (karite nuts), nutmeat, raw (incl butter)	RAC	0.062	NC	-	NC	-	0.34	0.02	NC	-	NC	-	NC	-
SO 0702	Sunflower seed, raw (incl oil)	RAC	<b>0.118</b>	7.40	0.87	35.86	4.23	1.15	0.14	8.76	1.03	5.45	0.64	13.62	1.61
-	Castor bean, raw (incl oil)	RAC	0.062	NC	-	0.10	0.01	NC	-	NC	-	NC	-	0.10	0.01
-	Cucurbitaceae seeds, raw (melonseeds, pumpkin seeds, watermelon seeds)	RAC	0.062	0.10	0.01	NC	-	1.08	0.07	0.38	0.02	0.10	0.01	0.25	0.02
HH 0721	Angelica herb, raw	RAC	0.33	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03	NC	-	0.10	0.03
HH 0722	Basil, raw (incl dried)	RAC	<b>3.08</b>	0.14	0.43	0.26	0.80	0.16	0.49	0.38	1.17	NC	-	0.19	0.59
HH 0730	Dill herb, raw	RAC	0.33	0.16	0.05	0.29	0.10	0.18	0.06	0.44	0.15	NC	-	0.21	0.07
HH 0738	Mints, raw	RAC	0.33	0.50	0.17	0.10	0.03	NC	-	NC	-	NC	-	NC	-
HH 0740	Parsley, raw (incl dried)	RAC	0.33	0.60	0.20	1.07	0.35	0.66	0.22	1.60	0.53	NC	-	0.77	0.25
HH 0741	Rosemary, raw	RAC	0.33	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03	NC	-	0.10	0.03
HH 0743	Sage and related Salvia species, raw	RAC	0.33	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03	NC	-	0.10	0.03
HH 0749	Tarragon, raw	RAC	0.33	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03	NC	-	0.10	0.03
HH 0750	Thyme, raw	RAC	0.33	0.14	0.05	0.10	0.03	0.10	0.03	0.55	0.18	0.55	0.18	0.29	0.10
HH 0756	Cilantro, raw (i.e. coriander leaves)	RAC	0.33	0.13	0.04	0.23	0.08	0.14	0.05	0.35	0.12	NC	-	0.17	0.06
DH 1100	Hops, dry	RAC	0.33	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03	NC	-	0.10	0.03
PM 0110	Poultry meat, raw (incl prepared)	RAC	<b>0</b>	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	<b>0</b>	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00

OXATHIAPIPROLIN (291)				International Estimated Daily Intake (IEDI)				ADI = 0 - 4 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as 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
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)=				85.4		143.9		119.6		126.3		138.6		168.3	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (µg//person)=				240000		240000		240000		240000		240000		240000	
%ADI=				0.0%		0.1%		0.0%		0.1%		0.1%		0.1%	
Rounded %ADI=				0%		0%		0%		0%		0%		0%	

OXATHIAPIPROLIN (291)				International Estimated Daily Intake (IEDI)				ADI = 0 - 4 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				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 (excl kumquat commodities)	RAC	0.056	33.99	1.90	49.07	2.75	24.40	1.37	50.01	2.80	34.01	1.90	464.99	26.04
JF 0001	Group of Citrus fruit, juice	PP	0.032	36.84	1.18	3.75	0.12	0.30	0.01	21.62	0.69	21.82	0.70	46.67	1.49
FC 0303	Kumquats, raw (incl juice)	RAC	0.057	4.67	0.27	5.86	0.33	1.96	0.11	1.45	0.08	17.05	0.97	1.37	0.08
FB 2005	Subgroup of Caneberries, raw	RAC	0.056	0.56	0.03	1.43	0.08	0.14	0.01	1.23	0.07	1.14	0.06	0.10	0.01
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.27	6.33	1.33	11.22	2.36	5.21	1.09	9.38	1.97	4.55	0.96	0.78	0.16
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.29	3.09	0.90	1.51	0.44	0.10	0.03	1.38	0.40	4.26	1.24	0.42	0.12
JF 0269	Grape juice (from wine grapes)	PP	0.034	0.56	0.02	1.96	0.07	0.10	0.00	2.24	0.08	2.27	0.08	0.34	0.01
-	Graps must (from wine-grapes)	PP	0.13	0.16	0.02	0.10	0.01	0.10	0.01	0.12	0.02	0.11	0.01	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.029	88.93	2.58	62.41	1.81	1.84	0.05	25.07	0.73	61.17	1.77	5.84	0.17
FB 0275	Strawberry, raw	RAC	0.08	4.49	0.36	5.66	0.45	0.10	0.01	6.63	0.53	5.75	0.46	0.10	0.01
VA 0381	Garlic, raw	RAC	0.066	0.98	0.06	1.49	0.10	12.88	0.85	3.74	0.25	2.05	0.14	1.14	0.08
-	Onions, dry, raw	RAC	0.066	19.69	1.30	29.83	1.97	24.64	1.63	31.35	2.07	9.72	0.64	12.59	0.83
VA 0384	Leek, raw	RAC	0.656	4.01	2.63	4.41	2.89	0.72	0.47	0.54	0.35	16.41	10.76	0.10	0.07
-	Onions, green, raw	RAC	0.656	1.55	1.02	0.74	0.49	1.05	0.69	3.74	2.45	0.94	0.62	6.45	4.23
VB 0400	Broccoli, raw	RAC	0.276	4.24	1.17	1.76	0.49	NC	-	0.51	0.14	3.79	1.05	0.26	0.07
VB 0404	Cauliflower, raw	RAC	0.136	5.27	0.72	5.01	0.68	NC	-	2.70	0.37	5.57	0.76	0.49	0.07
VB 0402	Brussels sprouts, raw	RAC	0.056	2.24	0.13	2.67	0.15	6.23	0.35	0.32	0.02	4.19	0.23	2.58	0.14
VB 0041	Cabbages, head, raw	RAC	0.196	8.97	1.76	27.12	5.32	1.44	0.28	24.96	4.89	4.55	0.89	11.23	2.20
VB 0467	Chinese cabbage, type pe-tsai, raw	RAC	0.056	NC	-	NC	-	17.39	0.97	9.44	0.53	NC	-	1.83	0.10

OXATHIAPIPROLIN (291)				International Estimated Daily Intake (IEDI)				ADI = 0 - 4 mg/kg bw								
Codex Code		Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as 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
VB 2016	Subgroup of Stem Brassicas, raw	RAC	0.056	NC	-	3.25	0.18	NC	-	NC	-	0.10	0.01	0.36	0.02	
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.03	27.81	0.83	41.93	1.26	123.30	3.70	49.47	1.48	15.95	0.48	35.99	1.08	
VO 0448	Tomato, raw	RAC	0.04	32.13	1.29	51.27	2.05	34.92	1.40	73.37	2.93	15.15	0.61	8.88	0.36	
-	Tomato, canned (& peeled)	PP	0.0016	7.57	0.01	2.66	0.00	0.30	0.00	0.97	0.00	7.31	0.01	0.41	0.00	
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.044	4.96	0.22	3.20	0.14	0.15	0.01	1.61	0.07	6.88	0.30	0.52	0.02	
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.006	0.80	0.00	0.10	0.00	0.10	0.00	0.61	0.00	0.40	0.00	0.10	0.00	
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.04	NC	-	NC	-	0.10	0.00	0.17	0.01	NC	-	0.72	0.03	
VO 0444	Peppers, chili, raw	RAC	0.04	5.57	0.22	14.00	0.56	8.25	0.33	5.77	0.23	6.44	0.26	2.53	0.10	
-	Peppers, chili, dried	PP	0.4	0.11	0.04	0.21	0.08	0.36	0.14	0.21	0.08	0.25	0.10	0.15	0.06	
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.04	0.82	0.03	1.53	0.06	10.85	0.43	4.59	0.18	1.84	0.07	2.00	0.08	
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.04	1.01	0.04	1.69	0.07	21.37	0.85	3.00	0.12	1.40	0.06	NC	-	
VL 0460	Amaranth leaves, raw (i.e. Bledo)	RAC	0.33	NC	-	NC	-	47.45	15.66	NC	-	NC	-	2.07	0.68	
VL 0464	Chard, raw (i.e. Beet leaves; Silver beet)	RAC	0.33	NC	-	NC	-	NC	-	NC	-	NC	-	0.75	0.25	
VL 0465	Chervil, raw	RAC	0.33	NC	-	NC	-	8.39	2.77	NC	-	NC	-	0.37	0.12	
VL 2752	Chrysanthemum, edible leaved	RAC	0.33	NC	-	NC	-	NC	-	0.32	0.11	NC	-	0.10	0.03	
VL 0470	Corn salad (Lambs lettuce)	RAC	0.33	1.41	0.47	4.28	1.41	NC	-	0.10	0.03	5.11	1.69	1.20	0.40	
VL 0474	Dandelion, raw (i.e. Laiteron, Pissenlit)	RAC	0.33	0.10	0.03	0.10	0.03	NC	-	NC	-	0.10	0.03	0.24	0.08	
VL 0476	Endive, raw (i.e. scarole)	RAC	0.33	0.21	0.07	0.93	0.31	NC	-	0.30	0.10	2.14	0.71	0.14	0.05	
VL 0483	Lettuce, leaf, raw	RAC	2.2	14.50	31.90	11.76	25.87	13.14	28.91	19.50	42.90	4.81	10.58	2.23	4.91	
VL 2765	Perilla leaves (Sesame leaves)	RAC	0.33	NC	-	NC	-	NC	-	2.23	0.74	NC	-	0.29	0.10	
VL 0492	Purslane, raw	RAC	0.33	0.10	0.03	NC	-	NC	-	NC	-	NC	-	0.10	0.03	
VL 0502	Spinach, raw	RAC	3.7	2.20	8.14	1.76	6.51	13.38	49.51	2.94	10.88	5.53	20.46	0.10	0.37	
VL 0503	Spinach, Indian, raw (i.e. vine spinach)	RAC	0.33	NC	-	NC	-	NC	-	NC	-	NC	-	0.10	0.03	
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	3.28	0.10	0.33	NC	-	26.78	87.84	5.00	16.40	0.58	1.90	5.68	18.63	
VL 2052	Subgroup of Leaves of Root and Tuber Vegetables	RAC	0.065	NC	-	NC	-	NC	-	NC	-	NC	-	0.33	0.02	
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.12	5.07	0.61	0.83	0.10	0.17	0.02	3.70	0.44	NC	-	NC	-	
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.12	2.42	0.29	6.09	0.73	4.33	0.52	2.09	0.25	18.99	2.28	0.17	0.02	
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.09	10.72	0.96	1.99	0.18	2.72	0.24	4.26	0.38	4.23	0.38	NC	-	
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.12	1.51	0.18	1.50	0.18	1.90	0.23	5.11	0.61	1.36	0.16	23.43	2.81	
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.12	0.10	0.01	0.10	0.01	1.16	0.14	0.40	0.05	NC	-	0.10	0.01	

OXATHIPIPROLIN (291)				International Estimated Daily Intake (IEDI)				ADI = 0 - 4 mg/kg bw								
Codex Code		Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as 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	0.12	NC	-	NC	-	0.16	0.02	0.10	0.01	NC	-	NC	-	
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.176	106.33	18.71	117.78	20.73	42.12	7.41	195.70	34.44	222.52	39.16	80.47	14.16	
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.12	0.10	0.01	NC	-	0.57	0.07	0.11	0.01	0.16	0.02	0.94	0.11	
VD 2066	Subgroup of dry peas, raw	RAC	0.12	5.01	0.60	3.76	0.45	1.82	0.22	3.44	0.41	3.49	0.42	5.15	0.62	
VD 2067	Subgroup of dry underground pulses, raw	RAC	0.12	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-	
VR 2070	Subgroup of Root vegetables, raw	RAC	0.06	64.22	3.85	65.78	3.95	49.73	2.98	57.68	3.46	113.82	6.83	37.27	2.24	
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0.116	226.09	26.23	234.58	27.21	161.10	18.69	185.04	21.46	234.85	27.24	100.25	11.63	
VS 2080	Subgroup of stems and petioles	RAC	0.056	9.31	0.52	8.57	0.48	NC	-	3.88	0.22	24.46	1.37	5.89	0.33	
VS 2081	Subgroup of young shoots	RAC	0.681	1.76	1.20	2.63	1.79	68.89	46.91	2.55	1.74	3.41	2.32	3.50	2.38	
VS 2082	Subgroup of other stalk and stem vegetables	RAC	0.056	1.49	0.08	4.37	0.24	3.61	0.20	1.68	0.09	0.92	0.05	0.75	0.04	
GC 2086	Subgroup of wheat, similar grains and pseudocereals without husks, raw (including processed)	RAC	0.056	256.28	14.35	280.29	15.70	134.94	7.56	241.61	13.53	217.88	12.20	167.40	9.37	
GC 2087	Subgroup of barley, similar grains, and pseudocereals with husks, raw (including processed)	RAC	0.056	43.68	2.45	60.49	3.39	9.72	0.54	40.47	2.27	49.83	2.79	18.90	1.06	
GC 2088	Subgroup of rice cereals	REP	0.056	20.96	1.17	16.04	0.90	339.67	19.02	75.51	4.23	16.86	0.94	86.13	4.82	
GC 2089	Subgroup of Sorghum Grain and Millet	RAC	0.056	0.10	0.01	0.16	0.01	3.19	0.18	1.85	0.10	NC	-	7.12	0.40	
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.112	18.51	2.07	26.18	2.93	26.04	2.92	39.99	4.48	7.36	0.82	64.58	7.23	
-	Cereals, NES, raw (including processed) : canagua, quihuicha, Job's tears and wild rice	RAC	0.056	6.17	0.35	3.01	0.17	0.76	0.04	3.30	0.18	3.38	0.19	15.84	0.89	
GC 2090	Subgroup of Sweet Corns	RAC	0.112	11.43	1.28	3.71	0.42	0.74	0.08	13.63	1.53	3.07	0.34	1.50	0.17	
SO 0090	Mustard seeds, raw (incl flour, incl oil)	RAC	0.062	0.30	0.02	0.48	0.03	0.33	0.02	0.63	0.04	1.03	0.06	0.40	0.02	
SO 0495	Rape seed, raw (incl oil)	RAC	0.062	32.68	2.03	19.91	1.23	7.83	0.49	15.69	0.97	NC	-	NC	-	
SO 0691	Cotton seed, raw (incl oil)	RAC	0.062	10.71	0.66	4.23	0.26	7.19	0.45	7.54	0.47	5.66	0.35	2.38	0.15	
SO 0693	Linseed, raw (incl oil)	RAC	0.062	NC	-	NC	-	0.10	0.01	0.10	0.01	NC	-	NC	-	

**OXATHIPIPROLIN (291)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as 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 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.062	5.63	0.35	2.75	0.17	9.58	0.59	5.82	0.36	13.71	0.85	1.84	0.11
SO 0698	Poppy seed, raw (incl oil)	RAC	<b>0.102</b>	0.10	0.01	0.25	0.03	0.10	0.01	0.10	0.01	NC	-	NC	-
SO 0699	Safflower seed, raw (incl oil)	RAC	0.062	0.10	0.01	0.10	0.01	0.10	0.01	0.16	0.01	NC	-	NC	-
SO 0700	Sesame seed, raw (incl oil)	RAC	0.062	0.61	0.04	0.10	0.01	1.53	0.09	0.85	0.05	0.10	0.01	0.14	0.01
SO 0701	Shea nut (karite nuts), nutmeat, raw (incl butter)	RAC	0.062	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
SO 0702	Sunflower seed, raw (incl oil)	RAC	<b>0.118</b>	23.40	2.76	29.33	3.46	1.24	0.15	13.85	1.63	6.48	0.76	6.91	0.82
-	Castor bean, raw (incl oil)	RAC	0.062	NC	-	NC	-	0.10	0.01	NC	-	NC	-	NC	-
-	Cucurbitaceae seeds, raw (melonseeds, pumpkin seeds, watermelon seeds)	RAC	0.062	NC	-	NC	-	0.10	0.01	NC	-	NC	-	NC	-
HH 0721	Angelica herb, raw	RAC	0.33	NC	-	NC	-	0.10	0.03	NC	-	NC	-	0.10	0.03
HH 0722	Basil, raw (incl dried)	RAC	<b>3.08</b>	0.52	1.60	0.10	0.31	3.23	9.95	0.18	0.55	0.12	0.37	0.27	0.83
HH 0730	Dill herb, raw	RAC	0.33	0.48	0.16	0.10	0.03	NC	-	1.17	0.39	NC	-	0.31	0.10
HH 0738	Mints, raw	RAC	0.33	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
HH 0740	Parsley, raw (incl dried)	RAC	0.33	1.43	0.47	2.14	0.71	NC	-	2.54	0.84	0.78	0.26	1.14	0.38
HH 0741	Rosemary, raw	RAC	0.33	0.10	0.03	0.10	0.03	NC	-	0.10	0.03	NC	-	0.10	0.03
HH 0743	Sage and related Salvia species, raw	RAC	0.33	0.10	0.03	0.10	0.03	NC	-	0.10	0.03	NC	-	0.10	0.03
HH 0749	Tarragon, raw	RAC	0.33	NC	-	NC	-	NC	-	NC	-	NC	-	0.10	0.03
HH 0750	Thyme, raw	RAC	0.33	0.17	0.06	0.10	0.03	NC	-	NC	-	0.26	0.09	0.10	0.03
HH 0756	Cilantro, raw (i.e. coriander leaves)	RAC	0.33	NC	-	NC	-	5.66	1.87	NC	-	NC	-	0.25	0.08
DH 1100	Hops, dry	RAC	0.33	NC	-	NC	-	0.10	0.03	0.10	0.03	NC	-	NC	-
PM 0110	Poultry meat, raw (incl prepared)	RAC	<b>0</b>	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	<b>0</b>	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	<b>0</b>	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	<b>0</b>	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)=

144.2

144.9

321.2

190.0

160.8

124.3

Bodyweight per region (kg bw) =

60

60

55

60

60

60

ADI (µg//person)=

240000

240000

220000

240000

240000

240000

%ADI=

0.1%

0.1%

0.1%

0.1%

0.1%

0.1%

Rounded %ADI=

0%

0%

0%

0%

0%

0%

## OXATHIPIPROLIN (291)

International Estimated Daily Intake (IEDI)

ADI = 0 - 4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Intake = daily intake: µg/person									
				Diets: g/person/day									
				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 (excl kumquat commodities)	RAC	0.056	2.57	0.14	2.12	0.12	28.93	1.62	0.10	0.01	1.10	0.06
JF 0001	Group of Citrus fruit, juice	PP	0.032	0.11	0.00	0.29	0.01	13.55	0.43	0.14	0.00	0.33	0.01
FC 0303	Kumquats, raw (incl juice)	RAC	0.057	18.35	1.05	0.23	0.01	1.78	0.10	0.10	0.01	3.35	0.19
FB 2005	Subgroup of Caneberries, raw	RAC	0.056	0.10	0.01	7.30	0.41	2.29	0.13	0.10	0.01	NC	-
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.21	0.14	0.03	0.36	0.08	15.22	3.20	0.10	0.02	0.10	0.02
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.29	0.10	0.03	0.13	0.04	1.06	0.31	0.10	0.03	0.10	0.03
JF 0269	Grape juice (from wine grapes)	PP	0.034	0.10	0.00	0.10	0.00	0.41	0.01	0.10	0.00	NC	-
-	Graps must (from wine-grapes)	PP	0.13	0.10	0.01	0.10	0.01	0.11	0.01	0.10	0.01	0.19	0.02
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.029	0.31	0.01	0.23	0.01	60.43	1.75	0.52	0.02	31.91	0.93
FB 0275	Strawberry, raw	RAC	0.08	0.10	0.01	0.10	0.01	3.35	0.27	0.10	0.01	0.10	0.01
VA 0381	Garlic, raw	RAC	0.066	0.82	0.05	2.06	0.14	3.79	0.25	0.10	0.01	0.29	0.02
-	Onions, dry, raw	RAC	0.066	9.01	0.59	20.24	1.34	30.90	2.04	9.61	0.63	2.11	0.14
VA 0384	Leek, raw	RAC	0.656	0.10	0.07	1.44	0.94	1.22	0.80	0.10	0.07	NC	-
-	Onions, green, raw	RAC	0.656	1.43	0.94	0.10	0.07	0.20	0.13	NC	-	6.30	4.13
VB 0400	Broccoli, raw	RAC	0.276	0.10	0.03	0.10	0.03	2.13	0.59	0.10	0.03	NC	-
VB 0404	Cauliflower, raw	RAC	0.136	0.10	0.01	0.10	0.01	2.73	0.37	0.10	0.01	NC	-
VB 0402	Brussels sprouts, raw	RAC	0.056	0.88	0.05	0.69	0.04	2.89	0.16	0.10	0.01	NC	-
VB 0041	Cabbages, head, raw	RAC	0.196	3.82	0.75	2.99	0.59	49.16	9.64	0.10	0.02	NC	-
VB 0467	Chinese cabbage, type pe-tsai, raw	RAC	0.056	0.62	0.03	0.49	0.03	NC	-	0.10	0.01	NC	-
VB 2016	Subgroup of Stem Brassicas, raw	RAC	0.056	0.12	0.01	0.10	0.01	1.81	0.10	0.10	0.01	NC	-
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.03	5.96	0.18	9.74	0.29	51.82	1.55	13.61	0.41	0.10	0.00
VO 0448	Tomato, raw	RAC	0.04	12.99	0.52	4.79	0.19	58.40	2.34	0.92	0.04	0.10	0.00
-	Tomato, canned (& peeled)	PP	0.0016	0.10	0.00	0.10	0.00	2.42	0.00	0.10	0.00	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.044	0.58	0.03	0.22	0.01	2.21	0.10	0.24	0.01	3.10	0.14
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.006	0.10	0.00	0.10	0.00	0.42	0.00	0.10	0.00	0.10	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.04	6.23	0.25	0.10	0.00	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw	RAC	0.04	3.47	0.14	3.56	0.14	16.30	0.65	0.10	0.00	NC	-
-	Peppers, chili, dried	PP	0.4	0.58	0.23	1.27	0.51	1.21	0.48	0.12	0.05	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.04	5.49	0.22	10.57	0.42	8.84	0.35	0.91	0.04	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.04	1.31	0.05	8.26	0.33	3.95	0.16	0.10	0.00	NC	-
VL 0460	Amaranth leaves, raw (i.e. Bledo)	RAC	0.33	1.87	0.62	1.35	0.45	NC	-	1.27	0.42	2.53	0.83

**OXATHIPIPROLIN (291)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		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
VL 0464	Chard, raw (i.e. Beet leaves; Silver beet)	RAC	0.33	0.68	0.22	0.49	0.16	NC	-	0.46	0.15	0.92	0.30
VL 0465	Chervil, raw	RAC	0.33	0.33	0.11	0.24	0.08	NC	-	0.22	0.07	0.45	0.15
VL 2752	Chrysanthemum, edible leaved	RAC	0.33	0.10	0.03	0.10	0.03	NC	-	0.10	0.03	0.10	0.03
VL 0470	Corn salad (Lambs lettuce)	RAC	0.33	1.09	0.36	0.79	0.26	NC	-	0.74	0.24	1.47	0.49
VL 0474	Dandelion, raw (i.e. Laiteron, Pissenlit)	RAC	0.33	0.22	0.07	0.16	0.05	NC	-	0.15	0.05	0.29	0.10
VL 0476	Endive, raw (i.e. scarole)	RAC	0.33	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03	NC	-
VL 0483	Lettuce, leaf, raw	RAC	2.2	0.29	0.64	0.10	0.22	6.71	14.76	0.10	0.22	NC	-
VL 2765	Perilla leaves (Sesame leaves)	RAC	0.33	0.26	0.09	0.19	0.06	NC	-	0.18	0.06	0.35	0.12
VL 0492	Purslane, raw	RAC	0.33	0.10	0.03	0.10	0.03	NC	-	0.10	0.03	0.10	0.03
VL 0502	Spinach, raw	RAC	3.7	0.17	0.63	0.10	0.37	0.81	3.00	0.10	0.37	NC	-
VL 0503	Spinach, Indian, raw (i.e. vine spinach)	RAC	0.33	0.10	0.03	0.10	0.03	NC	-	0.10	0.03	0.10	0.03
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	<b>3.28</b>	3.58	11.74	2.64	8.66	NC	-	1.83	6.00	3.65	11.97
VL 2052	Subgroup of Leaves of Root and Tuber Vegetables	RAC	0.065	0.30	0.02	0.22	0.01	NC	-	0.20	0.01	0.41	0.03
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.12	NC	-	NC	-	NC	-	NC	-	NC	-
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.12	0.37	0.04	3.14	0.38	4.88	0.59	0.10	0.01	NC	-
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.09	0.21	0.02	0.10	0.01	5.51	0.50	0.10	0.01	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.12	7.11	0.85	2.33	0.28	3.76	0.45	44.70	5.36	3.27	0.39
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.12	3.70	0.44	0.10	0.01	0.17	0.02	0.10	0.01	NC	-
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.12	12.77	1.53	0.99	0.12	0.10	0.01	4.33	0.52	NC	-
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	<b>0.176</b>	15.80	2.78	14.29	2.52	104.36	18.37	17.11	3.01	35.20	6.20
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrhizus erosus)	RAC	0.12	2.54	0.30	1.77	0.21	0.10	0.01	0.10	0.01	3.99	0.48
VD 2066	Subgroup of dry peas, raw	RAC	0.12	4.43	0.53	11.36	1.36	4.22	0.51	9.36	1.12	1.21	0.15
VD 2067	Subgroup of dry underground pulses, raw	RAC	0.12	0.20	0.02	NC	-	NC	-	NC	-	NC	-
VR 2070	Subgroup of Root vegetables, raw	RAC	0.06	31.84	1.91	23.38	1.40	68.28	4.10	17.52	1.05	71.01	4.26
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	<b>0.116</b>	250.41	29.05	208.74	24.21	213.64	24.78	602.70	69.91	388.95	45.12

**OXATHIPIPROLIN (291)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		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
VS 2080	Subgroup of stems and petioles	RAC	0.056	5.33	0.30	3.85	0.22	5.80	0.32	3.60	0.20	7.20	0.40
VS 2081	Subgroup of young shoots	RAC	<b>0.681</b>	3.13	2.13	2.26	1.54	1.69	1.15	2.12	1.44	4.23	2.88
VS 2082	Subgroup of other stalk and stem vegetables	RAC	0.056	0.68	0.04	0.49	0.03	0.10	0.01	0.46	0.03	0.91	0.05
GC 2086	Subgroup of wheat, similar grains and pseudocereals without husks, raw (including processed)	RAC	0.056	57.23	3.20	110.47	6.19	286.57	16.05	25.82	1.45	132.92	7.44
GC 2087	Subgroup of barley, similar grains, and pseudocereals with husks, raw (including processed)	RAC	0.056	11.99	0.67	5.22	0.29	49.50	2.77	3.82	0.21	16.26	0.91
GC 2088	Subgroup of rice cereals	REP	0.056	52.55	2.94	286.02	16.02	18.64	1.04	19.67	1.10	75.09	4.21
GC 2089	Subgroup of Sorghum Grain and Millet	RAC	0.056	150.90	8.45	2.80	0.16	NC	-	68.93	3.86	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	<b>0.112</b>	116.66	13.07	10.52	1.18	38.46	4.31	76.60	8.58	34.44	3.86
-	Cereals, NES, raw (including processed) : canagua, quihuicha, Job's tears and wild rice	RAC	0.056	17.71	0.99	2.00	0.11	9.61	0.54	0.45	0.03	4.55	0.25
GC 2090	Subgroup of Sweet Corns	RAC	<b>0.112</b>	3.63	0.41	20.50	2.30	8.78	0.98	0.10	0.01	0.17	0.02
SO 0090	Mustard seeds, raw (incl flour, incl oil)	RAC	0.062	0.10	0.01	0.19	0.01	0.32	0.02	0.10	0.01	0.10	0.01
SO 0495	Rape seed, raw (incl oil)	RAC	0.062	0.19	0.01	0.10	0.01	12.07	0.75	0.10	0.01	NC	-
SO 0691	Cotton seed, raw (incl oil)	RAC	0.062	8.14	0.50	0.32	0.02	2.84	0.18	2.69	0.17	0.97	0.06
SO 0693	Linseed, raw (incl oil)	RAC	0.062	0.10	0.01	NC	-	0.10	0.01	NC	-	NC	-
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.062	18.82	1.17	0.57	0.04	2.28	0.14	6.90	0.43	0.53	0.03
SO 0698	Poppy seed, raw (incl oil)	RAC	<b>0.102</b>	0.10	0.01	0.10	0.01	0.11	0.01	NC	-	NC	-
SO 0699	Safflower seed, raw (incl oil)	RAC	0.062	0.10	0.01	NC	-	NC	-	NC	-	NC	-
SO 0700	Sesame seed, raw (incl oil)	RAC	0.062	2.34	0.15	0.66	0.04	0.26	0.02	9.84	0.61	NC	-
SO 0701	Shea nut (karite nuts), nutmeat, raw (incl butter)	RAC	0.062	0.95	0.06	NC	-	NC	-	NC	-	NC	-
SO 0702	Sunflower seed, raw (incl oil)	RAC	<b>0.118</b>	0.94	0.11	0.22	0.03	32.01	3.78	12.12	1.43	0.48	0.06
-	Castor bean, raw (incl oil)	RAC	0.062	NC	-	NC	-	NC	-	NC	-	NC	-
-	Cucurbitaceae seeds, raw (melonseeds, pumpkin seeds, watermelon seeds)	RAC	0.062	1.81	0.11	NC	-	0.10	0.01	NC	-	NC	-
HH 0721	Angelica herb, raw	RAC	0.33	0.10	0.03	0.10	0.03	NC	-	0.10	0.03	0.10	0.03
HH 0722	Basil, raw (incl dried)	RAC	<b>3.08</b>	0.25	0.77	0.18	0.55	0.13	0.40	0.17	0.52	0.33	1.02
HH 0730	Dill herb, raw	RAC	0.33	0.28	0.09	0.20	0.07	0.65	0.21	0.19	0.06	0.38	0.13
HH 0738	Mints, raw	RAC	0.33	NC	-	NC	-	NC	-	NC	-	NC	-
HH 0740	Parsley, raw (incl dried)	RAC	0.33	1.03	0.34	0.74	0.24	1.87	0.62	0.70	0.23	1.39	0.46
HH 0741	Rosemary, raw	RAC	0.33	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03



**OXATHIPIPROLIN (291)**

## International Estimated Daily Intake (IEDI)

ADI = 0 - 4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		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
HH 0743	Sage and related Salvia species, raw	RAC	0.33	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03
HH 0749	Tarragon, raw	RAC	0.33	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03
HH 0750	Thyme, raw	RAC	0.33	0.10	0.03	0.37	0.12	0.12	0.04	0.10	0.03	0.33	0.11
HH 0756	Cilantro, raw (i.e. coriander leaves)	RAC	0.33	0.22	0.07	0.16	0.05	NC	-	0.15	0.05	0.30	0.10
DH 1100	Hops, dry	RAC	0.33	NC	-	NC	-	0.10	0.03	NC	-	NC	-
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)=	93.3	76.1	128.2	110.8	98.5
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (µg/person)=	240000	240000	240000	240000	240000
%ADI=	0.0%	0.0%	0.1%	0.0%	0.0%
Rounded %ADI=	0%	0%	0%	0%	0%

Annex 3

**PROFENOFOS (171)**

## International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

			STMR	Intake as µg/person/day											
Codex Code	Commodity description	Expr as	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
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.06	10.48	0.63	0.10	0.01	7.24	0.43	6.87	0.41	19.98	1.20	6.25	0.38
FI 0346	Mangosteen, raw (i.e. Mangostan)	RAC	2.1	0.10	0.21	0.10	0.21	0.10	0.21	0.10	0.21	NC	-	0.10	0.21
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	1.3	51.75	67.28	81.80	106.34	16.99	22.09	102.02	132.63	26.32	34.22	214.77	279.20
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.78	6.93	5.41	10.97	8.56	8.83	6.89	9.13	7.12	6.65	5.19	20.01	15.61
-	Peppers, chili, dried	PP	5.46	0.42	2.29	0.53	2.89	0.84	4.59	0.50	2.73	0.95	5.19	0.37	2.02
OR 0691	Cotton seed oil, edible	PP	0.14	3.22	0.45	1.54	0.22	1.01	0.14	0.74	0.10	1.12	0.16	2.93	0.41
SB 0716	Coffee beans, raw (i.e. green coffee)	RAC	0.02	0.96	0.02	0.16	0.00	0.91	0.02	0.27	0.01	1.37	0.03	0.46	0.01
-	Anise seeds, star anise seeds, caraway seeds, coriander seeds, cumin seeds, fennel seeds, juniper berries	RAC	0.635	0.48	0.30	0.10	0.06	0.10	0.06	1.12	0.71	0.25	0.16	0.27	0.17

519

**PROFENOFOS (171)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		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
-	Nutmeg, mace, cardamom, grains of paradise	RAC	0.3	0.10	0.03	0.10	0.03	0.10	0.03	0.92	0.28	0.10	0.03	0.10	0.03
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
039	EGGS	-	0	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (µg//person)=				76.6		118.3		34.5		144.2		46.2		298.0	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (µg//person)=				1800		1800		1800		1800		1800		1800	
%ADI=				4.3%		6.6%		1.9%		8.0%		2.6%		16.6%	
Rounded %ADI=				4%		7%		2%		8%		3%		20%	

**PROFENOFOS (171)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		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
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.06	1.80	0.11	0.63	0.04	10.05	0.60	1.07	0.06	3.52	0.21	16.44	0.99
FI 0346	Mangosteen, raw (i.e. Mangostan)	RAC	2.1	NC	-	NC	-	0.37	0.78	NC	-	NC	-	NC	-
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	1.3	64.74	84.16	68.31	88.80	36.05	46.87	82.09	106.72	54.50	70.85	11.69	15.20
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.78	6.36	4.96	15.46	12.06	10.74	8.38	7.28	5.68	8.21	6.40	3.58	2.79
-	Peppers, chili, dried	PP	5.46	0.11	0.60	0.21	1.15	0.36	1.97	0.21	1.15	0.25	1.37	0.15	0.82
OR 0691	Cotton seed oil, edible	PP	0.14	1.68	0.24	0.66	0.09	1.13	0.16	1.18	0.17	0.89	0.12	0.37	0.05
SB 0716	Coffee beans, raw (i.e. green coffee)	RAC	0.02	0.60	0.01	NC	-	0.62	0.01	1.71	0.03	NC	-	3.51	0.07
-	Anise seeds, star anise seeds, caraway seeds, coriander seeds, cumin seeds, fennel seeds, juniper berries	RAC	0.635	0.22	0.14	0.21	0.13	0.10	0.06	0.14	0.09	0.36	0.23	0.10	0.06
-	Nutmeg, mace, cardamom, grains of paradise	RAC	0.3	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03	0.17	0.05	0.10	0.03
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

PROFENOFOS (171)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.03 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				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	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	-
039	EGGS	-	0	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (µg//person)=				90.2		102.3		58.9		113.9		79.2		20.0	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (µg//person)=				1800		1800		1650		1800		1800		1800	
%ADI=				5.0%		5.7%		3.6%		6.3%		4.4%		1.1%	
Rounded %ADI=				5%		6%		4%		6%		4%		1%	

PROFENOFOS (171)				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		
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.06	12.25	0.74	6.83	0.41	0.76	0.05	0.10	0.01	20.12	1.21		
FI 0346	Mangosteen, raw (i.e. Mangostan)	RAC	2.1	0.10	0.21	0.10	0.21	NC	-	0.10	0.21	0.16	0.34		
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	1.3	15.50	20.15	5.78	7.51	71.52	92.98	2.00	2.60	12.50	16.25		
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.78	7.55	5.89	12.48	9.73	24.78	19.33	0.87	0.68	NC	-		
-	Peppers, chili, dried	PP	5.46	0.58	3.17	1.27	6.93	1.21	6.61	0.12	0.66	NC	-		
OR 0691	Cotton seed oil, edible	PP	0.14	1.28	0.18	0.10	0.01	0.45	0.06	0.42	0.06	0.15	0.02		
SB 0716	Coffee beans, raw (i.e. green coffee)	RAC	0.02	0.83	0.02	0.69	0.01	1.09	0.02	2.91	0.06	0.82	0.02		
-	Anise seeds, star anise seeds, caraway seeds, coriander seeds, cumin seeds, fennel seeds, juniper berries	RAC	0.635	0.10	0.06	1.49	0.95	0.22	0.14	0.10	0.06	0.10	0.06		
-	Nutmeg, mace, cardamom, grains of paradise	RAC	0.3	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03	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		

**PROFENOFOS (171)**

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
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	-
<b>039</b>	<b>EGGS</b>	-	0	-	-	-	-	-	-	-	-	-	-

Total intake (µg/person)=	30.4	25.8	119.2	4.4	17.9
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (µg/person)=	1800	1800	1800	1800	1800
%ADI=	1.7%	1.4%	6.6%	0.2%	1.0%
Rounded %ADI=	2%	1%	7%	0%	1%

**PROPAMOCARB (148)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 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
-	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
VA 0384	Leek, raw	RAC	2.5	0.18	0.45	1.59	3.98	0.10	0.25	0.28	0.70	0.10	0.25	3.21	8.03
VB 0400	Broccoli, raw	RAC	0.29	0.88	0.26	0.17	0.05	0.10	0.03	1.25	0.36	3.00	0.87	1.09	0.32
VB 0404	Cauliflower, raw	RAC	0.035	1.65	0.06	0.32	0.01	0.10	0.00	2.33	0.08	4.79	0.17	2.03	0.07
VB 0402	Brussels sprouts, raw	RAC	0.47	0.63	0.30	6.41	3.01	0.13	0.06	1.03	0.48	NC	-	2.35	1.10
VB 0041	Cabbages, head, raw	RAC	0.195	2.73	0.53	27.92	5.44	0.55	0.11	4.47	0.87	4.27	0.83	10.25	2.00
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.59	10.52	6.21	39.36	23.22	2.07	1.22	25.74	15.19	2.80	1.65	44.83	26.45
VC 0424	Cucumber, raw	RAC	0.59	8.01	4.73	30.66	18.09	1.45	0.86	19.84	11.71	0.27	0.16	34.92	20.60
VC 0425	Gherkin, raw	RAC	0.59	1.73	1.02	6.64	3.92	0.31	0.18	4.29	2.53	0.29	0.17	7.56	4.46
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.59	0.78	0.46	2.06	1.22	0.30	0.18	1.61	0.95	2.25	1.33	2.36	1.39
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.04	8.90	0.36	8.64	0.35	0.80	0.03	17.90	0.72	2.80	0.11	29.17	1.17
VC 0429	Pumpkins, raw	RAC	0.59	4.76	2.81	12.56	7.41	1.85	1.09	9.86	5.82	5.11	3.01	14.39	8.49
VC 0432	Watermelon, raw	RAC	0.04	28.96	1.16	25.65	1.03	1.56	0.06	39.26	1.57	4.94	0.20	66.90	2.68
VO 0448	Tomato, raw	RAC	0.515	41.73	21.49	75.65	38.96	10.66	5.49	82.87	42.68	24.75	12.75	200.93	103.48
-	Tomato, canned (& peeled)	PP	0.515	0.20	0.10	0.31	0.16	0.10	0.05	1.11	0.57	0.11	0.06	1.50	0.77
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	1.54	2.34	3.60	1.33	2.05	1.57	2.42	4.24	6.53	0.34	0.52	2.83	4.36
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.27	0.29	0.08	0.29	0.08	0.10	0.03	0.38	0.10	0.10	0.03	0.14	0.04

PROPAMOCARB (148)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.4 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	
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.265	4.49	1.19	6.44	1.71	7.21	1.91	5.68	1.51	9.52	2.52	8.92	2.36	
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.008	5.58	0.04	4.31	0.03	0.89	0.01	9.31	0.07	13.64	0.11	20.12	0.16	
VL 0483	Lettuce, leaf, raw	RAC	9.9	0.53	5.25	0.36	3.56	0.16	1.58	6.21	61.48	1.90	18.81	6.05	59.90	
VL 0502	Spinach, raw	RAC	11.2	0.74	8.29	0.22	2.46	0.10	1.12	0.91	10.19	0.10	1.12	2.92	32.70	
VL 0480	Kale (Borecole, Collards), raw	RAC	4	0.57	2.28	5.77	23.08	0.11	0.44	0.92	3.68	5.25	21.00	2.12	8.48	
VL 2832	Witloof chicory (sprouts)	RAC	0.6	0.10	0.06	0.10	0.06	0.10	0.06	0.36	0.22	0.10	0.06	0.35	0.21	
VR 0494	Radish roots, raw	RAC	0.33	2.31	0.76	4.09	1.35	2.53	0.83	6.15	2.03	5.88	1.94	2.97	0.98	
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.05	59.74	2.99	316.14	15.81	9.78	0.49	60.26	3.01	54.12	2.71	119.82	5.99	
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.016	31.20	0.50	72.44	1.16	20.88	0.33	47.98	0.77	33.08	0.53	36.25	0.58	
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.016	3.29	0.05	6.14	0.10	0.82	0.01	1.57	0.03	2.23	0.04	1.07	0.02	
MO 0105	Edible offal (mammalian), raw	RAC	0.45	4.79	2.16	9.68	4.36	2.97	1.34	5.49	2.47	3.84	1.73	5.03	2.26	
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	0.001	14.63	0.01	29.76	0.03	8.04	0.01	129.68	0.13	25.04	0.03	35.66	0.04	
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.001	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00	
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.002	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.01	0.24	0.00	0.10	0.00	
PE 0112	Eggs, raw, (incl dried)	RAC	0.001	7.84	0.01	23.08	0.02	2.88	0.00	14.89	0.01	9.81	0.01	14.83	0.01	
Total intake (µg//person)=					68.7		164.6		20.4		178.2		73.6		301.3	
Bodyweight per region (kg bw) =					60		60		60		60		60		60	
ADI (µg//person)=					24000		24000		24000		24000		24000		24000	
%ADI=					0.3%		0.7%		0.1%		0.7%		0.3%		1.3%	
Rounded %ADI=					0%		1%		0%		1%		0%		1%	

PROPAMOCARB (148)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.4 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
-	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
VA 0384	Leek, raw	RAC	2.5	4.01	10.03	4.41	11.03	0.72	1.80	0.54	1.35	16.41	41.03	0.10	0.25
VB 0400	Broccoli, raw	RAC	0.29	4.24	1.23	1.76	0.51	NC	-	0.51	0.15	3.79	1.10	0.26	0.08
VB 0404	Cauliflower, raw	RAC	0.035	5.27	0.18	5.01	0.18	NC	-	2.70	0.09	5.57	0.19	0.49	0.02

PROPAMOCARB (148)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.4 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
VB 0402	Brussels sprouts, raw	RAC	0.47	2.24	1.05	2.67	1.25	6.23	2.93	0.32	0.15	4.19	1.97	2.58	1.21
VB 0041	Cabbages, head, raw	RAC	0.195	8.97	1.75	27.12	5.29	1.44	0.28	24.96	4.87	4.55	0.89	11.23	2.19
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.59	7.14	4.21	16.92	9.98	37.58	22.17	15.16	8.94	4.42	2.61	12.67	7.48
VC 0424	Cucumber, raw	RAC	0.59	6.72	3.96	11.03	6.51	32.10	18.94	15.10	8.91	4.05	2.39	9.57	5.65
VC 0425	Gherkin, raw	RAC	0.59	0.41	0.24	5.89	3.48	NC	-	0.10	0.06	0.37	0.22	2.07	1.22
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.59	NC	-	NC	-	5.48	3.23	NC	-	NC	-	1.03	0.61
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.04	9.20	0.37	11.95	0.48	14.63	0.59	8.99	0.36	7.86	0.31	2.46	0.10
VC 0429	Pumpkins, raw	RAC	0.59	6.88	4.06	3.23	1.91	2.59	1.53	12.12	7.15	1.68	0.99	6.30	3.72
VC 0432	Watermelon, raw	RAC	0.04	4.60	0.18	9.82	0.39	68.50	2.74	13.19	0.53	1.99	0.08	14.56	0.58
VO 0448	Tomato, raw	RAC	0.515	32.13	16.55	51.27	26.40	34.92	17.98	73.37	37.79	15.15	7.80	8.88	4.57
-	Tomato, canned (& peeled)	PP	0.515	7.57	3.90	2.66	1.37	0.30	0.15	0.97	0.50	7.31	3.76	0.41	0.21
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	1.54	4.96	7.64	3.20	4.93	0.15	0.23	1.61	2.48	6.88	10.60	0.52	0.80
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.27	0.80	0.22	0.10	0.03	0.10	0.03	0.61	0.16	0.40	0.11	0.10	0.03
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.265	0.82	0.22	1.53	0.41	10.85	2.88	4.59	1.22	1.84	0.49	2.00	0.53
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.008	1.01	0.01	1.69	0.01	21.37	0.17	3.00	0.02	1.40	0.01	NC	-
VL 0483	Lettuce, leaf, raw	RAC	9.9	14.50	143.55	11.76	116.42	13.14	130.09	19.50	193.05	4.81	47.62	2.23	22.08
VL 0502	Spinach, raw	RAC	11.2	2.20	24.64	1.76	19.71	13.38	149.86	2.94	32.93	5.53	61.94	0.10	1.12
VL 0480	Kale (Borecole, Collards), raw	RAC	4	NC	-	NC	-	14.54	58.16	NC	-	NC	-	2.32	9.28
VL 2832	Witloof chicory (sprouts)	RAC	0.6	1.50	0.90	0.95	0.57	NC	-	1.84	1.10	0.65	0.39	0.13	0.08
VR 0494	Radish roots, raw	RAC	0.33	3.83	1.26	11.99	3.96	NC	-	5.26	1.74	2.19	0.72	4.37	1.44
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.05	225.03	11.25	234.24	11.71	71.48	3.57	177.55	8.88	234.55	11.73	37.71	1.89
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.016	140.03	2.24	150.89	2.41	79.32	1.27	111.24	1.78	120.30	1.92	51.27	0.82
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.016	6.44	0.10	15.51	0.25	3.79	0.06	8.29	0.13	18.44	0.30	8.00	0.13
MO 0105	Edible offal (mammalian), raw	RAC	0.45	15.17	6.83	5.19	2.34	6.30	2.84	6.78	3.05	3.32	1.49	3.17	1.43
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	0.001	73.76	0.07	53.86	0.05	23.98	0.02	87.12	0.09	53.38	0.05	84.45	0.08
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.001	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.002	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.001	25.84	0.03	29.53	0.03	28.05	0.03	33.19	0.03	36.44	0.04	8.89	0.01
Total intake (µg//person)=				247.7		233.1		422.8		319.1		201.2		68.2	

**PROPAMOCARB (148)**

## International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 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
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg//person)=				24000		24000		22000		24000		24000		24000
	%ADI=				1.0%		1.0%		1.9%		1.3%		0.8%		0.3%
	Rounded %ADI=				1%		1%		2%		1%		1%		0%

**PROPAMOCARB (148)**

## International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 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
-	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
VA 0384	Leek, raw	RAC	2.5	0.10	0.25	1.44	3.60	1.22	3.05	0.10	0.25	NC	-
VB 0400	Broccoli, raw	RAC	0.29	0.10	0.03	0.10	0.03	2.13	0.62	0.10	0.03	NC	-
VB 0404	Cauliflower, raw	RAC	0.035	0.10	0.00	0.10	0.00	2.73	0.10	0.10	0.00	NC	-
VB 0402	Brussels sprouts, raw	RAC	0.47	0.88	0.41	0.69	0.32	2.89	1.36	0.10	0.05	NC	-
VB 0041	Cabbages, head, raw	RAC	0.195	3.82	0.74	2.99	0.58	49.16	9.59	0.10	0.02	NC	-
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.59	0.92	0.54	3.20	1.89	13.55	7.99	1.91	1.13	0.10	0.06
VC 0424	Cucumber, raw	RAC	0.59	0.68	0.40	1.81	1.07	10.40	6.14	0.10	0.06	0.10	0.06
VC 0425	Gherkin, raw	RAC	0.59	0.15	0.09	0.39	0.23	3.15	1.86	0.10	0.06	0.10	0.06
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.59	0.10	0.06	1.01	0.60	NC	-	1.91	1.13	NC	-
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.04	0.19	0.01	0.10	0.00	4.98	0.20	0.10	0.00	NC	-
VC 0429	Pumpkins, raw	RAC	0.59	0.56	0.33	6.14	3.62	4.59	2.71	11.70	6.90	NC	-
VC 0432	Watermelon, raw	RAC	0.04	4.29	0.17	0.30	0.01	28.70	1.15	0.10	0.00	NC	-
VO 0448	Tomato, raw	RAC	0.515	12.99	6.69	4.79	2.47	58.40	30.08	0.92	0.47	0.10	0.05
-	Tomato, canned (& peeled)	PP	0.515	0.10	0.05	0.10	0.05	2.42	1.25	0.10	0.05	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	1.54	0.58	0.89	0.22	0.34	2.21	3.40	0.24	0.37	3.10	4.77
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.27	0.10	0.03	0.10	0.03	0.42	0.11	0.10	0.03	0.10	0.03
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.265	5.49	1.45	10.57	2.80	8.84	2.34	0.91	0.24	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.008	1.31	0.01	8.26	0.07	3.95	0.03	0.10	0.00	NC	-
VL 0483	Lettuce, leaf, raw	RAC	9.9	0.29	2.87	0.10	0.99	6.71	66.43	0.10	0.99	NC	-

**PROPAMOCARB (148)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 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
VL 0502	Spinach, raw	RAC	11.2	0.17	1.90	0.10	1.12	0.81	9.07	0.10	1.12	NC	-
VL 0480	Kale (Borecole, Collards), raw	RAC	4	0.79	3.16	0.62	2.48	NC	-	0.10	0.40	NC	-
VL 2832	Witloof chicory (sprouts)	RAC	0.6	0.10	0.06	0.10	0.06	0.10	0.06	0.10	0.06	NC	-
VR 0494	Radish roots, raw	RAC	0.33	3.96	1.31	2.86	0.94	3.30	1.09	2.67	0.88	5.34	1.76
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.05	23.96	1.20	13.56	0.68	213.41	10.67	104.35	5.22	8.56	0.43
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.016	29.18	0.47	50.89	0.81	121.44	1.94	22.58	0.36	72.14	1.15
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.016	1.05	0.02	1.14	0.02	18.69	0.30	0.94	0.02	3.12	0.05
MO 0105	Edible offal (mammalian), raw	RAC	0.45	4.64	2.09	1.97	0.89	10.01	4.50	3.27	1.47	3.98	1.79
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	0.001	3.92	0.00	12.03	0.01	57.07	0.06	5.03	0.01	55.56	0.06
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.001	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.002	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.001	3.84	0.00	4.41	0.00	27.25	0.03	1.13	0.00	7.39	0.01

Total intake (µg/person)=	25.7	26.7	167.7	21.8	10.4
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (µg/person)=	24000	24000	24000	24000	24000
%ADI=	0.1%	0.1%	0.7%	0.1%	0.0%
Rounded %ADI=	0%	0%	1%	0%	0%



**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
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.29	12.68	3.68	9.12	2.64	0.10	0.03	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	0.10	0.07	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	0.10	0.00	0.30	0.01	0.24	0.00	0.10	0.00
-	Graps must (from wine-grapes)	PP	0.31	0.33	0.10	0.13	0.04	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03
-	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
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (µg//person)=				4.2		4.2		0.3		5.9		1.5		17.6	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (µg//person)=				6000		6000		6000		6000		6000		6000	
%ADI=				0.1%		0.1%		0.0%		0.1%		0.0%		0.3%	

**PYDIFLUMETOFEN (309)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.1 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets 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	0.10	0.07	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	0.10	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	0.10	0.03	0.10	0.03	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
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (µg//person)=				12.2		10.1		1.8		6.1		10.0		1.1	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (µg//person)=				6000		6000		5500		6000		6000		6000	
%ADI=				0.2%		0.2%		0.0%		0.1%		0.2%		0.0%	
Rounded %ADI=				0%		0%		0%		0%		0%		0%	

**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	0.10	0.03	0.10	0.03
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.71	0.10	0.07	0.13	0.09	1.06	0.75	0.10	0.07	0.10	0.07
JF 0269	Grape juice (from wine grapes)	PP	0.017	0.10	0.00	0.10	0.00	0.41	0.01	0.10	0.00	NC	-
-	Graps must (from wine-grapes)	PP	0.31	0.10	0.03	0.10	0.03	0.11	0.03	0.10	0.03	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
Total intake (µg//person)=				0.2		0.3		10.7		0.2		3.1	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (µg//person)=				6000		6000		6000		6000		6000	
%ADI=				0.0%		0.0%		0.2%		0.0%		0.1%	
Rounded %ADI=				0%		0%		0%		0%		0%	

**PYRACLOSTROBIN (210)**

## International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		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	0.035	34.91	1.22	16.51	0.58	17.23	0.60	104.48	3.66	35.57	1.24	98.49	3.45
FP 0009	Group of Pomefruits, raw	RAC	0.12	19.24	2.31	33.89	4.07	3.34	0.40	25.53	3.06	7.59	0.91	56.76	6.81
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.012	0.32	0.00	3.07	0.04	0.10	0.00	5.00	0.06	0.29	0.00	5.57	0.07
-	Apple cider (i.e. fermented apple juice)	PP	0.012	0.10	0.00	0.12	0.00	10.66	0.13	0.15	0.00	0.10	0.00	0.10	0.00
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.07	11.60	0.81	23.79	1.67	0.25	0.02	11.84	0.83	2.41	0.17	33.44	2.34
FS 0013	Subgroup of Cherries, raw	RAC	0.51	0.92	0.47	9.15	4.67	0.10	0.05	0.61	0.31	0.10	0.05	6.64	3.39
FS 0014	Subgroup of Plums, raw	RAC	0.09	2.40	0.22	8.60	0.77	0.10	0.01	2.52	0.23	0.58	0.05	4.16	0.37
DF 0014	Plums, dried (prunes)	PP	0.41	0.10	0.04	0.10	0.04	0.10	0.04	0.18	0.07	0.10	0.04	0.10	0.04
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.07	8.01	0.56	5.87	0.41	0.18	0.01	8.19	0.57	1.64	0.11	22.46	1.57
FB 0272	Raspberries, red, black, raw	RAC	0.78	0.10	0.08	0.93	0.73	0.10	0.08	0.10	0.08	0.10	0.08	0.10	0.08
FB 0020	Blueberries, raw	RAC	0.34	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03
FB 0021	Currants, Black, Red, White, raw	RAC	0.185	0.10	0.02	0.74	0.14	0.10	0.02	0.10	0.02	0.10	0.02	0.10	0.02
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.44	12.68	5.58	9.12	4.01	0.10	0.04	16.88	7.43	3.70	1.63	54.42	23.94
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.36	0.51	0.69	0.51	0.69	0.10	0.14	1.27	1.73	0.12	0.16	2.07	2.82

**PYRACLOSTROBIN (210)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		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 0269	Grape juice (from wine grapes)	PP	0.005	0.14	0.00	0.29	0.00	0.10	0.00	0.30	0.00	0.24	0.00	0.10	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 0275	Strawberry, raw	RAC	0.2	0.70	0.14	2.01	0.40	0.10	0.02	1.36	0.27	0.37	0.07	2.53	0.51
FT 0305	Table olives, raw (incl preserved)	RAC	0.01	0.70	0.01	0.32	0.00	0.10	0.00	1.53	0.02	0.17	0.00	1.85	0.02
FI 0326	Avocado, raw	RAC	0.053	0.13	0.01	0.10	0.01	2.05	0.11	2.54	0.13	2.34	0.12	0.12	0.01
FI 0345	Mango, raw	RAC	0.11	10.38	1.14	0.10	0.01	7.24	0.80	6.85	0.75	19.53	2.15	4.52	0.50
FI 0353	Pineapple, raw	RAC	0.002	0.10	0.00	0.10	0.00	7.15	0.01	1.84	0.00	7.01	0.01	0.46	0.00
FI 0351	Passion fruit, raw	RAC	0.045	0.58	0.03	0.10	0.00	0.59	0.03	0.60	0.03	0.18	0.01	0.10	0.00
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	0.02	29.36	0.59	37.50	0.75	3.56	0.07	34.78	0.70	18.81	0.38	43.38	0.87
VA 0384	Leek, raw	RAC	0.22	0.18	0.04	1.59	0.35	0.10	0.02	0.28	0.06	0.10	0.02	3.21	0.71
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.02	2.54	0.05	0.49	0.01	0.10	0.00	3.57	0.07	7.79	0.16	3.12	0.06
VB 0402	Brussels sprouts, raw	RAC	0.03	0.63	0.02	6.41	0.19	0.13	0.00	1.03	0.03	NC	-	2.35	0.07
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	0.08	8.01	0.64	30.66	2.45	1.45	0.12	19.84	1.59	0.27	0.02	34.92	2.79
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.15	0.78	0.12	2.06	0.31	0.30	0.05	1.61	0.24	2.25	0.34	2.36	0.35
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.105	8.90	0.93	8.64	0.91	0.80	0.08	17.90	1.88	2.80	0.29	29.17	3.06
VO 0448	Tomato, raw	RAC	0.12	41.73	5.01	75.65	9.08	10.66	1.28	82.87	9.94	24.75	2.97	200.93	24.11
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.08	6.93	0.55	10.97	0.88	8.83	0.71	9.13	0.73	6.65	0.53	20.01	1.60
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.08	4.49	0.36	6.44	0.52	7.21	0.58	5.68	0.45	9.52	0.76	8.92	0.71
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.12	5.58	0.67	4.31	0.52	0.89	0.11	9.31	1.12	13.64	1.64	20.12	2.41
VL 0502	Spinach, raw	RAC	0.09	0.74	0.07	0.22	0.02	0.10	0.01	0.91	0.08	0.10	0.01	2.92	0.26
VL 0480	Kale (Borecole, Collards), raw	RAC	0.175	0.57	0.10	5.77	1.01	0.11	0.02	0.92	0.16	5.25	0.92	2.12	0.37
VL 2832	Witloof chicory (sprouts)	RAC	0.029	0.10	0.00	0.10	0.00	0.10	0.00	0.36	0.01	0.10	0.00	0.35	0.01
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.07	0.68	0.05	NC	-	NC	-	0.39	0.03	0.22	0.02	0.49	0.03
<b>014B</b>	<b>Peas with pods</b>	-	0.075	-	-	-	-	-	-	-	-	-	-	-	-
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.01	1.56	0.02	0.60	0.01	0.49	0.00	1.18	0.01	0.90	0.01	7.79	0.08
VP 0523	Broad bean without pods (succulent seeds) (Vicia spp), raw	RAC	0.01	3.51	0.04	0.43	0.00	0.10	0.00	0.60	0.01	0.29	0.00	0.78	0.01
VP 2063	Subgroup of succulent peas without pods	RAC	0.01	1.97	0.02	0.51	0.01	0.10	0.00	0.79	0.01	3.68	0.04	3.80	0.04
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.02	0.58	0.01	0.10	0.00	0.37	0.01	0.10	0.00	1.65	0.03	0.30	0.01

**PYRACLOSTROBIN (210)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		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 0541	Soya oil, refined	PP	0.012	12.99	0.16	10.43	0.13	3.63	0.04	13.10	0.16	10.70	0.13	13.10	0.16
VD 2066	Subgroup of dry peas, raw	RAC	0.059	9.09	0.54	3.35	0.20	1.06	0.06	9.48	0.56	15.11	0.89	10.58	0.62
VR 2070	Subgroup of Root vegetables, raw	RAC	0.12	24.72	2.97	57.71	6.93	17.01	2.04	49.58	5.95	9.33	1.12	114.41	13.73
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 0624	Celery	RAC	0.15	2.14	0.32	3.79	0.57	2.35	0.35	5.69	0.85	0.10	0.02	2.75	0.41
VS 0621	Asparagus, raw	RAC	0.01	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.21	0.00
VS 0620	Artichoke globe, raw	RAC	0.25	0.69	0.17	0.10	0.03	0.10	0.03	0.32	0.08	0.26	0.07	1.21	0.30
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.02	0.10	0.00	1.12	0.02	NC	-	0.10	0.00	0.56	0.01	NC	-
CF 1210	Wheat, germ	PP	0.016	NC	-	NC	-	0.10	0.00	0.10	0.00	0.14	0.00	0.10	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.012	301.24	3.61	268.64	3.22	30.21	0.36	222.51	2.67	134.73	1.62	343.12	4.12
GC 0640	Barley, raw	RAC	0.345	2.49	0.86	NC	-	0.10	0.03	0.10	0.03	0.18	0.06	0.38	0.13
-	Barley beer	PP	0.23	4.87	1.12	93.78	21.57	24.28	5.58	12.76	2.93	39.28	9.03	18.15	4.17
-	Barley Malt	PP	0.4	0.10	0.04	1.04	0.42	0.18	0.07	0.33	0.13	0.10	0.04	0.10	0.04
GC 0647	Oats, raw (incl rolled)	RAC	0.17	0.10	0.02	7.05	1.20	0.10	0.02	1.71	0.29	0.96	0.16	0.10	0.02
CM 0649 (GC 0649)	Rice, husked, dry ( incl oil, incl beverages, incl starch, excl polished, excl flour)	REP	0.023	1.20	0.03	1.30	0.03	31.05	0.71	4.79	0.11	0.61	0.01	2.16	0.05
CM 1205	Rice polished, dry	PP	0.01	34.21	0.34	10.39	0.10	41.72	0.42	82.38	0.82	150.24	1.50	70.47	0.70
-	Rice flour	PP	0.004	0.10	0.00	0.22	0.00	0.10	0.00	0.50	0.00	0.22	0.00	0.10	0.00
-	Rice, Fermented Beverages (rice wine, sake)	PP	0.004	NC	-	NC	-	NC	-	NC	-	0.10	0.00	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.02	29.81	0.60	44.77	0.90	108.95	2.18	52.37	1.05	60.28	1.21	75.69	1.51
GS 0659	Sugar cane, raw	RAC	0.025	38.16	0.95	NC	-	12.58	0.31	0.34	0.01	17.79	0.44	42.78	1.07
-	Sugar cane, molasses	PP	0.005	NC	-	NC	-	NC	-	NC	-	0.10	0.00	NC	-
-	Sugar cane, sugar (incl non-centrifugal sugar, incl refined sugar and maltose)	PP	0.0025	61.52	0.15	86.27	0.22	18.80	0.05	80.02	0.20	66.39	0.17	56.32	0.14
TN 0660	Almonds, nutmeat	RAC	0.02	1.38	0.03	0.10	0.00	0.10	0.00	1.00	0.02	0.10	0.00	0.81	0.02
TN 0672	Pecan nuts, nutmeat	RAC	0.02	0.10	0.00	0.10	0.00	0.10	0.00	0.14	0.00	0.10	0.00	0.13	0.00
TN 0675	Pistachio nut, nutmeat	RAC	0.22	0.41	0.09	0.10	0.02	0.10	0.02	0.85	0.19	0.10	0.02	1.08	0.24
SO 0305	Olives for oil production, raw	RAC	0.01	1.47	0.01	0.67	0.01	NC	-	1.26	0.01	0.10	0.00	7.63	0.08
-	Olive oil (virgin and residue oil)	PP	0.062	2.17	0.13	0.13	0.01	0.10	0.01	1.32	0.08	0.10	0.01	2.76	0.17
SO 0495	Rape seed, raw	RAC	0.04	0.10	0.00	NC	-	NC	-	0.10	0.00	0.75	0.03	0.10	0.00

PYRACLOSTROBIN (210)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.03 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				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 0495	Rape seed oil, edible	PP	0.053	0.35	0.02	0.44	0.02	0.19	0.01	0.97	0.05	3.28	0.17	0.77	0.04
SO 0691	Cotton seed, raw (incl oil)	RAC	0.025	20.53	0.51	9.80	0.25	6.42	0.16	4.73	0.12	7.14	0.18	18.68	0.47
OR 0691	Cotton seed oil, edible	PP	0.0045	3.22	0.01	1.54	0.01	1.01	0.00	0.74	0.00	1.12	0.01	2.93	0.01
SO 0697	Peanuts, nutmeat, raw	RAC	0.02	0.40	0.01	1.01	0.02	6.60	0.13	1.47	0.03	1.17	0.02	1.82	0.04
SO 0702	Sunflower seed, raw	RAC	0.055	0.10	0.01	0.33	0.02	0.10	0.01	0.24	0.01	0.10	0.01	0.10	0.01
OR 0702	Sunflower seed oil, edible	PP	0.00077	2.97	0.00	14.42	0.01	0.43	0.00	3.46	0.00	2.20	0.00	5.53	0.00
SB 0715	Cocoa beans, raw (incl roasted, incl powder, incl butter, incl paste, incl nes products)	RAC	0.01	0.72	0.01	4.20	0.04	0.60	0.01	4.21	0.04	0.42	0.00	0.78	0.01
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.025	1.36	0.03	3.59	0.09	1.44	0.04	5.18	0.13	2.02	0.05	1.70	0.04
DH 1100	Hops, dry	RAC	4	0.10	0.40	0.10	0.40	0.10	0.40	0.10	0.40	NC	-	0.10	0.40
DT 1114	Tea, green or black, fermented and dried	RAC	0.965	2.28	2.20	1.92	1.85	0.46	0.44	2.40	2.32	1.29	1.24	3.04	2.93
-	Tea concentrates	PP	0.0009	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.0181	24.96	0.45	57.95	1.05	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	0.166	6.24	1.04	14.49	2.41	4.18	0.69	9.60	1.59	6.62	1.10	7.25	1.20
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.166	3.29	0.55	6.14	1.02	0.82	0.14	1.57	0.26	2.23	0.37	1.07	0.18
MO 0105	Edible offal (mammalian), raw	RAC	0.015	4.79	0.07	9.68	0.15	2.97	0.04	5.49	0.08	3.84	0.06	5.03	0.08
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0095	289.65	2.75	485.88	4.62	26.92	0.26	239.03	2.27	199.91	1.90	180.53	1.72
Total intake (µg//person)=				43.0		84.1		20.6		60.9		37.5		119.4	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (µg//person)=				1800		1800		1800		1800		1800		1800	
%ADI=				2.4%		4.7%		1.1%		3.4%		2.1%		6.6%	
Rounded %ADI=				2%		5%		1%		3%		2%		7%	

PYRACLOSTROBIN (210)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.03 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				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	0.035	114.42	4.00	62.91	2.20	26.97	0.94	96.72	3.39	96.22	3.37	563.19	19.71

**PYRACLOSTROBIN (210)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		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 Pomefruits, raw	RAC	0.12	37.39	4.49	58.13	6.98	37.64	4.52	44.80	5.38	62.17	7.46	6.47	0.78
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.012	14.88	0.18	11.98	0.14	0.15	0.00	9.98	0.12	30.32	0.36	3.47	0.04
-	Apple cider (i.e. fermented apple juice)	PP	0.012	10.05	0.12	5.34	0.06	3.72	0.04	0.36	0.00	0.25	0.00	0.93	0.01
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.07	19.98	1.40	24.87	1.74	14.41	1.01	19.54	1.37	10.78	0.75	0.50	0.04
FS 0013	Subgroup of Cherries, raw	RAC	0.51	1.40	0.71	4.21	2.15	0.10	0.05	2.93	1.49	1.50	0.77	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.09	3.75	0.34	3.33	0.30	5.94	0.53	2.64	0.24	2.50	0.23	0.10	0.01
DF 0014	Plums, dried (prunes)	PP	0.41	0.61	0.25	0.35	0.14	0.10	0.04	0.35	0.14	0.49	0.20	0.13	0.05
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.07	13.03	0.91	16.29	1.14	8.29	0.58	12.95	0.91	5.35	0.37	0.10	0.01
FB 0272	Raspberries, red, black, raw	RAC	0.78	0.47	0.37	0.91	0.71	0.10	0.08	0.99	0.77	1.14	0.89	NC	-
FB 0020	Blueberries, raw	RAC	0.34	0.10	0.03	0.23	0.08	0.10	0.03	0.83	0.28	0.33	0.11	NC	-
FB 0021	Currants, Black, Red, White, raw	RAC	0.185	0.48	0.09	4.23	0.78	NC	-	1.51	0.28	0.49	0.09	NC	-
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.44	6.33	2.79	11.22	4.94	5.21	2.29	9.38	4.13	4.55	2.00	0.78	0.34
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.36	3.09	4.20	1.51	2.05	0.10	0.14	1.38	1.88	4.26	5.79	0.42	0.57
JF 0269	Grape juice (from wine grapes)	PP	0.005	0.56	0.00	1.96	0.01	0.10	0.00	2.24	0.01	2.27	0.01	0.34	0.00
-	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 0275	Strawberry, raw	RAC	0.2	4.49	0.90	5.66	1.13	0.10	0.02	6.63	1.33	5.75	1.15	0.10	0.02
FT 0305	Table olives, raw (incl preserved)	RAC	0.01	2.00	0.02	2.48	0.02	0.10	0.00	1.21	0.01	1.64	0.02	0.27	0.00
FI 0326	Avocado, raw	RAC	0.053	2.65	0.14	0.87	0.05	0.46	0.02	1.64	0.09	1.30	0.07	0.96	0.05
FI 0345	Mango, raw	RAC	0.11	1.80	0.20	0.63	0.07	9.73	1.07	1.07	0.12	3.52	0.39	16.44	1.81
FI 0353	Pineapple, raw	RAC	0.002	3.29	0.01	2.19	0.00	3.77	0.01	3.75	0.01	0.77	0.00	15.72	0.03
FI 0351	Passion fruit, raw	RAC	0.045	0.10	0.00	0.10	0.00	NC	-	NC	-	0.10	0.00	NC	-
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	0.02	19.69	0.39	29.83	0.60	24.64	0.49	31.35	0.63	9.72	0.19	12.59	0.25
VA 0384	Leek, raw	RAC	0.22	4.01	0.88	4.41	0.97	0.72	0.16	0.54	0.12	16.41	3.61	0.10	0.02
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.02	9.50	0.19	6.77	0.14	NC	-	3.21	0.06	9.36	0.19	0.75	0.02
VB 0402	Brussels sprouts, raw	RAC	0.03	2.24	0.07	2.67	0.08	6.23	0.19	0.32	0.01	4.19	0.13	2.58	0.08
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
VC 0424	Cucumber, raw	RAC	0.08	6.72	0.54	11.03	0.88	32.10	2.57	15.10	1.21	4.05	0.32	9.57	0.77
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini), raw	RAC	0.15	NC	-	NC	-	5.48	0.82	NC	-	NC	-	1.03	0.15
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.105	9.20	0.97	11.95	1.25	14.63	1.54	8.99	0.94	7.86	0.83	2.46	0.26
VO 0448	Tomato, raw	RAC	0.12	32.13	3.86	51.27	6.15	34.92	4.19	73.37	8.80	15.15	1.82	8.88	1.07

PYRACLOSTROBIN (210)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.03 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		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 0444	Peppers, chili, raw (incl dried)	RAC	0.08	6.36	0.51	15.46	1.24	10.74	0.86	7.28	0.58	8.21	0.66	3.58	0.29
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.08	0.82	0.07	1.53	0.12	10.85	0.87	4.59	0.37	1.84	0.15	2.00	0.16
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.12	1.01	0.12	1.69	0.20	21.37	2.56	3.00	0.36	1.40	0.17	NC	
VL 0502	Spinach, raw	RAC	0.09	2.20	0.20	1.76	0.16	13.38	1.20	2.94	0.26	5.53	0.50	0.10	0.01
VL 0480	Kale (Borecole, Collards), raw	RAC	0.175	NC	-	NC	-	14.54	2.54	NC	-	NC	-	2.32	0.41
VL 2832	Witloof chicory (sprouts)	RAC	0.029	1.50	0.04	0.95	0.03	NC	-	1.84	0.05	0.65	0.02	0.13	0.00
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.07	5.07	0.35	0.83	0.06	0.17	0.01	3.70	0.26	NC	-	NC	-
014B	Peas with pods	-	0.075	-	-	-	-	-	-	-	-	-	-	-	-
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.01	2.21	0.02	5.25	0.05	4.17	0.04	1.61	0.02	16.95	0.17	0.17	0.00
VP 0523	Broad bean without pods (succulent seeds) (Vicia spp), raw	RAC	0.01	0.22	0.00	0.84	0.01	0.15	0.00	0.48	0.00	2.04	0.02	NC	-
VP 2063	Subgroup of succulent peas without pods	RAC	0.01	10.72	0.11	1.99	0.02	2.72	0.03	4.26	0.04	4.23	0.04	NC	-
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.02	0.10	0.00	0.33	0.01	6.64	0.13	3.94	0.08	NC	-	5.78	0.12
OR 0541	Soya oil, refined	PP	0.012	19.06	0.23	21.06	0.25	5.94	0.07	33.78	0.41	40.05	0.48	13.39	0.16
VD 2066	Subgroup of dry peas, raw	RAC	0.059	5.01	0.30	3.76	0.22	1.82	0.11	3.44	0.20	3.49	0.21	5.15	0.30
VR 2070	Subgroup of Root vegetables, raw	RAC	0.12	64.22	7.71	65.78	7.89	49.73	5.97	57.68	6.92	113.82	13.66	37.27	4.47
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 0624	Celery	RAC	0.15	7.68	1.15	2.85	0.43	NC	-	3.34	0.50	16.83	2.52	4.04	0.61
VS 0621	Asparagus, raw	RAC	0.01	0.84	0.01	2.08	0.02	7.11	0.07	1.01	0.01	1.69	0.02	0.10	0.00
VS 0620	Artichoke globe, raw	RAC	0.25	0.98	0.25	3.65	0.91	0.10	0.03	1.67	0.42	0.26	0.07	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.02	NC	-	NC	-	0.10	0.00	0.83	0.02	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.016	0.97	0.02	0.10	0.00	0.10	0.00	0.10	0.00	NC	-	0.10	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.012	198.08	2.38	193.03	2.32	106.24	1.27	185.09	2.22	168.67	2.02	131.59	1.58
GC 0640	Barley, raw	RAC	0.345	0.10	0.03	NC	-	0.10	0.03	1.36	0.47	NC	-	NC	-
-	Barley beer	PP	0.23	180.21	41.45	259.46	59.68	45.91	10.56	172.36	39.64	234.42	53.92	65.30	15.02
-	Barley Malt	PP	0.4	0.19	0.08	NC	-	0.10	0.04	0.10	0.04	NC	-	2.14	0.86
GC 0647	Oats, raw (incl rolled)	RAC	0.17	7.50	1.28	6.26	1.06	0.15	0.03	4.87	0.83	3.16	0.54	2.98	0.51

**PYRACLOSTROBIN (210)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		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
CM 0649 (GC 0649)	Rice, husked, dry (incl oil, incl beverages, incl starch, excl polished, excl flour)	REP	0.023	2.43	0.06	1.62	0.04	0.58	0.01	1.69	0.04	NC	-	5.03	0.12
CM 1205	Rice polished, dry	PP	0.01	13.38	0.13	10.80	0.11	262.08	2.62	57.16	0.57	12.83	0.13	62.78	0.63
-	Rice flour	PP	0.004	0.98	0.00	0.38	0.00	0.72	0.00	0.10	0.00	0.23	0.00	0.10	0.00
-	Rice, Fermented Beverages (rice wine, sake)	PP	0.004	NC	-	NC	-	0.10	0.00	2.77	0.01	NC	-	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.02	18.51	0.37	26.18	0.52	26.04	0.52	39.99	0.80	7.36	0.15	64.58	1.29
GS 0659	Sugar cane, raw	RAC	0.025	NC	-	NC	-	4.27	0.11	0.10	0.00	NC	-	3.24	0.08
-	Sugar cane, molasses	PP	0.005	NC	-	NC	-	0.10	0.00	NC	-	NC	-	NC	-
-	Sugar cane, sugar (incl non-centrifugal sugar, incl refined sugar and maltose)	PP	0.0025	92.24	0.23	95.72	0.24	24.12	0.06	77.39	0.19	117.73	0.29	100.67	0.25
TN 0660	Almonds, nutmeat	RAC	0.02	0.81	0.02	2.21	0.04	0.10	0.00	1.02	0.02	1.47	0.03	NC	-
TN 0672	Pecan nuts, nutmeat	RAC	0.02	0.38	0.01	NC	-	NC	-	0.27	0.01	NC	-	0.26	0.01
TN 0675	Pistachio nut, nutmeat	RAC	0.22	0.35	0.08	0.48	0.11	0.10	0.02	0.39	0.09	0.23	0.05	0.10	0.02
SO 0305	Olives for oil production, raw	RAC	0.01	0.35	0.00	0.10	0.00	0.10	0.00	0.57	0.01	0.10	0.00	NC	-
-	Olive oil (virgin and residue oil)	PP	0.062	3.40	0.21	9.49	0.59	0.10	0.01	4.28	0.27	2.74	0.17	0.48	0.03
SO 0495	Rape seed, raw	RAC	0.04	NC	-	NC	-	0.10	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.053	12.52	0.66	7.63	0.40	3.00	0.16	6.01	0.32	NC	-	NC	-
SO 0691	Cotton seed, raw (incl oil)	RAC	0.025	10.71	0.27	4.23	0.11	7.19	0.18	7.54	0.19	5.66	0.14	2.38	0.06
OR 0691	Cotton seed oil, edible	PP	0.0045	1.68	0.01	0.66	0.00	1.13	0.01	1.18	0.01	0.89	0.00	0.37	0.00
SO 0697	Peanuts, nutmeat, raw	RAC	0.02	2.39	0.05	2.05	0.04	5.25	0.11	4.39	0.09	1.30	0.03	0.62	0.01
SO 0702	Sunflower seed, raw	RAC	0.055	0.10	0.01	1.32	0.07	0.10	0.01	1.17	0.06	NC	-	0.10	0.01
OR 0702	Sunflower seed oil, edible	PP	0.00077	9.50	0.01	11.37	0.01	0.49	0.00	5.15	0.00	2.63	0.00	2.80	0.00
SB 0715	Cocoa beans, raw (incl roasted, incl powder, incl butter, incl paste, incl nes products)	RAC	0.01	7.54	0.08	5.59	0.06	0.29	0.00	4.14	0.04	1.27	0.01	5.29	0.05
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.025	10.90	0.27	12.44	0.31	0.77	0.02	9.48	0.24	22.07	0.55	8.15	0.20
DH 1100	Hops, dry	RAC	4	NC	-	NC	-	0.10	0.40	0.10	0.40	NC	-	NC	-
DT 1114	Tea, green or black, fermented and dried	RAC	0.965	2.71	2.62	0.82	0.79	1.14	1.10	1.59	1.53	1.82	1.76	0.53	0.51
-	Tea concentrates	PP	0.0009	0.20	0.00	0.91	0.00	0.10	0.00	0.26	0.00	0.47	0.00	0.21	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.0181	112.02	2.03	120.71	2.18	63.46	1.15	88.99	1.61	96.24	1.74	41.02	0.74



**PYRACLOSTROBIN (210)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		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) - 20% as fat	RAC	0.166	28.01	4.65	30.18	5.01	15.86	2.63	22.25	3.69	24.06	3.99	10.25	1.70
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.166	6.44	1.07	15.51	2.57	3.79	0.63	8.29	1.38	18.44	3.06	8.00	1.33
MO 0105	Edible offal (mammalian), raw	RAC	0.015	15.17	0.23	5.19	0.08	6.30	0.09	6.78	0.10	3.32	0.05	3.17	0.05
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0095	388.92	3.69	335.88	3.19	49.15	0.47	331.25	3.15	468.56	4.45	245.45	2.33

Total intake (µg//person)=	104.9	129.1	58.8	103.9	125.5	60.5
Bodyweight per region (kg bw) =	60	60	55	60	60	60
ADI (µg//person)=	1800	1800	1650	1800	1800	1800
%ADI=	5.8%	7.2%	3.6%	5.8%	7.0%	3.4%
Rounded %ADI=	6%	7%	4%	6%	7%	3%

**PYRACLOSTROBIN (210)**

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
FC 0001	Group of Citrus fruit, raw (incl citrus fruit juice, incl kumquat commodities)	RAC	0.035	21.16	0.74	2.94	0.10	58.52	2.05	0.44	0.02	5.13	0.18
FP 0009	Group of Pomefruits, raw	RAC	0.12	2.39	0.29	10.93	1.31	69.47	8.34	1.59	0.19	19.56	2.35
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.012	0.10	0.00	0.10	0.00	7.19	0.09	0.10	0.00	NC	-
-	Apple cider (i.e. fermented apple juice)	PP	0.012	48.75	0.59	0.10	0.00	0.99	0.01	138.03	1.66	NC	-
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.07	0.10	0.01	0.10	0.01	33.36	2.34	0.10	0.01	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	0.51	0.10	0.05	0.10	0.05	5.96	3.04	0.10	0.05	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.09	0.10	0.01	0.10	0.01	15.56	1.40	0.10	0.01	NC	-
DF 0014	Plums, dried (prunes)	PP	0.41	0.10	0.04	0.10	0.04	0.37	0.15	0.10	0.04	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.07	0.10	0.01	0.10	0.01	10.76	0.75	0.10	0.01	NC	-
FB 0272	Raspberries, red, black, raw	RAC	0.78	0.10	0.08	0.10	0.08	2.04	1.59	0.10	0.08	NC	-
FB 0020	Blueberries, raw	RAC	0.34	NC	-	NC	-	0.20	0.07	NC	-	NC	-
FB 0021	Currants, Black, Red, White, raw	RAC	0.185	0.10	0.02	NC	-	0.74	0.14	NC	-	NC	-
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.44	0.14	0.06	0.36	0.16	15.22	6.70	0.10	0.04	0.10	0.04
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.36	0.10	0.14	0.13	0.18	1.06	1.44	0.10	0.14	0.10	0.14
JF 0269	Grape juice (from wine grapes)	PP	0.005	0.10	0.00	0.10	0.00	0.41	0.00	0.10	0.00	NC	-
-	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 0275	Strawberry, raw	RAC	0.2	0.10	0.02	0.10	0.02	3.35	0.67	0.10	0.02	0.10	0.02
FT 0305	Table olives, raw (incl preserved)	RAC	0.01	0.10	0.00	0.10	0.00	1.75	0.02	0.10	0.00	0.24	0.00
FI 0326	Avocado, raw	RAC	0.053	1.12	0.06	0.10	0.01	0.84	0.04	0.10	0.01	6.60	0.35
FI 0345	Mango, raw	RAC	0.11	12.25	1.35	6.74	0.74	0.76	0.08	0.10	0.01	20.12	2.21
FI 0353	Pineapple, raw	RAC	0.002	6.09	0.01	6.05	0.01	1.04	0.00	0.15	0.00	24.94	0.05
FI 0351	Passion fruit, raw	RAC	0.045	0.12	0.01	0.10	0.00	0.10	0.00	0.18	0.01	3.81	0.17
VA 0381	Garlic, raw	RAC	0.05	0.82	0.04	2.06	0.10	3.79	0.19	0.10	0.01	0.29	0.01
-	Onions, dry, raw	RAC	0.02	9.01	0.18	20.24	0.40	30.90	0.62	9.61	0.19	2.11	0.04
VA 0384	Leek, raw	RAC	0.22	0.10	0.02	1.44	0.32	1.22	0.27	0.10	0.02	NC	-
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.02	0.10	0.00	0.10	0.00	4.86	0.10	0.10	0.00	NC	-
VB 0402	Brussels sprouts, raw	RAC	0.03	0.88	0.03	0.69	0.02	2.89	0.09	0.10	0.00	NC	-
VB 0041	Cabbages, head, raw	RAC	0.02	3.82	0.08	2.99	0.06	49.16	0.98	0.10	0.00	NC	-
VC 0424	Cucumber, raw	RAC	0.08	0.68	0.05	1.81	0.14	10.40	0.83	0.10	0.01	0.10	0.01
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.15	0.10	0.02	1.01	0.15	NC	-	1.91	0.29	NC	-

**PYRACLOSTROBIN (210)**

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
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.105	0.19	0.02	0.10	0.01	4.98	0.52	0.10	0.01	NC	-
VO 0448	Tomato, raw	RAC	0.12	12.99	1.56	4.79	0.57	58.40	7.01	0.92	0.11	0.10	0.01
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.08	7.55	0.60	12.48	1.00	24.78	1.98	0.87	0.07	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.08	5.49	0.44	10.57	0.85	8.84	0.71	0.91	0.07	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.12	1.31	0.16	8.26	0.99	3.95	0.47	0.10	0.01	NC	-
VL 0502	Spinach, raw	RAC	0.09	0.17	0.02	0.10	0.01	0.81	0.07	0.10	0.01	NC	-
VL 0480	Kale (Borecole, Collards), raw	RAC	0.175	0.79	0.14	0.62	0.11	NC	-	0.10	0.02	NC	-
VL 2832	Witloof chicory (sprouts)	RAC	0.029	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	NC	-
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.07	NC	-	NC	-	NC	-	NC	-	NC	-
<b>014B</b>	<b>Peas with pods</b>	-	0.075	-	-	-	-	-	-	-	-	-	-
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.01	0.30	0.00	3.13	0.03	4.11	0.04	0.10	0.00	NC	-
VP 0523	Broad bean without pods (succulent seeds) (Vicia spp), raw	RAC	0.01	0.10	0.00	0.10	0.00	0.76	0.01	NC	-	NC	-
VP 2063	Subgroup of succulent peas without pods	RAC	0.01	0.21	0.00	0.10	0.00	5.51	0.06	0.10	0.00	NC	-
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.02	2.76	0.06	0.10	0.00	0.33	0.01	3.16	0.06	NC	-
OR 0541	Soya oil, refined	PP	0.012	2.32	0.03	2.54	0.03	18.70	0.22	2.51	0.03	6.29	0.08
VD 2066	Subgroup of dry peas, raw	RAC	0.059	4.43	0.26	11.36	0.67	4.22	0.25	9.36	0.55	1.21	0.07
VR 2070	Subgroup of Root vegetables, raw	RAC	0.12	31.84	3.82	23.38	2.81	68.28	8.19	17.52	2.10	71.01	8.52
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 0624	Celery	RAC	0.15	3.66	0.55	2.65	0.40	4.84	0.73	2.47	0.37	4.94	0.74
VS 0621	Asparagus, raw	RAC	0.01	0.10	0.00	0.10	0.00	0.17	0.00	0.10	0.00	NC	-
VS 0620	Artichoke globe, raw	RAC	0.25	0.10	0.03	NC	-	0.10	0.03	0.10	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	0.02	0.10	0.00	NC	-	NC	-	NC	-	0.97	0.02
CF 1210	Wheat, germ	PP	0.016	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	NC	-
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.012	44.78	0.54	86.96	1.04	214.05	2.57	20.31	0.24	103.60	1.24
GC 0640	Barley, raw	RAC	0.345	0.10	0.03	0.10	0.03	0.16	0.06	NC	-	NC	-
-	Barley beer	PP	0.23	16.25	3.74	11.36	2.61	225.21	51.80	19.49	4.48	52.17	12.00
-	Barley Malt	PP	0.4	0.10	0.04	0.11	0.04	0.67	0.27	0.10	0.04	4.61	1.84
GC 0647	Oats, raw (incl rolled)	RAC	0.17	0.37	0.06	0.10	0.02	2.79	0.47	0.10	0.02	NC	-

**PYRACLOSTROBIN (210)**

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
CM 0649 (GC 0649)	Rice, husked, dry ( incl oil, incl beverages, incl starch, excl polished, excl flour)	REP	0.023	13.54	0.31	4.12	0.09	1.96	0.05	0.10	0.00	8.84	0.20
CM 1205	Rice polished, dry	PP	0.01	30.20	0.30	218.34	2.18	12.77	0.13	15.24	0.15	51.35	0.51
-	Rice flour	PP	0.004	0.10	0.00	0.13	0.00	0.16	0.00	0.10	0.00	NC	-
-	Rice, Fermented Beverages (rice wine, sake)	PP	0.004	NC	-	NC	-	NC	-	NC	-	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.02	116.66	2.33	10.52	0.21	38.46	0.77	76.60	1.53	34.44	0.69
GS 0659	Sugar cane, raw	RAC	0.025	5.62	0.14	50.91	1.27	NC	-	11.04	0.28	0.10	0.00
-	Sugar cane, molasses	PP	0.005	NC	-	NC	-	NC	-	NC	-	NC	-
-	Sugar cane, sugar (incl non-centrifugal sugar, incl refined sugar and maltose)	PP	0.0025	28.13	0.07	55.38	0.14	78.09	0.20	18.04	0.05	45.60	0.11
TN 0660	Almonds, nutmeat	RAC	0.02	0.10	0.00	0.10	0.00	0.61	0.01	0.10	0.00	NC	-
TN 0672	Pecan nuts, nutmeat	RAC	0.02	0.15	0.00	0.22	0.00	0.31	0.01	0.10	0.00	0.10	0.00
TN 0675	Pistachio nut, nutmeat	RAC	0.22	0.10	0.02	0.10	0.02	0.15	0.03	0.10	0.02	NC	-
SO 0305	Olives for oil production, raw	RAC	0.01	NC	-	NC	-	0.10	0.00	NC	-	NC	-
-	Olive oil (virgin and residue oil)	PP	0.062	0.10	0.01	0.10	0.01	2.14	0.13	0.10	0.01	0.10	0.01
SO 0495	Rape seed, raw	RAC	0.04	NC	-	0.10	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.053	0.10	0.01	0.10	0.01	4.62	0.24	0.10	0.01	NC	-
SO 0691	Cotton seed, raw (incl oil)	RAC	0.025	8.14	0.20	0.32	0.01	2.84	0.07	2.69	0.07	0.97	0.02
OR 0691	Cotton seed oil, edible	PP	0.0045	1.28	0.01	0.10	0.00	0.45	0.00	0.42	0.00	0.15	0.00
SO 0697	Peanuts, nutmeat, raw	RAC	0.02	7.12	0.14	0.32	0.01	1.34	0.03	6.21	0.12	0.53	0.01
SO 0702	Sunflower seed, raw	RAC	0.055	0.10	0.01	0.10	0.01	0.10	0.01	2.23	0.12	NC	-
OR 0702	Sunflower seed oil, edible	PP	0.00077	0.37	0.00	0.10	0.00	12.98	0.01	4.01	0.00	0.20	0.00
SB 0715	Cocoa beans, raw (incl roasted, incl powder, incl butter, incl paste, incl nes products)	RAC	0.01	0.11	0.00	0.89	0.01	6.28	0.06	0.17	0.00	2.31	0.02
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.025	0.95	0.02	1.32	0.03	11.64	0.29	2.96	0.07	14.73	0.37
DH 1100	Hops, dry	RAC	4	NC	-	NC	-	0.10	0.40	NC	-	NC	-
DT 1114	Tea, green or black, fermented and dried	RAC	0.965	0.53	0.51	5.25	5.07	0.63	0.61	0.56	0.54	0.82	0.79
-	Tea concentrates	PP	0.0009	0.10	0.00	0.10	0.00	0.23	0.00	0.10	0.00	0.10	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.0181	23.34	0.42	40.71	0.74	97.15	1.76	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	0.166	5.84	0.97	10.18	1.69	24.29	4.03	4.52	0.75	14.43	2.40

**PYRACLOSTROBIN (210)**

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
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.166	1.05	0.17	1.14	0.19	18.69	3.10	0.94	0.16	3.12	0.52
MO 0105	Edible offal (mammalian), raw	RAC	0.015	4.64	0.07	1.97	0.03	10.01	0.15	3.27	0.05	3.98	0.06
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0095	108.75	1.03	70.31	0.67	436.11	4.14	61.55	0.58	79.09	0.75

Total intake (µg/person)=	22.8	27.6	126.1	15.9	38.9
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (µg/person)=	1800	1800	1800	1800	1800
%ADI=	1.3%	1.5%	7.0%	0.9%	2.2%
Rounded %ADI=	1%	2%	7%	1%	2%

**PYRIFENONE (310)**

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
FB 2005	Subgroup of Caneberries, raw	RAC	0.265	0.42	0.11	1.05	0.28	0.10	0.03	0.10	0.03	0.10	0.03	1.24	0.33
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.34	0.53	0.18	1.31	0.45	0.40	0.14	1.66	0.56	0.10	0.03	0.99	0.34
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.23	12.68	2.92	9.12	2.10	0.10	0.02	16.88	3.88	3.70	0.85	54.42	12.52
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.64	0.51	0.33	0.51	0.33	0.10	0.06	1.27	0.81	0.12	0.08	2.07	1.32
JF 0269	Grape juice (from wine grapes)	PP	0.014	0.14	0.00	0.29	0.00	0.10	0.00	0.30	0.00	0.24	0.00	0.10	0.00
-	Graps must (from wine-grapes)	PP	0.1	0.33	0.03	0.13	0.01	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.032	0.67	0.02	12.53	0.40	2.01	0.06	1.21	0.04	3.53	0.11	4.01	0.13
FB 2009	Subgroup of Low growing berries, raw	RAC	0.17	0.71	0.12	2.02	0.34	0.10	0.02	1.39	0.24	0.37	0.06	2.53	0.43
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.04	53.14	2.13	86.21	3.45	6.28	0.25	92.76	3.71	15.64	0.63	155.30	6.21

Total intake (µg/person)=	5.8	7.4	0.6	9.3	1.8	21.3
Bodyweight per region (kg bw) =	60	60	60	60	60	60
ADI (µg/person)=	5400	5400	5400	5400	5400	5400
%ADI=	0.1%	0.1%	0.0%	0.2%	0.0%	0.4%
Rounded %ADI=	0%	0%	0%	0%	0%	0%

ADI = 0 - 0.09 mg/kg bw

				Diets as g/person/day		Intake as µg//person/day										
Codex Code	Commodity description	Expr as	STMR mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake	
FB 2005	Subgroup of Caneberries, raw	RAC	0.265	0.56	0.15	1.43	0.38	0.14	0.04	1.23	0.33	1.14	0.30	0.10	0.03	
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.34	1.31	0.45	5.50	1.87	0.10	0.03	2.57	0.87	0.82	0.28	2.15	0.73	
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.23	6.33	1.46	11.22	2.58	5.21	1.20	9.38	2.16	4.55	1.05	0.78	0.18	
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.64	3.09	1.98	1.51	0.97	0.10	0.06	1.38	0.88	4.26	2.73	0.42	0.27	
JF 0269	Grape juice (from wine grapes)	PP	0.014	0.56	0.01	1.96	0.03	0.10	0.00	2.24	0.03	2.27	0.03	0.34	0.00	
-	Graps must (from wine-grapes)	PP	0.1	0.16	0.02	0.10	0.01	0.10	0.01	0.12	0.01	0.11	0.01	NC	-	
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.032	88.93	2.85	62.41	2.00	1.84	0.06	25.07	0.80	61.17	1.96	5.84	0.19	
FB 2009	Subgroup of Low growing berries, raw	RAC	0.17	4.55	0.77	5.66	0.96	0.10	0.02	7.85	1.33	5.86	1.00	0.10	0.02	
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.04	27.81	1.11	41.93	1.68	123.30	4.93	49.47	1.98	15.95	0.64	35.99	1.44	
Total intake (µg//person)=					8.8		10.5		6.4		8.4		8.0		2.9	
Bodyweight per region (kg bw) =					60		60		55		60		60		60	
ADI (µg//person) =					5400		5400		4950		5400		5400		5400	
%ADI=					0.2%		0.2%		0.1%		0.2%		0.1%		0.1%	
Rounded %ADI=					0%		0%		0%		0%		0%		0%	

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
FB 2005	Subgroup of Caneberries, raw	RAC	0.265	0.10	0.03	7.30	1.93	2.29	0.61	0.10	0.03	NC	-
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.34	0.82	0.28	4.05	1.38	5.94	2.02	0.43	0.15	2.66	0.90
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.23	0.14	0.03	0.36	0.08	15.22	3.50	0.10	0.02	0.10	0.02
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.64	0.10	0.06	0.13	0.08	1.06	0.68	0.10	0.06	0.10	0.06
JF 0269	Grape juice (from wine grapes)	PP	0.014	0.10	0.00	0.10	0.00	0.41	0.01	0.10	0.00	NC	-
-	Graps must (from wine-grapes)	PP	0.1	0.10	0.01	0.10	0.01	0.11	0.01	0.10	0.01	0.19	0.02
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.032	0.31	0.01	0.23	0.01	60.43	1.93	0.52	0.02	31.91	1.02
FB 2009	Subgroup of Low growing berries, raw	RAC	0.17	0.10	0.02	0.10	0.02	3.37	0.57	0.10	0.02	0.10	0.02
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.04	5.96	0.24	9.74	0.39	51.82	2.07	13.61	0.54	0.10	0.00
Total intake (µg//person)=				0.7		3.9		11.4		0.8		2.1	
Bodyweight per region (kg bw) =				60		60		60		60		60	

PYRIOFENONE (310)				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	G13	G14	G14	G15	G15	G16	G16	G17	G17
				diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
					5400		5400		5400		5400		5400
					0.0%		0.1%		0.2%		0.0%		0.0%
					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 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	0.013	4.82	0.06	2.45	0.03	3.93	0.05	25.44	0.33	8.74	0.11	16.23	0.21	
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.013	6.18	0.08	3.66	0.05	0.25	0.00	6.82	0.09	3.49	0.05	19.38	0.25	
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.013	20.66	0.27	5.23	0.07	11.90	0.15	37.90	0.49	21.16	0.28	56.46	0.73	
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.0036	1.27	0.00	2.20	0.01	0.10	0.00	11.81	0.04	0.46	0.00	1.69	0.01	
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.013	0.66	0.01	0.69	0.01	0.96	0.01	10.20	0.13	1.25	0.02	2.97	0.04	
FI 0350	Papaya, raw	RAC	0.07	0.35	0.02	0.10	0.01	3.05	0.21	0.80	0.06	7.28	0.51	1.00	0.07	
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0.01	0.61	0.01	1.56	0.02	7.89	0.08	9.36	0.09	8.76	0.09	1.30	0.01	
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 0425	Gherkin, raw	RAC	0.01	1.73	0.02	6.64	0.07	0.31	0.00	4.29	0.04	0.29	0.00	7.56	0.08	
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	0.016	8.90	0.14	8.64	0.14	0.80	0.01	17.90	0.29	2.80	0.04	29.17	0.47	
VO 0448	Tomato, raw	RAC	0.1	41.73	4.17	75.65	7.57	10.66	1.07	82.87	8.29	24.75	2.48	200.93	20.09	
-	Tomato, canned (& peeled)	PP	0.018	0.20	0.00	0.31	0.01	0.10	0.00	1.11	0.02	0.11	0.00	1.50	0.03	
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.12	2.34	0.28	1.33	0.16	1.57	0.19	4.24	0.51	0.34	0.04	2.83	0.34	
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.018	0.29	0.01	0.29	0.01	0.10	0.00	0.38	0.01	0.10	0.00	0.14	0.00	
VO 0444	Peppers, chili, raw	RAC	0.17	3.99	0.68	7.30	1.24	2.93	0.50	5.62	0.96	NC	-	17.44	2.96	
-	Peppers, chili, dried	PP	1.7	0.42	0.71	0.53	0.90	0.84	1.43	0.50	0.85	0.95	1.62	0.37	0.63	
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.17	4.49	0.76	6.44	1.09	7.21	1.23	5.68	0.97	9.52	1.62	8.92	1.52	
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.17	5.58	0.95	4.31	0.73	0.89	0.15	9.31	1.58	13.64	2.32	20.12	3.42	
OR 0691	Cotton seed oil, edible	PP	0.002	3.22	0.01	1.54	0.00	1.01	0.00	0.74	0.00	1.12	0.00	2.93	0.01	

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										
				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	
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	
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Total intake (µg//person)=					8.3		12.4		5.1		15.0		9.2		31.2	
Bodyweight per region (kg bw) =					60		60		60		60		60		60	
ADI (µg//person)=					6000		6000		6000		6000		6000		6000	
%ADI=					0.1%		0.2%		0.1%		0.2%		0.2%		0.5%	
Rounded %ADI=					0%		0%		0%		0%		0%		1%	
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	
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 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	-	0.10	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	0.10	0.00	0.10	0.00	0.61	0.01	0.40	0.01	0.10	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	



**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									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
-	Peppers, chili, dried	PP	1.7	0.11	0.19	0.21	0.36	0.36	0.61	0.21	0.36	0.25	0.43	0.15	0.26
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.17	0.82	0.14	1.53	0.26	10.85	1.84	4.59	0.78	1.84	0.31	2.00	0.34
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.17	1.01	0.17	1.69	0.29	21.37	3.63	3.00	0.51	1.40	0.24	NC	-
OR 0691	Cotton seed oil, edible	PP	0.002	1.68	0.00	0.66	0.00	1.13	0.00	1.18	0.00	0.89	0.00	0.37	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
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

Total intake (µg//person)=	6.5	10.1	12.1	11.5	6.1	9.4
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%	0.2%	0.2%	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		
SULFOXAFLOR (252)				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
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.038	4.82	0.18	2.45	0.09	3.93	0.15	25.44	0.97	8.74	0.33	16.23	0.62
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.26	6.18	1.61	3.66	0.95	0.25	0.07	6.82	1.77	3.49	0.91	19.38	5.04
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.26	23.26	6.05	9.71	2.52	12.09	3.14	62.02	16.13	22.09	5.74	59.91	15.58
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.036	1.27	0.05	2.20	0.08	0.10	0.00	11.81	0.43	0.46	0.02	1.69	0.06
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.0125	0.66	0.01	0.69	0.01	0.96	0.01	10.20	0.13	1.25	0.02	2.97	0.04
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.067	19.35	1.30	34.06	2.28	17.87	1.20	25.74	1.72	7.69	0.52	56.85	3.81
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.027	0.32	0.01	3.07	0.08	0.10	0.00	5.00	0.14	0.29	0.01	5.57	0.15
FS 0013	Subgroup of Cherries, raw	RAC	0.34	0.92	0.31	9.15	3.11	0.10	0.03	0.61	0.21	0.10	0.03	6.64	2.26
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.038	2.67	0.10	8.77	0.33	0.10	0.00	3.03	0.12	0.70	0.03	4.34	0.16
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.061	8.01	0.49	5.87	0.36	0.18	0.01	8.19	0.50	1.64	0.10	22.46	1.37
FB 0269	Grapes, raw (incl must, incl juice, excl dried, excl wine)	RAC	0.14	13.19	1.85	9.61	1.35	0.10	0.01	17.28	2.42	4.00	0.56	54.50	7.63
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.49	0.51	0.25	0.51	0.25	0.10	0.05	1.27	0.62	0.12	0.06	2.07	1.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.098	0.67	0.07	12.53	1.23	2.01	0.20	1.21	0.12	3.53	0.35	4.01	0.39
FB 0275	Strawberry, raw	RAC	0.19	0.70	0.13	2.01	0.38	0.10	0.02	1.36	0.26	0.37	0.07	2.53	0.48
VA 0381	Garlic, raw	RAC	0.01	2.29	0.02	5.78	0.06	0.11	0.00	3.69	0.04	1.65	0.02	3.91	0.04
-	Onions, dry, raw	RAC	0	29.36	0.00	37.50	0.00	3.56	0.00	34.78	0.00	18.81	0.00	43.38	0.00
-	Onions, green, raw	RAC	0.11	2.45	0.27	1.49	0.16	1.02	0.11	2.60	0.29	0.60	0.07	2.03	0.22
VB 0400	Broccoli, raw	RAC	0.074	0.88	0.07	0.17	0.01	0.10	0.01	1.25	0.09	3.00	0.22	1.09	0.08
VB 0404	Cauliflower, raw	RAC	0.012	1.65	0.02	0.32	0.00	0.10	0.00	2.33	0.03	4.79	0.06	2.03	0.02
VB 0041	Cabbages, head, raw	RAC	0.099	2.73	0.27	27.92	2.76	0.55	0.05	4.47	0.44	4.27	0.42	10.25	1.01
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.029	53.14	1.54	86.21	2.50	6.28	0.18	92.76	2.69	15.64	0.45	155.30	4.50
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.11	42.04	4.62	76.13	8.37	10.69	1.18	84.59	9.30	24.92	2.74	203.27	22.36
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.23	2.34	0.54	1.33	0.31	1.57	0.36	4.24	0.98	0.34	0.08	2.83	0.65

**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		
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.052	0.29	0.02	0.29	0.02	0.10	0.01	0.38	0.02	0.10	0.01	0.14	0.01	
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.11	1.97	0.22	NC	-	3.68	0.40	3.24	0.36	5.72	0.63	1.57	0.17	
VO 0444	Peppers, chili, raw	RAC	0.11	3.99	0.44	7.30	0.80	2.93	0.32	5.62	0.62	NC	-	17.44	1.92	
-	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	
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.11	4.49	0.49	6.44	0.71	7.21	0.79	5.68	0.62	9.52	1.05	8.92	0.98	
VO 0440	Egg plant, raw (i.e. aubergine)	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	1.2	3.93	4.72	5.28	6.34	3.07	3.68	14.53	17.44	8.25	9.90	12.75	15.30	
VL 0473	Watercress, raw	RAC	1	1.21	1.21	2.15	2.15	1.33	1.33	3.24	3.24	11.36	11.36	1.56	1.56	
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.075	2.39	0.18	1.61	0.12	10.47	0.79	1.84	0.14	12.90	0.97	7.44	0.56	
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.011	0.63	0.01	1.09	0.01	0.40	0.00	1.40	0.02	1.68	0.02	0.48	0.01	
OR 0541	Soya oil, refined	PP	0.0033	12.99	0.04	10.43	0.03	3.63	0.01	13.10	0.04	10.70	0.04	13.10	0.04	
VR 0574	Beetroot, raw	RAC	0.01	3.42	0.03	6.06	0.06	3.75	0.04	9.11	0.09	NC	-	4.39	0.04	
VR 0575	Burdock, greater or edible, raw	RAC	0.01	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	
VR 0578	Celeriac, raw	RAC	0.01	1.70	0.02	3.01	0.03	1.87	0.02	4.53	0.05	NC	-	2.19	0.02	
VR 0469	Chicory, roots, raw	RAC	0.01	0.10	0.00	0.20	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	
VR 0583	Horseradish, raw	RAC	0.01	0.51	0.01	0.91	0.01	0.56	0.01	1.37	0.01	NC	-	0.66	0.01	
VR 0587	Parsley turnip-rooted, raw	RAC	0.01	0.32	0.00	0.57	0.01	0.35	0.00	0.85	0.01	NC	-	0.41	0.00	
VR 0588	Parsnip, raw	RAC	0.01	0.59	0.01	1.05	0.01	0.65	0.01	1.58	0.02	NC	-	0.76	0.01	
VR 0494	Radish roots, raw	RAC	0.01	2.31	0.02	4.09	0.04	2.53	0.03	6.15	0.06	5.88	0.06	2.97	0.03	
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.01	1.90	0.02	3.36	0.03	2.08	0.02	5.06	0.05	NC	-	2.44	0.02	
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.01	0.21	0.00	0.37	0.00	0.23	0.00	0.55	0.01	NC	-	0.27	0.00	
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.01	0.13	0.00	NC	-	0.10	0.00	0.66	0.01	0.47	0.00	88.94	0.89	
VR 0596	Sugar beet, raw	RAC	0.014	NC	-	NC	-	NC	-	NC	-	0.10	0.00	NC	-	
-	Sugar beet, sugar	PP	0.025	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00	12.63	0.32	
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.01	1.58	0.02	2.80	0.03	1.74	0.02	4.21	0.04	NC	-	2.03	0.02	
VR 0506	Turnip, garden, raw	RAC	0.01	2.50	0.03	4.44	0.04	2.75	0.03	6.67	0.07	0.14	0.00	3.22	0.03	
VR 0573	Arrowroot, raw	RAC	0.01	1.53	0.02	0.10	0.00	0.93	0.01	1.33	0.01	0.47	0.00	0.10	0.00	
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.01	0.10	0.00	0.10	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	0.10	0.00	0.96	0.01	1.36	0.01	0.48	0.00	0.10	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	
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	

**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		
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.01	NC	-	NC	-	NC	-	0.10	0.00	0.26	0.00	1.27	0.01
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.01	0.10	0.00	NC	-	25.12	0.25	0.10	0.00	0.10	0.00	0.97	0.01
VR 0600	Yams, raw (incl dried)	RAC	0.01	0.10	0.00	NC	-	90.40	0.90	6.45	0.06	0.74	0.01	0.65	0.01
VS 0624	Celery	RAC	0.19	2.14	0.41	3.79	0.72	2.35	0.45	5.69	1.08	0.10	0.02	2.75	0.52
GC 0653	Triticale, raw (incl flour)	RAC	0.025	NC	-	NC	-	NC	-	0.10	0.00	0.39	0.01	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.025	381.15	9.53	341.55	8.54	38.35	0.96	281.89	7.05	172.83	4.32	434.07	10.85
GC 0640	Barley, raw (incl malt extract, incl malt, excl pot&pearled, excl flour & grits, excl beer)	RAC	0.063	2.62	0.17	1.50	0.09	0.37	0.02	0.60	0.04	0.38	0.02	0.53	0.03
-	Barley, pot&pearled	PP	0.044	7.12	0.31	7.34	0.32	0.10	0.00	0.10	0.00	0.67	0.03	0.20	0.01
-	Barley, flour (white flour and wholemeal flour)	PP	0.05	2.93	0.15	0.30	0.02	0.10	0.01	0.10	0.01	0.48	0.02	0.10	0.01
-	Barley beer	PP	0.013	4.87	0.06	93.78	1.22	24.28	0.32	12.76	0.17	39.28	0.51	18.15	0.24
CM 0649 (GC 0649)	Rice, husked, dry ( incl oil, incl beverages, incl starch, excl polished, excl flour)	REP	0.39	1.20	0.47	1.30	0.51	31.05	12.11	4.79	1.87	0.61	0.24	2.16	0.84
CM 1205	Rice polished, dry	PP	0.27	34.21	9.24	10.39	2.81	41.72	11.26	82.38	22.24	150.24	40.56	70.47	19.03
-	Rice flour	PP	0.2	0.10	0.02	0.22	0.04	0.10	0.02	0.50	0.10	0.22	0.04	0.10	0.02
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.03	4.34	0.13	0.10	0.00	16.25	0.49	15.82	0.47	10.97	0.33	2.92	0.09
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.007	29.81	0.21	44.77	0.31	108.95	0.76	52.37	0.37	60.28	0.42	75.69	0.53
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0	0.14	0.00	0.94	0.00	5.70	0.00	2.61	0.00	1.94	0.00	0.22	0.00
TN 0085	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	0.045	0.10	0.00	NC	-	NC	-	0.10	0.00	0.75	0.03	0.10	0.00
OR 0495	Rape seed oil, edible	PP	0.014	0.35	0.00	0.44	0.01	0.19	0.00	0.97	0.01	3.28	0.05	0.77	0.01
OR 0691	Cotton seed oil, edible	PP	0.002	3.22	0.01	1.54	0.00	1.01	0.00	0.74	0.00	1.12	0.00	2.93	0.01
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.16	24.96	3.99	57.95	9.27	16.70	2.67	38.38	6.14	26.46	4.23	29.00	4.64
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.06	6.24	0.37	14.49	0.87	4.18	0.25	9.60	0.58	6.62	0.40	7.25	0.44
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.06	3.29	0.20	6.14	0.37	0.82	0.05	1.57	0.09	2.23	0.13	1.07	0.06
MO 0105	Edible offal (mammalian), raw	RAC	0.44	4.79	2.11	9.68	4.26	2.97	1.31	5.49	2.42	3.84	1.69	5.03	2.21
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.14	289.65	40.55	485.88	68.02	26.92	3.77	239.03	33.46	199.91	27.99	180.53	25.27

**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		
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.64	13.17	8.43	26.78	17.14	7.24	4.63	116.71	74.70	22.54	14.42	32.09	20.54
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.02	1.46	0.03	2.98	0.06	0.80	0.02	12.97	0.26	2.50	0.05	3.57	0.07
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.02	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.18	0.12	0.02	0.12	0.02	0.11	0.02	5.37	0.97	0.24	0.04	0.10	0.02
PE 0112	Eggs, raw, (incl dried)	RAC	0.07	7.84	0.55	23.08	1.62	2.88	0.20	14.89	1.04	9.81	0.69	14.83	1.04
Total intake (µg/person)=				105.5		157.6		60.4		217.3		135.7		179.6	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (µg/person)=				3000		3000		3000		3000		3000		3000	
%ADI=				3.5%		5.3%		2.0%		7.2%		4.5%		6.0%	
Rounded %ADI=				4%		5%		2%		7%		5%		6%	

**SULFOXAFLOR (252)**

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
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.038	10.12	0.38	15.69	0.60	2.88	0.11	12.30	0.47	22.32	0.85	6.59	0.25
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.26	12.42	3.23	14.99	3.90	16.08	4.18	10.78	2.80	9.94	2.58	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.26	83.66	21.75	27.64	7.19	7.37	1.92	67.80	17.63	43.97	11.43	187.74	48.81
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.036	33.31	1.20	1.78	0.06	0.28	0.01	18.97	0.68	14.01	0.50	13.36	0.48
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.0125	8.21	0.10	4.60	0.06	0.64	0.01	5.85	0.07	19.98	0.25	368.86	4.61
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.067	51.09	3.42	65.40	4.38	42.71	2.86	45.29	3.03	62.51	4.19	7.74	0.52
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.027	14.88	0.40	11.98	0.32	0.15	0.00	9.98	0.27	30.32	0.82	3.47	0.09
FS 0013	Subgroup of Cherries, raw	RAC	0.34	1.40	0.48	4.21	1.43	0.10	0.03	2.93	1.00	1.50	0.51	NC	-
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.038	5.55	0.21	4.37	0.17	6.08	0.23	3.66	0.14	3.93	0.15	0.46	0.02
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.061	13.03	0.79	16.29	0.99	8.29	0.51	12.95	0.79	5.35	0.33	0.10	0.01
FB 0269	Grapes, raw (incl must, incl juice, excl dried, excl wine)	RAC	0.14	7.18	1.01	13.73	1.92	5.24	0.73	12.27	1.72	7.46	1.04	1.21	0.17
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.49	3.09	1.51	1.51	0.74	0.10	0.05	1.38	0.68	4.26	2.09	0.42	0.21

**SULFOXAFLOL (252)**

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
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.098	88.93	8.72	62.41	6.12	1.84	0.18	25.07	2.46	61.17	5.99	5.84	0.57
FB 0275	Strawberry, raw	RAC	0.19	4.49	0.85	5.66	1.08	0.10	0.02	6.63	1.26	5.75	1.09	0.10	0.02
VA 0381	Garlic, raw	RAC	0.01	0.98	0.01	1.49	0.01	12.88	0.13	3.74	0.04	2.05	0.02	1.14	0.01
-	Onions, dry, raw	RAC	0	19.69	0.00	29.83	0.00	24.64	0.00	31.35	0.00	9.72	0.00	12.59	0.00
-	Onions, green, raw	RAC	0.11	1.55	0.17	0.74	0.08	1.05	0.12	3.74	0.41	0.94	0.10	6.45	0.71
VB 0400	Broccoli, raw	RAC	0.074	4.24	0.31	1.76	0.13	NC	-	0.51	0.04	3.79	0.28	0.26	0.02
VB 0404	Cauliflower, raw	RAC	0.012	5.27	0.06	5.01	0.06	NC	-	2.70	0.03	5.57	0.07	0.49	0.01
VB 0041	Cabbages, head, raw	RAC	0.099	8.97	0.89	27.12	2.68	1.44	0.14	24.96	2.47	4.55	0.45	11.23	1.11
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.029	27.81	0.81	41.93	1.22	123.30	3.58	49.47	1.43	15.95	0.46	35.99	1.04
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.11	43.88	4.83	55.41	6.10	35.38	3.89	74.88	8.24	26.50	2.92	9.51	1.05
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.23	4.96	1.14	3.20	0.74	0.15	0.03	1.61	0.37	6.88	1.58	0.52	0.12
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.052	0.80	0.04	0.10	0.01	0.10	0.01	0.61	0.03	0.40	0.02	0.10	0.01
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.11	NC	-	NC	-	0.10	0.01	0.17	0.02	NC	-	0.72	0.08
VO 0444	Peppers, chili, raw	RAC	0.11	5.57	0.61	14.00	1.54	8.25	0.91	5.77	0.63	6.44	0.71	2.53	0.28
-	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
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.11	0.82	0.09	1.53	0.17	10.85	1.19	4.59	0.50	1.84	0.20	2.00	0.22
VO 0440	Egg plant, raw (i.e. aubergine)	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	1.2	18.38	22.06	18.73	22.48	82.36	98.83	25.32	30.38	17.60	21.12	7.37	8.84
VL 0473	Watercress, raw	RAC	1	0.35	0.35	3.13	3.13	0.32	0.32	NC	-	NC	-	2.30	2.30
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.075	1.51	0.11	1.50	0.11	1.90	0.14	5.11	0.38	1.36	0.10	23.43	1.76
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.011	0.47	0.01	0.77	0.01	9.12	0.10	8.05	0.09	0.10	0.00	6.06	0.07
OR 0541	Soya oil, refined	PP	0.0033	19.06	0.06	21.06	0.07	5.94	0.02	33.78	0.11	40.05	0.13	13.39	0.04
VR 0574	Beetroot, raw	RAC	0.01	9.91	0.10	6.34	0.06	NC	-	9.65	0.10	19.11	0.19	6.47	0.06
VR 0575	Burdock, greater or edible, raw	RAC	0.01	NC	-	NC	-	NC	-	0.48	0.00	NC	-	0.10	0.00
VR 0578	Celeriac, raw	RAC	0.01	2.97	0.03	1.79	0.02	NC	-	0.10	0.00	16.91	0.17	3.22	0.03
VR 0469	Chicory, roots, raw	RAC	0.01	0.10	0.00	0.51	0.01	0.10	0.00	0.10	0.00	21.12	0.21	NC	-
VR 0583	Horseradish, raw	RAC	0.01	0.10	0.00	0.42	0.00	13.01	0.13	0.26	0.00	2.70	0.03	0.97	0.01
VR 0587	Parsley turnip-rooted, raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	0.61	0.01
VR 0588	Parsnip, raw	RAC	0.01	4.42	0.04	0.10	0.00	NC	-	NC	-	NC	-	1.12	0.01
VR 0494	Radish roots, raw	RAC	0.01	3.83	0.04	11.99	0.12	NC	-	5.26	0.05	2.19	0.02	4.37	0.04
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.01	NC	-	NC	-	26.64	0.27	18.92	0.19	NC	-	3.59	0.04
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.01	1.02	0.01	0.52	0.01	NC	-	NC	-	2.08	0.02	0.39	0.00

SULFOXAFLOR (252)				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
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.01	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	NC	-	NC	-
VR 0596	Sugar beet, raw	RAC	0.014	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	NC	-	NC	-
-	Sugar beet, sugar	PP	0.025	0.10	0.00	NC	-	0.10	0.00	NC	-	NC	-	NC	-
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.01	10.01	0.10	1.66	0.02	NC	-	NC	-	3.06	0.03	2.99	0.03
VR 0506	Turnip, garden, raw	RAC	0.01	5.78	0.06	15.35	0.15	NC	-	6.54	0.07	1.95	0.02	4.73	0.05
VR 0573	Arrowroot, raw	RAC	0.01	0.10	0.00	0.10	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	0.10	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	0.10	0.00	NC	-	0.22	0.00	NC	-	0.78	0.01
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
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	-	0.10	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	-	0.10	0.00	0.71	0.01	NC	-	17.57	0.18
VS 0624	Celery	RAC	0.19	7.68	1.46	2.85	0.54	NC	-	3.34	0.63	16.83	3.20	4.04	0.77
GC 0653	Triticale, raw (incl flour)	RAC	0.025	0.10	0.00	0.17	0.00	0.29	0.01	0.10	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	0.025	253.07	6.33	244.73	6.12	134.44	3.36	235.10	5.88	216.39	5.41	167.40	4.19
GC 0640	Barley, raw (incl malt extract, incl malt, excl pot&pearled, excl flour & grits,excl beer)	RAC	0.063	0.93	0.06	0.15	0.01	0.14	0.01	1.56	0.10	0.33	0.02	3.42	0.22
-	Barley, pot&pearled	PP	0.044	0.57	0.03	2.56	0.11	0.33	0.01	0.56	0.02	0.36	0.02	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	0.05	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01	0.68	0.03	0.10	0.01
-	Barley beer	PP	0.013	180.21	2.34	259.46	3.37	45.91	0.60	172.36	2.24	234.42	3.05	65.30	0.85
CM 0649 (GC 0649)	Rice, husked, dry ( incl oil, incl beverages, incl starch, excl polished, excl flour)	REP	0.39	2.43	0.95	1.62	0.63	0.58	0.23	1.69	0.66	NC	-	5.03	1.96
CM1205	Rice polished, dry	PP	0.27	13.38	3.61	10.80	2.92	262.08	70.76	57.16	15.43	12.83	3.46	62.78	16.95
-	Rice flour	PP	0.2	0.98	0.20	0.38	0.08	0.72	0.14	0.10	0.02	0.23	0.05	0.10	0.02
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.03	NC	-	NC	-	1.44	0.04	1.15	0.03	NC	-	7.12	0.21
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.007	18.51	0.13	26.18	0.18	26.04	0.18	39.99	0.28	7.36	0.05	64.58	0.45



SULFOXAFLO (252)				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	
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0	11.43	0.00	3.71	0.00	0.74	0.00	13.63	0.00	3.07	0.00	1.50	0.00	
TN 0085	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	0.045	NC	-	NC	-	0.10	0.00	NC	-	NC	-	NC	-	
OR 0495	Rape seed oil, edible	PP	0.014	12.52	0.18	7.63	0.11	3.00	0.04	6.01	0.08	NC	-	NC	-	
OR 0691	Cotton seed oil, edible	PP	0.002	1.68	0.00	0.66	0.00	1.13	0.00	1.18	0.00	0.89	0.00	0.37	0.00	
MM0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.16	112.02	17.92	120.71	19.31	63.46	10.15	88.99	14.24	96.24	15.40	41.02	6.56	
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.06	28.01	1.68	30.18	1.81	15.86	0.95	22.25	1.33	24.06	1.44	10.25	0.62	
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.06	6.44	0.39	15.51	0.93	3.79	0.23	8.29	0.50	18.44	1.11	8.00	0.48	
MO0105	Edible offal (mammalian), raw	RAC	0.44	15.17	6.67	5.19	2.28	6.30	2.77	6.78	2.98	3.32	1.46	3.17	1.39	
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.14	388.92	54.45	335.88	47.02	49.15	6.88	331.25	46.38	468.56	65.60	245.45	34.36	
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.64	66.38	42.49	48.47	31.02	21.58	13.81	78.41	50.18	48.04	30.75	76.01	48.64	
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.02	7.38	0.15	5.39	0.11	2.40	0.05	8.71	0.17	5.34	0.11	8.45	0.17	
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.02	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.01	NC	-	
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.18	0.33	0.06	0.72	0.13	0.27	0.05	0.35	0.06	0.80	0.14	NC	-	
PE 0112	Eggs, raw, (incl dried)	RAC	0.07	25.84	1.81	29.53	2.07	28.05	1.96	33.19	2.32	36.44	2.55	8.89	0.62	
Total intake (µg//person)=					219.4		189.3		237.1		224.5		197.2		193.5	
Bodyweight per region (kg bw) =					60		60		55		60		60		60	
ADI (µg//person)=					3000		3000		2750		3000		3000		3000	
%ADI=					7.3%		6.3%		8.6%		7.5%		6.6%		6.4%	
Rounded %ADI=					7%		6%		9%		7%		7%		6%	

SULFOXAFLOR (252)				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
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.038	18.97	0.72	0.97	0.04	6.23	0.24	0.10	0.00	3.35	0.13
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.26	0.16	0.04	0.27	0.07	9.06	2.36	0.10	0.03	0.10	0.03

**SULFOXAFLOL (252)**

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
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.26	1.34	0.35	1.65	0.43	40.03	10.41	0.33	0.09	1.76	0.46
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.036	0.10	0.00	0.26	0.01	12.61	0.45	0.14	0.01	0.33	0.01
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.0125	0.68	0.01	0.10	0.00	3.21	0.04	0.10	0.00	NC	-
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.067	68.85	4.61	10.93	0.73	70.82	4.74	189.78	12.72	19.56	1.31
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.027	0.10	0.00	0.10	0.00	7.19	0.19	0.10	0.00	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	0.34	0.10	0.03	0.10	0.03	5.96	2.03	0.10	0.03	NC	-
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.038	0.10	0.00	0.10	0.00	16.65	0.63	0.10	0.00	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.061	0.10	0.01	0.10	0.01	10.76	0.66	0.10	0.01	NC	-
FB 0269	Grapes, raw (incl must, incl juice, excl dried, excl wine)	RAC	0.14	0.15	0.02	0.38	0.05	15.84	2.22	0.10	0.01	0.28	0.04
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.49	0.10	0.05	0.13	0.06	1.06	0.52	0.10	0.05	0.10	0.05
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.098	0.31	0.03	0.23	0.02	60.43	5.92	0.52	0.05	31.91	3.13
FB 0275	Strawberry, raw	RAC	0.19	0.10	0.02	0.10	0.02	3.35	0.64	0.10	0.02	0.10	0.02
VA 0381	Garlic, raw	RAC	0.01	0.82	0.01	2.06	0.02	3.79	0.04	0.10	0.00	0.29	0.00
-	Onions, dry, raw	RAC	0	9.01	0.00	20.24	0.00	30.90	0.00	9.61	0.00	2.11	0.00
-	Onions, green, raw	RAC	0.11	1.43	0.16	0.10	0.01	0.20	0.02	NC	-	6.30	0.69
VB 0400	Broccoli, raw	RAC	0.074	0.10	0.01	0.10	0.01	2.13	0.16	0.10	0.01	NC	-
VB 0404	Cauliflower, raw	RAC	0.012	0.10	0.00	0.10	0.00	2.73	0.03	0.10	0.00	NC	-
VB 0041	Cabbages, head, raw	RAC	0.099	3.82	0.38	2.99	0.30	49.16	4.87	0.10	0.01	NC	-
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.029	5.96	0.17	9.74	0.28	51.82	1.50	13.61	0.39	0.10	0.00
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.11	13.10	1.44	4.90	0.54	62.16	6.84	1.04	0.11	0.10	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.23	0.58	0.13	0.22	0.05	2.21	0.51	0.24	0.06	3.10	0.71
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.052	0.10	0.01	0.10	0.01	0.42	0.02	0.10	0.01	0.10	0.01
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.11	6.23	0.69	0.10	0.01	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw	RAC	0.11	3.47	0.38	3.56	0.39	16.30	1.79	0.10	0.01	NC	-
-	Peppers, chili, dried	PP	0.1	0.58	0.06	1.27	0.13	1.21	0.12	0.12	0.01	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.11	5.49	0.60	10.57	1.16	8.84	0.97	0.91	0.10	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.11	1.31	0.14	8.26	0.91	3.95	0.43	0.10	0.01	NC	-
VL 2050	Subgroup of Leafy greens	RAC	1.2	4.99	5.99	3.29	3.95	7.53	9.04	3.05	3.66	6.09	7.31

**SULFOXAFLOR (252)**

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
VL 0473	Watercress, raw	RAC	1	2.08	2.08	1.50	1.50	0.10	0.10	1.41	1.41	2.81	2.81
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.075	7.11	0.53	2.33	0.17	3.76	0.28	44.70	3.35	3.27	0.25
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.011	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	0.0033	2.32	0.01	2.54	0.01	18.70	0.06	2.51	0.01	6.29	0.02
VR 0574	Beetroot, raw	RAC	0.01	5.86	0.06	4.23	0.04	9.46	0.09	3.96	0.04	7.91	0.08
VR 0575	Burdock, greater or edible, raw	RAC	0.01	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00
VR 0578	Celeriac, raw	RAC	0.01	2.91	0.03	2.10	0.02	7.59	0.08	1.97	0.02	3.93	0.04
VR 0469	Chicory, roots, raw	RAC	0.01	0.10	0.00	0.10	0.00	0.10	0.00	NC	-	NC	-
VR 0583	Horseradish, raw	RAC	0.01	0.88	0.01	0.63	0.01	0.54	0.01	0.59	0.01	1.19	0.01
VR 0587	Parsley turnip-rooted, raw	RAC	0.01	0.55	0.01	0.40	0.00	4.29	0.04	0.37	0.00	0.74	0.01
VR 0588	Parsnip, raw	RAC	0.01	1.02	0.01	0.74	0.01	3.50	0.04	0.69	0.01	1.37	0.01
VR 0494	Radish roots, raw	RAC	0.01	3.96	0.04	2.86	0.03	3.30	0.03	2.67	0.03	5.34	0.05
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.01	3.25	0.03	2.35	0.02	NC	-	2.20	0.02	4.39	0.04
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.01	0.36	0.00	0.26	0.00	NC	-	0.24	0.00	0.48	0.00
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.01	3.93	0.04	1.68	0.02	NC	-	NC	-	36.12	0.36
VR 0596	Sugar beet, raw	RAC	0.014	0.10	0.00	NC	-	NC	-	NC	-	NC	-
-	Sugar beet, sugar	PP	0.025	0.56	0.01	0.24	0.01	NC	-	NC	-	5.13	0.13
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.01	2.71	0.03	1.96	0.02	7.80	0.08	1.83	0.02	3.66	0.04
VR 0506	Turnip, garden, raw	RAC	0.01	4.29	0.04	3.10	0.03	6.41	0.06	2.90	0.03	5.79	0.06
VR 0573	Arrowroot, raw	RAC	0.01	13.83	0.14	18.24	0.18	0.10	0.00	0.10	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	0.10	0.00	0.10	0.00	20.14	0.20
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
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	-
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.01	NC	-	NC	-	0.10	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	0.10	0.00	5.65	0.06	30.85	0.31
VS 0624	Celery	RAC	0.19	3.66	0.70	2.65	0.50	4.84	0.92	2.47	0.47	4.94	0.94
GC 0653	Triticale, raw (incl flour)	RAC	0.025	0.10	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	0.025	57.20	1.43	110.47	2.76	272.62	6.82	25.82	0.65	132.04	3.30



**SULFOXAFLO (252)**

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		
		%ADI=			2.2%		3.5%		6.5%		1.7%		3.5%		
		Rounded %ADI=			2%		3%		6%		2%		3%		

**TIOXAZAFEN (311)**

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
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.012	0.63	0.01	1.09	0.01	0.40	0.00	1.40	0.02	1.68	0.02	0.48	0.01
OR 0541	Soya oil, refined	PP	0	12.99	0.00	10.43	0.00	3.63	0.00	13.10	0.00	10.70	0.00	13.10	0.00
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
SO 0691	Cotton seed, raw (incl oil)	RAC	0	20.53	0.00	9.80	0.00	6.42	0.00	4.73	0.00	7.14	0.00	18.68	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.01	31.20	0.31	72.44	0.72	20.88	0.21	47.98	0.48	33.08	0.33	36.25	0.36
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	0.01	4.79	0.05	9.68	0.10	2.97	0.03	5.49	0.05	3.84	0.04	5.03	0.05
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	289.65	2.90	485.88	4.86	26.92	0.27	239.03	2.39	199.91	2.00	180.53	1.81
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.01	14.63	0.15	29.76	0.30	8.04	0.08	129.68	1.30	25.04	0.25	35.66	0.36
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	0.02	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	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)=					3.4		6.1		0.6		4.4		2.7		2.6
Bodyweight per region (kg bw) =					60		60		60		60		60		60
ADI (µg//person)=					3000		3000		3000		3000		3000		3000
%ADI=					0.1%		0.2%		0.0%		0.1%		0.1%		0.1%
Rounded %ADI=					0%		0%		0%		0%		0%		0%



**TIOXAZAFEN (311)**

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
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.012	2.89	0.03	0.21	0.00	0.48	0.01	3.16	0.04	0.26	0.00
OR 0541	Soya oil, refined	PP	0	2.32	0.00	2.54	0.00	18.70	0.00	2.51	0.00	6.29	0.00
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
SO 0691	Cotton seed, raw (incl oil)	RAC	0	8.14	0.00	0.32	0.00	2.84	0.00	2.69	0.00	0.97	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.01	29.18	0.29	50.89	0.51	121.44	1.21	22.58	0.23	72.14	0.72
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	0.01	4.64	0.05	1.97	0.02	10.01	0.10	3.27	0.03	3.98	0.04
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	108.75	1.09	70.31	0.70	436.11	4.36	61.55	0.62	79.09	0.79
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.01	3.92	0.04	12.03	0.12	57.07	0.57	5.03	0.05	55.56	0.56
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	0.02	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	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00

Total intake (µg//person)=	1.5	1.4	6.5	1.0	2.1
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (µg//person)=	3000	3000	3000	3000	3000
%ADI=	0.1%	0.0%	0.2%	0.0%	0.1%
Rounded %ADI=	0%	0%	0%	0%	0%





## Annex 4: International estimates of short-term dietary exposure of pesticide residues

### ABAMECTIN (177)

Acute RfD= 0.003 mg/kg bw (3 µg/kg bw)

### IESTI

Maximum %ARfD:

40%  
all

30%  
gen pop

40%  
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
FC 0004	Subgroup of Oranges, sweet, sour (incl orange-like hybrids)	Oil (refined)	0.0275		1.000	NL	Gen pop, > 1 yrs	0	NC	NR	NR	3	NC	NC	NC	NC
FB 0264	Blackberries (all commodities)	highest utilisation: Total	0.018	0.11	1.000	PRIMO-UK	toddler	P97.5	155.40	<25	NR	1	0 - 1.18	0% - 40%	0% - 30%	0% - 40%
FB 0266	Dewberries (incl Boysenberry, Loganberry) (all commodities)	highest utilisation: Total		0.11	1.000	PRIMO-UK	toddler	P97.5	25.50	<25	NR	1	0.19 - 0.19	6% - 6%	5% - 5%	6% - 6%
FB 0272	Raspberries, red, black (all commodities)	highest utilisation: Total	0.018	0.11	1.000	PRIMO-IE	child	P97.5	184.76	<25	NR	1	0.01 - 1.02	0% - 30%	0% - 20%	0% - 30%
FB 0269	Grapes (all commodities)	highest utilisation: raw with skin	0.0021 - 0.0059	0.016 - 0.045	1.000	CN	Child, 1-6 yrs	232	366.72	637	3	2b	0.01 - 1.09	0% - 40%	0% - 20%	0% - 40%
FB 1235	Table grapes (all commodities)	highest utilisation: raw with skin	0.0021	0.016	1.000	CN	Child, 1-6 yrs	232	366.72	637	3	2b	0.01 - 1.09	0% - 40%	0% - 20%	0% - 40%
FB 1236	Wine grapes (all commodities)	highest utilisation: juice (pasteurised)	0.0021		1.000	PRIMO-NL	child	P100	803.20	NR	NR	3	0.01 - 0.09	0% - 3%	0% - 2%	0% - 3%
FI 0353	Pineapple (all commodities)	highest utilisation: raw without peel	0	0	1.000	JP	Child, 1-6 yrs	67	499.80	1116	3	2b	0 - 0	0% - 0%	0% - 0%	0% - 0%
VA 0384	Leek (all commodities)	highest utilisation: cooked/boiled	0.002	0.004	1.000	PRIMO-NL	toddler	E	100.70	142	3	2b	0 - 0.12	0% - 4%	0% - 2%	0% - 4%
VA 0387	Onion, Welsh (Japanese bunching onion, Multiplying onion) (all commodities)	highest utilisation: Total		0.004	1.000	PRIMO-UK	child, 4-6 yrs	P97.5	93.60	38	3	2a	0.03 - 0.03	1% - 1%	0% - 1%	1% - 1%
VA 0389	Spring onion (all commodities)	highest utilisation: Total		0.004	1.000	PRIMO-UK	child, 4-6 yrs	P97.5	93.60	38	3	2a	0.01 - 0.03	0% - 1%	0% - 0%	0% - 1%

**ABAMECTIN (177)**

Acute RfD= 0.003 mg/kg bw (3 µg/kg bw)

IESTI

Maximum %ArfD:

40%  
all30%  
gen pop40%  
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
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds) (all commodities)	highest utilisation: Total	0.002	0.002	1.000	PRIMO-IE	child	P97.5	157.79	<25	NR	1	0 - 0.02	0% - 1%	0% - 0%	0% - 1%
VP 0523	Broad bean without pods (succulent seeds) (Vicia spp) (all commodities)	highest utilisation: frozen	0.002	0.002	1.000	NL	Child, 2-6 yrs	E	100.00	6	NR	1	0 - 0.01	0% - 0%	0% - 0%	0% - 0%
VP 0541	Soya bean without pods (succulent seeds) (Glycine max) (all commodities)	highest utilisation: cooked/boiled	0.002	0.002	1.000	CN	Child, 1-6 yrs	195	260.25	<25	NR	1	0 - 0.03	0% - 1%	0% - 1%	0% - 1%
GC 3081	Baby corn (all commodities)	highest utilisation: canned/preserved (imm cobs)		0.002	1.000	NL	Child, 2-6 yrs	E	75.00	12	NR	1	0.01 - 0.01	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)	0.002	0.002	1.000	TH	Child, 3-6 yrs	1383	196.99	191	3	2a	0 - 0.07	0% - 2%	0% - 1%	0% - 2%
GC 1275	Sweet corn (whole kernel without cob or husk) (all commodities)	highest utilisation: canned/preserved (kernels)	0.002	0.002	1.000	CA	Child, <6 yrs	289	153.76	NR	NR	3	0 - 0.02	0% - 1%	0% - 0%	0% - 1%
HH 0624	Celery leaves (all commodities)	highest utilisation: cooked/boiled	0.003	0.008	1.000	NL	Gen pop, > 1 yrs	291	13.69	<25	NR	1	0 - 0	0% - 0%	0% - 0%	0% - 0%
HH 0720	Angelica, including Garden Angelica (all commodities)	highest utilisation: cooked/boiled	0.003	0.008	1.000	NL	Gen pop, > 1 yrs	291	13.69	<25	NR	1	0 - 0	0% - 0%	0% - 0%	0% - 0%
HH 0722	Basil (all commodities)	highest utilisation: Total	0.003	0.008	1.000	AU	Child, 2-16 yrs	143	44.19	<25	NR	1	0 - 0.01	0% - 0%	0% - 0%	0% - 0%
HH 0723	Bay leaves (all commodities)	highest utilisation: raw	0.003	0.008	1.000	DE	Gen pop, 14-80 yrs	50	23.10	<25	NR	1	0 - 0	0% - 0%	0% - 0%	0% - 0%
HH 0727	Chives (all commodities)	highest utilisation: Total		0.008	1.000	PRIMO-CZ	Child, child, 7-10 yrs	P97.5	26.49	<25	NR	1	0 - 0.01	0% - 0%	0% - 0%	0% - 0%

**ABAMECTIN (177)**

Acute RfD= 0.003 mg/kg bw (3 µg/kg bw)

IESTI

Maximum %ArfD:

 40%  
all

 30%  
gen pop

 40%  
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
HH 0730	Dill (all commodities)	highest utilisation: cooked/boiled		0.008	1.000	NL	Gen pop, > 1 yrs	291	13.69	<25	NR	1	0 - 0	0% - 0%	0% - 0%	0% - 0%
HH 0731	Fennel (herb) (all commodities)	highest utilisation: raw		0.008	1.000	CN	Gen pop, > 1 yrs	570	389.94	<25	NR	1	0.01 - 0.06	0% - 2%	0% - 2%	0% - 0%
HH 0733	Hyssop (all commodities)	highest utilisation: Total	0.003	0.008	1.000	DE	Child, 2-4 yrs	27	1.10	<25	NR	1	0 - 0	0% - 0%	0% - 0%	0% - 0%
HH 0735	Lovage (all commodities)	highest utilisation: cooked/boiled		0.008	1.000	NL	Gen pop, > 1 yrs	291	13.69	<25	NR	1	0 - 0	0% - 0%	0% - 0%	0% - 0%
HH 0736	Marjoram (incl Oregano) (all commodities)	highest utilisation: Total	0.003	0.008	1.000	DE	Child, 2-4 yrs	70	6.10	<25	NR	1	0 - 0	0% - 0%	0% - 0%	0% - 0%
HH 0738	Mints (all commodities)	highest utilisation: raw	0.003	0.008	1.000	DE	Child, 2-4 yrs	138	11.10	<25	NR	1	0 - 0.01	0% - 0%	0% - 0%	0% - 0%
HH 0740	Parsley (all commodities)	highest utilisation: Total	0.003	0.008	1.000	PRIMO-UK	vegetarian	P97.5	79.90	<25	NR	1	0 - 0.01	0% - 0%	0% - 0%	0% - 0%
HH 0741	Rosemary (all commodities)	highest utilisation: Total	0.003	0.008	1.000	PRIMO-DE	Gen pop	P97.5	7.64	<25	NR	1	0 - 0	0% - 0%	0% - 0%	0% - 0%
HH 0743	Sage and related salvia species (all commodities)	highest utilisation: Total	0.003	0.008	1.000	PRIMO-IE	child	P97.5	15.14	<25	NR	1	0 - 0.01	0% - 0%	0% - 0%	0% - 0%
HH 0745	Savory, summer, winter (all commodities)	highest utilisation: Total	0.003	0.008	1.000	US	Child, < 6 yrs	2528	1.02	<25	NR	1	0 - 0	0% - 0%	0% - 0%	0% - 0%
HH 0749	Tarragon (all commodities)	highest utilisation: Total	0.003	0.008	1.000	PRIMO-DE	women, 14-50 yrs	P97.5	6.75	<25	NR	1	0 - 0	0% - 0%	0% - 0%	0% - 0%
HH 0750	Thyme (all commodities)	highest utilisation: Total	0.003	0.008	1.000	PRIMO-DE	Gen pop	P97.5	7.64	<25	NR	1	0 - 0	0% - 0%	0% - 0%	0% - 0%
HH 0751	Land cress (all commodities)	highest utilisation: raw		0.008	1.000	DE	Women, 14-50 yrs	1556	2.90	<25	NR	1	0 - 0	0% - 0%	0% - 0%	0% - 0%
HH 0756	Cilantro/coriander leaves (all commodities)	highest utilisation: raw	0.003	0.008	1.000	CN	Gen pop, > 1 yrs	1073	157.79	<25	NR	1	0.01 - 0.02	0% - 1%	0% - 1%	0% - 0%
HH 0761	Lemongrass (all commodities)	highest utilisation: Total	0.003	0.008	1.000	AU	Child, 2-6 yrs	2	0.53	<25	NR	1	0 - 0	0% - 0%	0% - 0%	0% - 0%
-	Toona leaves	Total		0.008	1.000	CN	Gen pop, > 1 yrs	133	313.10	<25	NR	1	0.047	2%	2%	-

**ABAMECTIN (177)**

Acute RfD= 0.003 mg/kg bw (3 µg/kg bw)

IESTI

Maximum %ArfD:

40%  
all30%  
gen pop40%  
child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia- bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
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**BENTAZONE (172)**

Acute RfD= 0.5 mg/kg bw (500 µg/kg bw)

IESTI

Maximum %ArfD:

0%  
all0%  
gen pop0%  
child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia- bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VD 0071	Beans (dry) (Phaseolus spp) (all commodities)	highest utilisation: Total	0.09		1.000	PRIMO-UK	infant	P97.5	159.00	<25	NR	3	0.18 - 1.64	0% - 0%	0% - 0%	0% - 0%
VD 0523	Broad bean (dry) (Vicia spp) (all commodities)	highest utilisation: cooked/boiled	0.09		0.400	CN	Gen pop, > 1 yrs	737	1190.24	<25	NR	3	0.06 - 0.81	0% - 0%	0% - 0%	0% - 0%
VD 0531	Lablab bean (dry) (Lablab spp) (all commodities)	highest utilisation: cooked/boiled	0.09		0.400	CN	Gen pop, > 1 yrs	1219	972.42	<25	NR	3	0.66 - 0.66	0% - 0%	0% - 0%	0% - 0%
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilisation: Total	0.09		1.000	CN	Child, 1-6 yrs	179	239.05	<25	NR	3	0 - 1.33	0% - 0%	0% - 0%	0% - 0%
VD 0072	Peas (dry) (Pisum spp) (all commodities)	highest utilisation: cooked/boiled	0.09		0.400	CN	Gen pop, > 1 yrs	268	1673.82	<25	NR	3	0.07 - 1.13	0% - 0%	0% - 0%	0% - 0%
VD 0524	Chick-pea (dry) (Cicer spp) (all commodities)	highest utilisation: canned/preserved	0.09		0.400	PRIMO-NL	child	P100	328.80	<25	NR	3	0.07 - 0.64	0% - 0%	0% - 0%	0% - 0%
VD 0533	Lentil (dry) (Lens spp) (all commodities)	highest utilisation: Total	0.09		1.000	PRIMO-UK	Child, 11-14 yrs	P97.5	321.50	<25	NR	3	0.18 - 0.6	0% - 0%	0% - 0%	0% - 0%
VD 0537	Pigeon pea (dry) (Cajanus spp)	Total	0.09		1.000	AU	Gen pop, > 2 yrs	129	95.83	<25	NR	3	0.129	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%

**ABAMECTIN (177)**

Acute RfD= 0.003 mg/kg bw (3 µg/kg bw)

## IESTI

Maximum %ARfD:

40%  
all30%  
gen pop40%  
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
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		0.035	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	0.329	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%

**CHLORFENAPYR (254)**

Acute RfD= 0.03 mg/kg bw (30 µg/kg bw)

## IESTI

Maximum %ARfD:

60%  
all60%  
gen pop60%  
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
FC 0303	Kumquats (all commodities)	highest utilisation: Total	0	0.71	1.000	JP	Gen pop, > 1 yrs	135	120.00	<25	NR	1	0.13 - 1.7	0% - 6%	0% - 6%	5% - 5%
FC 0204	Lemon (all commodities)	highest utilisation: Total	0.004	0.012	1.000	PRIMO-DE	child	P95	125.50	71	3	2a	0 - 0.2	0% - 1%	0% - 0%	0% - 1%
FC 0205	Lime (all commodities)	highest utilisation: Total	0.004	0.012	1.000	AU	Gen pop, > 2 yrs	579	259.21	49	3	2a	0 - 0.06	0% - 0%	0% - 0%	0% - 0%
FC 0004	Subgroup of Oranges, sweet, sour (incl orange-like hybrids) (all commodities)	highest utilisation: Total	0.011	0.021	1.000	AU	Child, 2-6 yrs	1735	800.83	156	3	2a	0.01 - 1.23	0% - 4%	0% - 2%	0% - 4%
FI 0350	Papaya (all commodities)	highest utilisation: Total	0.072	0.17	1.000	US	Child, < 6 yrs	86	167.57	204	3	2b	0.12 - 5.89	0% - 20%	0% - 20%	1% - 20%

**CHLORFENAPYR (254)**

Acute RfD= 0.03 mg/kg bw (30 µg/kg bw)

IESTI

Maximum %ARfD:

60%  
all60%  
gen pop60%  
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
VA 0381	Garlic (all commodities)	highest utilisation: raw without skin	0.01	0.01	1.000	CN	Child, 1-6 yrs	290	174.44	62	3	2a	0 - 0.19	0% - 1%	0% - 0%	0% - 1%
VA 0385	Onion, bulb (all commodities)	highest utilisation: raw without skin	0.01	0.01	1.000	JP	Child, 1-6 yrs	748	102.00	244	3	2b	0 - 0.19	0% - 1%	0% - 0%	0% - 1%
VC 0046	Melons, except watermelon (Cantaloupe) (all commodities)	highest utilisation: Total	0.01	0.01	1.000	PRIMO-BE	toddler	P100	540.00	540	3	2b	0 - 0.91	0% - 3%	0% - 2%	0% - 3%
VO 0448	Tomato (all commodities)	highest utilisation: raw with peel	0.065	0.19	1.000	CN	Child, 1-6 yrs	1117	263.76	175	3	2a	0.22 - 7.22	1% - 20%	1% - 9%	1% - 20%
VO 0444	Peppers, chili	dried (incl powder)	0.5	1.5	1.000	CN	Gen Pop, > 1 yrs	1583	32.22	0	NR	1	0.908	3%	3%	1%
VO 0445	Peppers, sweet (incl. pimiento) (Bell pepper, Paprika) (all commodities)	highest utilisation: raw with skin	0.05	0.15	1.000	CN	Child, 1-6 yrs	1002	169.85	170	3	2b	0.01 - 4.74	0% - 20%	0% - 6%	0% - 20%
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilisation: Total	0.01 - 0.045	0	1.000	CN	Child, 1-6 yrs	179	239.05	<25	NR	3	0 - 0.15	0% - 0%	0% - 0%	0% - 0%
VR 0589	Potato (all commodities)	highest utilisation: Total	0.01	0.01	1.000	PRIMO-UK	infant	P97.5	191.10	216	3	2b	0.01 - 0.66	0% - 2%	0% - 1%	0% - 2%
DT 1114	Tea, green, black (black, fermented and dried) (all commodities)	highest utilisation: Total	12	0	1.000	PRIMO-IE	child	P97.5	30.60	<25	NR	3	9.81 - 18.36	30% - 60%	20% - 60%	40% - 60%
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	10%	9%	10%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		1	1.000	CN	Child, 1-6 yrs	302	52.97	NR	NR	1	3.283	10%	8%	10%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.026	1.000	CN	Child, 1-6 yrs	302	211.87	NR	NR	1	0.341	1%	1%	1%

**CHLORFENAPYR (254)**

Acute RfD= 0.03 mg/kg bw (30 µg/kg bw)

IESTI

Maximum %ARfD:

60%  
all60%  
gen pop60%  
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
MF 0100	Mammalian fats (except milk fats)	Total		1	1.000	PRIMO-FR	adult	P97.5	134.79	NR	NR	1	2.030	7%	7%	7%
MO 0105	Edible offal (mammalian)	Total		0.54	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	5.076	20%	20%	10%
ML 0106	Milks	Total	0.043		1.000	PRIMO-UK	infant	P97.5	1080.70	NR	NR	3	5.341	20%	7%	20%
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		0.018	1.000	CN	Child, 1-6 yrs	175	34.70	NR	NR	1	0.039	0%	0%	0%
PM 0110	Poultry meat: 90% as muscle	Total		0.007	1.000	CN	Child, 1-6 yrs	175	312.30	NR	NR	1	0.135	0%	0%	0%
PF 0111	Poultry, fats	Total		0.018	1.000	CA	Child, <6 yrs	66	49.38	NR	NR	1	0.052	0%	0%	0%
PO 0111	Poultry, edible offal (includes kidney, liver and skin)	Total		0.058	1.000	CN	Gen pop, > 1 yrs	421	345.63	NR	NR	1	0.377	1%	1%	1%
PE 0112	Eggs	Total		0.047	1.000	PRIMO-UK	infant	P97.5	108.00	NR	NR	1	0.583	2%	1%	2%

**CYAZOFAMID (CCIM Metabolite only) (281)**

Acute RfD= 0.2 mg/kg bw (200 µg/kg bw)

IESTI  
 Maximum %ARfD:

3%  
all

1%  
gen pop

3%  
child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VA 0381	Garlic	raw without skin	0.0615	0.03	1.000	CN	Child, 1-6 yrs	290	174.44	62	3	2a	0.556	0%	0%	0%
VA 0385	Onion, bulb	raw without skin	0.0615	0.03	1.000	JP	Child, 1-6 yrs	748	102.00	244	3	2b	0.560	0%	0%	0%
VA 0386	Onion, Chinese	raw	0.0615	0.03	1.000	CN	Child, 1-6 yrs	196	136.53	130	3	2a	0.736	0%	0%	0%
VA 0388	Shallot	raw without skin	0.0615	0.03	1.000	CN	Child, 1-6 yrs	480	115.81	51	3	2a	0.406	0%	0%	0%
VA 0384	Leek	cooked/boiled		0.2	1.000	PRIMO-NL	toddler	E	100.70	142	3	2b	5.924	3%	1%	3%
VA 0387	Onion, Welsh (Japanese bunching onion, Multiplying onion)	raw		0.2	1.000	JP	Child, 1-6 yrs	305	35.70	97	3	2b	1.260	1%	0%	1%
VA 0389	Spring onion	raw		0.2	1.000	TH	Child, 3-6 yrs	566	52.84	<25	NR	1	0.618	0%	0%	0%



**DIQUAT (31)**

Acute RfD= 0.8 mg/kg bw (800 µg/kg bw)

IESTI

Maximum %ARfD:

10%  
all10%  
gen pop7%  
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
VD 0071	Beans (dry) (Phaseolus spp) (all commodities)	highest utilisation: Total	0.05	0	1.000	PRIMO-UK	infant	P97.5	159.00	<25	NR	3	0.1 - 0.91	0% - 0%	0% - 0%	0% - 0%
VD 0523	Broad bean (dry) (Vicia spp) (all commodities)	highest utilisation: cooked/boiled	0.05	0	0.400	CN	Gen pop, > 1 yrs	737	1190.24	<25	NR	3	0.03 - 0.45	0% - 0%	0% - 0%	0% - 0%
VD 0531	Lablab bean (dry) (Lablab spp) (all commodities)	highest utilisation: cooked/boiled	0.05	0	0.400	CN	Gen pop, > 1 yrs	1219	972.42	<25	NR	3	0.37 - 0.37	0% - 0%	0% - 0%	0% - 0%
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilisation: Total	0.00275 - 0.05	0	1.000	CN	Child, 1-6 yrs	179	239.05	<25	NR	3	0 - 0.74	0% - 0%	0% - 0%	0% - 0%
VD 0072	Peas (dry) (Pisum spp) (all commodities)	highest utilisation: cooked/boiled	0.17	0	0.400	CN	Gen pop, > 1 yrs	268	1673.82	<25	NR	3	0.13 - 2.14	0% - 0%	0% - 0%	0% - 0%
VD 0524	Chick-pea (dry) (Cicer spp) (all commodities)	highest utilisation: canned/preserved	0.24	0	0.400	PRIMO-NL	child	P100	328.80	<25	NR	3	0.18 - 1.72	0% - 0%	0% - 0%	0% - 0%
VD 0533	Lentil (dry) (Lens spp) (all commodities)	highest utilisation: Total	0.17	0	1.000	PRIMO-UK	Child, 11-14 yrs	P97.5	321.50	<25	NR	3	0.33 - 1.14	0% - 0%	0% - 0%	0% - 0%
VD 0537	Pigeon pea (dry) (Cajanus spp)	Total	0.17		1.000	AU	Gen pop, > 2 yrs	129	95.83	<25	NR	3	0.243	0%	0%	0%
GC 0650	Rye (all commodities)	highest utilisation: flakes	0.505	0	1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.73 - 17.32	0% - 2%	0% - 0%	0% - 2%
GC 0653	Triticale	Total	0.505		1.000	DE	Gen pop, 14-80 yrs	27100	394.70	<25	NR	3	2.610	0%	0%	0%
GC 0640	Barley (all commodities)	highest utilisation: beer	1.55	0	0.190	CA	Gen pop, all ages	2514	21271.20	NR	NR	3	0.14 - 79.62	0% - 10%	0% - 10%	0% - 7%
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%
PF 0111	Poultry, fats	Total		0	1.000	CA	Child, <6 yrs	66	49.38	NR	NR	1	0.000	0%	0%	0%

**FENPYROXIMATE (193)**  
Acute RfD= 0.01 mg/kg bw (10 µg/kg bw)

IESTI  
 Maximum %ARfD:  
 60% all      20% gen pop      60% 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
<b>012A</b>	<b>Tomato and tomato-like commodities</b>	-		<b>0.17</b>	-	-	-	-	-	-	-	-	-	-	-	-
VO 2704	Goji berry (all commodities)	highest utilisation: Dried	0	0.17	3.000	AU	Child, 2-6 yrs	1	28.36	<25	NR	1	0.16 - 0.76	2% - 8%	0% - 0%	2% - 8%
VO 0448	Tomato (all commodities)	highest utilisation: raw with peel	0.064 - 0.1	0.17	1.000	CN	Child, 1-6 yrs	1117	263.76	175	3	2a	0.24 - 6.46	2% - 60%	2% - 20%	5% - 60%

**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	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
FC 0303	Kumquats (all commodities)	highest utilisation: Total		0.59	1.000	JP	Gen pop, > 1 yrs	135	120.00	<25	NR	1	0.11 - 1.41	0% - 0%	0% - 0%	0% - 0%
FC 0204	Lemon (all commodities)	highest utilisation: Total	0.015 - 20	0.59 - 1.1	1.000	PRIMO-DE	child	P95	125.50	71	3	2a	0.03 - 9.8	0% - 3%	0% - 1%	0% - 3%
FC 0205	Lime (all commodities)	highest utilisation: Total	0.015 - 20	0.59	1.000	AU	Gen pop, > 2 yrs	579	259.21	49	3	2a	0.03 - 3.15	0% - 1%	0% - 1%	0% - 1%
FC 0003	Subgroup of Mandarins (incl mandarin-like hybrids) (all commodities)	highest utilisation: raw, without peel	0.015 - 0.33	0.59	1.000	CN	Child, 1-6 yrs	151	586.75	124	3	2a	0.07 - 30.55	0% - 10%	0% - 5%	0% - 10%
FC 0004	Subgroup of Oranges, sweet, sour (incl orange-like hybrids) (all commodities)	highest utilisation: Total	0.015 - 20	0.59 - 1.1	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	0.015 - 20	0.59	1.000	PRIMO-DE	child	P90	253.56	270	3	2b	0.06 - 27.79	0% - 9%	0% - 5%	0% - 9%
FI 0345	Mango (all commodities)	highest utilisation: raw without peel	0.145	0.37	1.000	NL	toddler, 8-20 m	11	160.43	289	3	2b	0.04 - 17.46	0% - 6%	0% - 2%	0% - 6%
FI 0350	Papaya (all commodities)	highest utilisation: Total	0.054	0.51	1.000	US	Child, < 6 yrs	86	167.57	204	3	2b	0.09 - 17.68	0% - 6%	0% - 6%	0% - 6%
VR 0573	Arrowroot (all commodities)	highest utilisation: starch	0.01	0.03	1.000	PRIMO-NL	child	E	12.40	NR	NR	3	0 - 0.01	0% - 0%	0% - 0%	0% - 0%
VR 0463	Cassava (Manioc) (all commodities)	highest utilisation: cooked/boiled (without peel)	0.01	0.03	1.000	PRIMO-NL	Gen pop	E	250.00	356	3	2b	0.01 - 0.34	0% - 0%	0% - 0%	0% - 0%
VR 0585	Jerusalem artichoke (i.e. Topinambur) (all commodities)	highest utilisation: cooked/boiled (without peel)		0.03	1.000	PRIMO-NL	child	E	133.30	56	3	2a	0.16 - 0.4	0% - 0%	0% - 0%	0% - 0%
VR 0589	Potato (all commodities)	highest utilisation: Total	0.018 - 0.035	0.018 - 0.06	1.000	PRIMO-UK	infant	P97.5	191.10	216	3	2b	0.02 - 3.95	0% - 1%	0% - 0%	0% - 1%

**FLUXAPYROXAD (256)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum %ARfD:

10%  
all6%  
gen pop10%  
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
VR 0508	Sweet potato (all commodities)	highest utilisation: Total	0.01	0.03	1.000	CA	Child, <6 yrs	91	358.61	546	3	2b	0.07 - 2.53	0% - 1%	0% - 0%	0% - 1%
VR 0504	Tannia (Tanier, Yautia) (all commodities)	highest utilisation: cooked/boiled (without peel)	0.01	0.03	1.000	NL	Gen pop, > 1 yrs	E	249.97	170	3	2a	0.01 - 0.27	0% - 0%	0% - 0%	0% - 0%
VR 0505	Taro (Dasheen, Eddoe) (all commodities)	highest utilisation: cooked/boiled (without peel)		0.03	1.000	CN	Child, 1-6 yrs	199	384.18	668	3	2b	0.22 - 2.14	0% - 1%	0% - 0%	0% - 1%
VR 0600	Yams (all commodities)	highest utilisation: Total		0.03	1.000	PRIMO-UK	adult	P97.5	693.70	365	3	2a	0.22 - 0.56	0% - 0%	0% - 0%	0% - 0%
SO 0691	Cotton seed (all commodities)	highest utilisation: Oil (refined)	0.0036 - 0.08		1.000	US	Child, < 6 yrs	6354	3.13	NR	NR	3	0 - 0	0% - 0%	0% - 0%	0% - 0%
SB 0716	Coffee beans (all commodities)	highest utilisation: extract (beverage)	0.042		0.180	CA	women, 15-49 yrs	2666	2088.65	NR	NR	3	0 - 0.23	0% - 0%	0% - 0%	0% - 0%

**IMAZALIL (110)**

Acute RfD= 0.05 mg/kg bw (50 µg/kg bw)

IESTI

Maximum %ARfD:

 90%  
all

 90%  
gen pop

 40%  
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
FC 0303	Kumquats (all commodities)	highest utilisation: Total		9.7	1.000	JP	Gen pop, > 1 yrs	135	120.00	<25	NR	1	1.77 - 23.19	4% - 50%	4% - 50%	40% - 40%
FC 0204	Lemon (all commodities)	highest utilisation: Total	0.18	0.36	1.000	PRIMO-DE	child	P95	125.50	71	3	2a	0.07 - 5.98	0% - 10%	0% - 4%	0% - 10%
FC 0205	Lime (all commodities)	highest utilisation: Total	0.18	0.36	1.000	AU	Gen pop, > 2 yrs	579	259.21	49	3	2a	0.02 - 1.92	0% - 4%	0% - 4%	0% - 2%
FC 0004	Subgroup of Oranges, sweet, sour (incl orange-like hybrids) (all commodities)	highest utilisation: Total	0.003 - 2.6	0.26	1.000	AU	Child, 2-6 yrs	1735	800.83	156	3	2a	0.02 - 15.22	0% - 30%	0% - 20%	0% - 30%
FI 0327	Banana (incl Dwarf banana & Plantain) (all commodities)	highest utilisation: raw without peel	0.05	0.1	1.000	CN	Child, 1-6 yrs	286	455.81	767	3	2b	0.02 - 8.47	0% - 20%	0% - 9%	0% - 20%
VO 0448	Tomato (all commodities)	highest utilisation: dried	0.13	0.24	14.000	AU	Gen pop, > 2 yrs	61	861.10	8	NR	1	0.43 - 43.18	1% - 90%	1% - 90%	1% - 20%
VR 0589	Potato (all commodities)	highest utilisation: baked (with peel)	0.004 - 1.3	0.009 - 2.8	1.000	BR	Gen pop, > 10 yrs	4471	420.00	140	3	2a	0.01 - 30.36	0% - 60%	0% - 60%	0% - 7%
GC 0653	Triticale	Total	0		1.000	DE	Gen pop, 14-80 yrs	####	394.70	<25	NR	3	0.000	0%	0%	0%
GC 0654	Wheat (all commodities)	highest utilisation: flakes	0		1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0 - 0	0% - 0%	0% - 0%	0% - 0%
GC 0640	Barley (all commodities)	highest utilisation: beer	0		0.190	CA	Gen pop, all ages	2514	#####	NR	NR	3	0 - 0	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		0.04	1.000	CN	Child, 1-6 yrs	302	52.97	NR	NR	1	0.131	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.04	1.000	CN	Child, 1-6 yrs	302	211.87	NR	NR	1	0.525	1%	1%	1%

**IMAZALIL (110)**

Acute RfD= 0.05 mg/kg bw (50 µg/kg bw)

IESTI

Maximum %ARfD:

90%  
all90%  
gen pop40%  
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
MF 0100	Mammalian fats (except milk fats)	Total		0.04	1.000	PRIMO-FR	adult	P97.5	134.79	NR	NR	1	0.081	0%	0%	0%
MO 0105	Edible offal (mammalian)	Total		0.5	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	4.700	9%	9%	8%
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	2%	1%	2%
PM 0110	Poultry meat: 10% as fat	Total		0.04	1.000	CN	Child, 1-6 yrs	175	34.70	NR	NR	1	0.086	0%	0%	0%
PM 0110	Poultry meat: 90% as muscle	Total		0.04	1.000	CN	Child, 1-6 yrs	175	312.30	NR	NR	1	0.774	2%	1%	2%
PF 0111	Poultry, fats	Total		0.04	1.000	CA	Child, <6 yrs	66	49.38	NR	NR	1	0.116	0%	0%	0%
PO 0111	Poultry, edible offal (includes kidney, liver and skin)	Total		0.04	1.000	CN	Gen pop, > 1 yrs	421	345.63	NR	NR	1	0.260	1%	1%	0%
PE 0112	Eggs	Total		0.02	1.000	PRIMO-UK	infant	P97.5	108.00	NR	NR	1	0.248	0%	0%	0%

**ISOFETAMID (290)**

Acute RfD= 3 mg/kg bw (3000 µg/kg bw)

IESTI

Maximum %ArfD:

3%  
all

1%  
gen pop

3%  
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
FP 0226	Apple (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.04 - 0.135	0.42	1.000	CN	Child, 1-6 yrs	1314	403.39	255	3	2a	0.69 - 23.77	0% - 1%	0% - 0%	0% - 1%
FP 2220	Azaro (Mediterranean medlar) (all commodities)	highest utilisation: juice (pasteurised)	0.135	0.42	1.000	PRIMO-DE	child	P97.5	89.63	NR	NR	3	0.38 - 0.75	0% - 0%	0% - 0%	0% - 0%
FP 0227	Crab-apple (all commodities)	highest utilisation: raw with peel		0.42	1.000	CN	Gen pop, > 1 yrs	204	488.33	<25	NR	1	3.85 - 3.85	0% - 0%	0% - 0%	0% - 0%
FP 0228	Loquat (Japanese medlar) (all commodities)	highest utilisation: raw without peel		0.42	1.000	JP	Gen pop, > 1 yrs	113	326.40	49	3	2a	0.74 - 3.29	0% - 0%	0% - 0%	0% - 0%
FP 0229	Medlar (all commodities)	highest utilisation: Total		0.42	1.000	PRIMO-ES	child	P97.5	116.99	60	3	2a	2.89 - 2.89	0% - 0%	0% - 0%	0% - 0%
FP 0230	Pear (all commodities)	highest utilisation: Total	0.135	0.42	1.000	CA	Child, <6 yrs	175	498.28	255	3	2a	0.03 - 29.09	0% - 1%	0% - 0%	0% - 1%
FP 0307	Persimmon, Japanese (i.e. Kaki fruit) (all commodities)	highest utilisation: raw with peel (incl consumption without peel)		0.42	1.000	TH	Child, 3-6 yrs	20	264.88	228	3	2a	15.99 - 17.68	1% - 1%	0% - 0%	1% - 1%
FP 0231	Quince (all commodities)	highest utilisation: Total	0.135	0.42	1.000	PRIMO-ES	child	P97.5	169.60	301	3	2b	0 - 6.2	0% - 0%	0% - 0%	0% - 0%
FS 0013	Subgroup of Cherries (all commodities)	highest utilisation: Total	1.1	3.4	1.000	PRIMO-DK	child	P97.5	269.00	<25	NR	1	0.45 - 41.57	0% - 1%	0% - 1%	0% - 1%
FS 0014	Subgroup of Plums (all commodities)	highest utilisation: dried (prunes)	0.175	0.39 - 1.5	1.000	AU	Child, 2-6 yrs	13	447.59	10	NR	1	0.08 - 35.34	0% - 1%	0% - 0%	0% - 1%
FS 0240	Apricot (all commodities)	highest utilisation: Total	0.76	1.7	1.000	PRIMO-DE	child	P95	264.86	50	3	2a	0.32 - 38.41	0% - 1%	0% - 1%	0% - 1%
FS 2237	Japanese apricot (ume)	Total		1.7	1.000	JP	Child, 1-6 yrs	25	25.50	<25	NR	1	2.395	0%	0%	0%
FS 0245	Nectarine (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.76	1.7	1.000	NL	toddler, 8-20 m	6	183.60	131	3	2a	0.31 - 74.25	0% - 2%	0% - 1%	0% - 2%

**ISOFETAMID (290)**

Acute RfD= 3 mg/kg bw (3000 µg/kg bw)

**IESTI**

Maximum %ArfD:

3%  
all1%  
gen pop3%  
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
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.76	1.7	1.000	JP	Child, 1-6 yrs	76	306.00	255	3	2a	0.31 - 89.5	0% - 3%	0% - 1%	0% - 3%
FB 0264	Blackberries (all commodities)	highest utilisation: Total	0.68	1.2	1.000	PRIMO-UK	toddler	P97.5	155.40	<25	NR	1	0.12 - 12.86	0% - 0%	0% - 0%	0% - 0%
FB 0266	Dewberries (incl Boysenberry, Loganberry) (all commodities)	highest utilisation: Total		1.2	1.000	PRIMO-UK	toddler	P97.5	25.50	<25	NR	1	2.11 - 2.11	0% - 0%	0% - 0%	0% - 0%
FB 0272	Raspberries, red, black (all commodities)	highest utilisation: Total	0.68	1.2	1.000	PRIMO-IE	child	P97.5	184.76	<25	NR	1	0.39 - 11.09	0% - 0%	0% - 0%	0% - 0%
FB 0020	Blueberries (all commodities)	highest utilisation: Total	0.31	3	1.000	CA	Child, <6 yrs	189	176.21	<25	NR	1	0.04 - 34.34	0% - 1%	0% - 1%	0% - 1%
FB 0021	Currants, black, red, white (all commodities)	highest utilisation: Total	0.31	3	1.000	AU	Gen pop, > 2 yrs	322	797.60	<25	NR	1	0.2 - 35.71	0% - 1%	0% - 1%	0% - 1%
FB 0268	Gooseberry (all commodities)	highest utilisation: Total	0.31	3	1.000	PRIMO-DE	child	P100	94.96	<25	NR	1	0.06 - 17.64	0% - 1%	0% - 1%	0% - 1%
FB 0273	Rose hips (all commodities)	highest utilisation: Total	0.31	3	1.000	PRIMO-FI	women	P97.5	156.60	<25	NR	1	0.2 - 6.6	0% - 0%	0% - 0%	0% - 0%
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds) (all commodities)	highest utilisation: Total	0.096	0.36	1.000	CA	Child, <6 yrs	261	203.31	<25	NR	1	0.14 - 4.86	0% - 0%	0% - 0%	0% - 0%
VP 0522	Broad bean with pods (immature pods + succulent seeds) (Vicia spp) (all commodities)	highest utilisation: Total		0.36	1.000	US	Child, < 6 yrs	221	93.96	9	NR	1	0.99 - 2.33	0% - 0%	0% - 0%	0% - 0%
VP 0542	Sword bean with pods (immature pods + succulent seeds) (Canavalia spp) (all commodities)	highest utilisation: cooked/boiled		0.36	1.000	CN	Gen pop, > 1 yrs	891	316.83	<25	NR	1	2.14 - 2.14	0% - 0%	0% - 0%	0% - 0%



**ISOFETAMID (290)**  
Acute RfD= 3 mg/kg bw (3000 µg/kg bw)

IESTI  
Maximum %ARfD:

3% all      1% gen pop      3% 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
VP 0063	Peas with pods (Pisum spp) immature pods + succulent seeds) (all commodities)	highest utilisation: cooked/boiled	0.096	0.36	1.000	CN	Child, 1-6 yrs	1056	290.21	6	NR	1	1.77 - 6.47	0% - 0%	0% - 0%	0% - 0%
VP 0553	Lentil with pods (immature pods + succulent seeds) (Lens spp) (all commodities)	highest utilisation: cooked/boiled		0.36	1.000	CN	Child, 1-6 yrs	371	345.76	<25	NR	1	2.07 - 7.71	0% - 0%	0% - 0%	0% - 0%
VD 0071	Beans (dry) (Phaseolus spp) (all commodities)	highest utilisation: Total	0.01		1.000	PRIMO-UK	infant	P97.5	159.00	<25	NR	3	0.02 - 0.18	0% - 0%	0% - 0%	0% - 0%
VD 0523	Broad bean (dry) (Vicia spp) (all commodities)	highest utilisation: cooked/boiled	0.01		0.400	CN	Gen pop, > 1 yrs	737	1190.24	<25	NR	3	0.01 - 0.09	0% - 0%	0% - 0%	0% - 0%
VD 0531	Lablab bean (dry) (Lablab spp) (all commodities)	highest utilisation: cooked/boiled	0.01		0.400	CN	Gen pop, > 1 yrs	1219	972.42	<25	NR	3	0.07 - 0.07	0% - 0%	0% - 0%	0% - 0%
VD 0072	Peas (dry) (Pisum spp) (all commodities)	highest utilisation: cooked/boiled	0.01		0.400	CN	Gen pop, > 1 yrs	268	1673.82	<25	NR	3	0.01 - 0.13	0% - 0%	0% - 0%	0% - 0%
VD 0524	Chick-pea (dry) (Cicer spp) (all commodities)	highest utilisation: canned/preserved	0.01		0.400	PRIMO-NL	child	P100	328.80	<25	NR	3	0.01 - 0.07	0% - 0%	0% - 0%	0% - 0%
VD 0533	Lentil (dry) (Lens spp) (all commodities)	highest utilisation: Total	0.01		1.000	PRIMO-UK	Child, 11-14 yrs	P97.5	321.50	<25	NR	3	0.02 - 0.07	0% - 0%	0% - 0%	0% - 0%
VD 0537	Pigeon pea (dry) (Cajanus spp)	Total	0.01		1.000	AU	Gen pop, > 2 yrs	129	95.83	<25	NR	3	0.014	0%	0%	0%

**NORFLURAZON (308)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum %ARfD:

10%  
all4%  
gen pop10%  
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 0460	Amaranth leaves (Bledo) (all commodities)	highest utilisation: raw		0.53	1.000	CN	Gen pop, > 1 yrs	714	581.72	86	3	2a	2.49 - 7.5	1% - 3%	1% - 3%	0% - 0%
VL 0464	Chard (Beet leaves, Silver beet) (all commodities)	highest utilisation: cooked/boiled		0.53	1.000	PRIMO-NL	child	P100	81.80	105	3	2b	1.88 - 7.07	1% - 2%	1% - 2%	2% - 2%
VL 0465	Chervil (all commodities)	highest utilisation: Total	0.053	0.53	1.000	PRIMO-BE	toddler	P100	23.00	<25	NR	1	0.01 - 0.68	0% - 0%	0% - 0%	0% - 0%
VL 0469	Chicory leaves (green and red cultivars) (Sugar loaf) (all commodities)	highest utilisation: raw		0.53	1.000	DE	Child, 2-4 yrs	16	82.40	280	3	2b	1.1 - 8.11	0% - 3%	0% - 1%	0% - 3%
VL 2752	Chrysanthemum, edible leaved (all commodities)	highest utilisation: raw		0.53	1.000	CN	Gen pop, > 1 yrs	993	332.67	<25	NR	1	1.85 - 3.31	1% - 1%	0% - 1%	1% - 1%
VL 0470	Corn salad (Lambs lettuce) (all commodities)	highest utilisation: Total		0.53	1.000	PRIMO-BE	toddler	P100	50.00	<25	NR	1	0.45 - 1.49	0% - 0%	0% - 0%	0% - 0%
VL 0510	Cos lettuce (all commodities)	highest utilisation: Total	0.053	0.53	1.000	PRIMO-NL	child	P97.5	140.10	290	3	2b	0.03 - 12.11	0% - 4%	0% - 2%	0% - 4%
VL 0474	Dandelion (Laiteron, Pissenlit) (all commodities)	highest utilisation: raw		0.53	1.000	NL	gen pop, > 1 yrs	E	49.88	35	3	2a	0.37 - 0.97	0% - 0%	0% - 0%	0% - 0%
VL 0476	Endive (i.e. Scarole) (all commodities)	highest utilisation: cooked/boiled	0.053	0.53	1.000	PRIMO-NL	toddler	P95	135.20	251	3	2b	0.21 - 21.08	0% - 7%	0% - 3%	0% - 7%
VL 0482	Lettuce, head (all commodities)	highest utilisation: Total	0.053	0.53	1.000	PRIMO-NL	child	P97.5	140.10	290	3	2b	0.03 - 12.11	0% - 4%	0% - 2%	0% - 4%
VL 0483	Lettuce, leaf (all commodities)	highest utilisation: Total	0.053	0.53	1.000	CN	Child, 1-6 yrs	243	387.25	305	3	2a	0.03 - 32.78	0% - 10%	0% - 4%	0% - 10%
VL 0492	Purslane (all commodities)	highest utilisation: cooked/boiled		0.53	1.000	PRIMO-NL	Gen pop	P100	271.20	<25	NR	1	0.58 - 2.18	0% - 1%	0% - 1%	0% - 0%
VL 0501	Sowthistle (all commodities)	highest utilisation: raw		0.53	1.000	CN	Gen pop, > 1 yrs	1187	592.49	35	3	2a	6.6 - 6.6	2% - 2%	2% - 2%	0% - 0%
VL 0502	Spinach (all commodities)	highest utilisation: Total	0.053	0.53	1.000	PRIMO-BE	toddler	P97.5	402.30	<25	NR	1	0.01 - 11.98	0% - 4%	0% - 3%	0% - 4%

**NORFLURAZON (308)**  
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI  
Maximum %ARfD:

10%  
all  
4%  
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
VL 0401	Broccoli, Chinese (i.e. kailan) (all commodities)	highest utilisation: raw		0.22	1.000	CN	Child, 1-6 yrs	334	222.48	311	3	2b	0.46 - 9.1	0% - 3%	0% - 1%	0% - 3%
VL 0466	Chinese cabbage (type Pak-choi) (i.e. celery mustard) (all commodities)	highest utilisation: raw	0.096	0.22	1.000	CN	Child, 1-6 yrs	1966	327.07	1548	3	2b	0.03 - 13.38	0% - 4%	0% - 2%	0% - 4%
VL 0472	Cress, Garden (all commodities)	highest utilisation: raw		0.22	1.000	CN	Gen pop, > 1 yrs	1443	352.50	<25	NR	1	0.08 - 1.46	0% - 0%	0% - 0%	0% - 0%
VL 0468	Flowering white cabbage (Choisum) (all commodities)	highest utilisation: raw	0.096	0.22	1.000	CN	Gen pop, > 1 yrs	1639	556.56	300	3	2a	0.32 - 4.78	0% - 2%	0% - 2%	0% - 0%
VL 0480	Kale (Borecole, Collards) (all commodities)	highest utilisation: Total	0.096	0.22	1.000	PRIMO-DE	child	P100	142.12	672	3	2b	0.18 - 5.81	0% - 2%	0% - 1%	0% - 2%
VL 0481	Komatsuna	Total		0.22	1.000	JP	Child, 1-6 yrs	73	71.40	<25	NR	1	0.935	0%	0%	0%
VL 2781	Mizuna	Total		0.22	1.000	JP	Gen pop, > 1 yrs	1787	137.70	<25	NR	1	0.541	0%	0%	0%
VL 0485	Mustard greens (Indian mustard, Amsoi, mustard cabbage, red mustards) (all commodities)	highest utilisation: raw	0.096	0.22	1.000	CN	Child, 1-6 yrs	635	299.31	245	3	2a	0.42 - 10.76	0% - 4%	0% - 1%	4% - 4%
VL 0494	Radish leaves	Total		0.22	1.000	BR	Gen pop, > 10 yrs	-	258.24	<25	NR	1	0.880	0%	0%	-
VL 0495	Rape greens (all commodities)	highest utilisation: cooked/boiled		0.22	1.000	JP	Gen pop, > 1 yrs	533	147.90	34	3	2a	0.85 - 0.85	0% - 0%	0% - 0%	0% - 0%
VL 0496	Rucola (Arrugula, Rocket salad, Roquette, Roman rocket) (all commodities)	highest utilisation: Total		0.22	1.000	PRIMO-DE	child	P100	43.44	<25	NR	1	0.26 - 0.59	0% - 0%	0% - 1%	0% - 0%
VL 0506	Turnip greens (Namenia, Tendergreen) (all commodities)	highest utilisation: Total		0.22	1.000	DE	Child, 2-4 yrs	1	67.00	35	3	2a	0.36 - 1.87	0% - 1%	0% - 0%	0% - 1%

**NORFLURAZON (308)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum %ARfD:

10%  
all4%  
gen pop10%  
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 0574	Beetroot (all commodities)	highest utilisation: Total	0.04	0.21	1.000	AU	Child, 2-6 yrs	53	314.08	135	3	2a	0.02 - 6.47	0% - 2%	0% - 1%	0% - 2%
VR 0575	Burdock, greater or edible	Total		0.21	1.000	JP	Child, 1-6 yrs	122	35.70	68	3	2b	1.371	0%	0%	0%
VR 0577	Carrot (all commodities)	highest utilisation: raw with skin	0.04	0.21	1.000	CN	Child, 1-6 yrs	400	234.68	300	3	2b	0 - 9.16	0% - 3%	0% - 1%	0% - 3%
VR 0578	Celeriac (Turnip rooted celery) (all commodities)	highest utilisation: Total	0.04	0.21	1.000	PRIMO-BE	toddler	P100	196.90	749	3	2b	0.01 - 6.97	0% - 2%	0% - 1%	0% - 2%
VR 0469	Chicory, roots (all commodities)	highest utilisation: Total	0.04	0.21	1.000	AU	Gen pop, > 2 yrs	175	26.16	48	3	2b	0.03 - 0.25	0% - 0%	0% - 0%	0% - 0%
VR 0583	Horseradish (all commodities)	highest utilisation: Total		0.21	1.000	PRIMO-DE	Gen pop	P97.5	79.50	220	3	2b	0.01 - 0.66	0% - 0%	0% - 0%	0% - 0%
VR 0587	Parsley, turnip-rooted (Hamburg roots) (all commodities)	highest utilisation: Total	0.04	0.21	1.000	PRIMO-NL	Gen pop	P97.5	96.60	140	3	2b	0.28 - 0.92	0% - 0%	0% - 0%	0% - 0%
VR 0588	Parsnip (all commodities)	highest utilisation: cooked/boiled (without skin)	0.04	0.21	1.000	PRIMO-NL	child	E	133.30	227	3	2b	0.48 - 4.56	0% - 2%	0% - 0%	1% - 2%
VR 0494	Radish (all commodities)	highest utilisation: Total	0.04	0.21	1.000	PRIMO-NL	child	E	64.40	172	3	2b	0 - 2.21	0% - 1%	0% - 0%	0% - 1%
VR 0590	Radish, black (all commodities)	highest utilisation: Total	0.04	0.21	1.000	PRIMO-NL	child	E	64.40	172	3	2b	0 - 2.21	0% - 1%	0% - 0%	0% - 1%
VR 0591	Radish, Japanese (Chinese radish, Daikon) (all commodities)	highest utilisation: raw without skin	0.04	0.21	1.000	CN	Child, 1-6 yrs	1187	293.37	1000	3	2b	0 - 11.45	0% - 4%	0% - 2%	0% - 4%
VR 0498	Salsify (Oyster plant) (all commodities)	highest utilisation: Total	0.04	0.21	1.000	PRIMO-BE	toddler	P100	99.90	75	3	2a	0 - 2.96	0% - 1%	0% - 0%	0% - 1%
VR 0596	Sugar beet (all commodities)	highest utilisation: composite foods; unspecified ind processed	0.04		1.000	NL	Child, 2-6 yrs	2554	168.93	NR	NR	3	0.09 - 0.37	0% - 0%	0% - 0%	0% - 0%
VR 0497	Swede (Rutabaga) (all commodities)	highest utilisation: Total	0.04	0.21	1.000	PRIMO-UK	infant	P97.5	90.00	500	3	2b	0 - 6.52	0% - 2%	0% - 1%	0% - 2%

**NORFLURAZON (308)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum %ARfD:

10%  
all

4%  
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
VR 0506	Turnip, garden (all commodities)	highest utilisation: Total	0.04	0.21	1.000	US	Gen pop, 0-85 yrs	53	1533.22	105	3	2a	0.29 - 5.18	0% - 2%	0% - 2%	0% - 1%
GC 0648	Quinoa	Total	0.04		1.000	AU	Child, 2-16 yrs	32	78.18	<25	NR	3	0.082	0%	-	0%
GC 0650	Rye (all commodities)	highest utilisation: flakes	0.04		1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.06 - 1.37	0% - 0%	0% - 0%	0% - 0%
GC 0653	Triticale	Total	0.04		1.000	DE	Gen pop, 14-80 yrs	####	394.70	<25	NR	3	0.207	0%	0%	0%
GC 0654	Wheat (all commodities)	highest utilisation: flakes	0.04		1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.03 - 1.37	0% - 0%	0% - 0%	0% - 0%
GC 0649	Rice (all commodities)	highest utilisation: Total	0.1		1.000	CA	Child, <6 yrs	666	461.40	<25	NR	3	0.01 - 3.02	0% - 1%	0% - 1%	1% - 1%
GC 0650	Rice	Rice milk	0.1		0.400	AU	Child, 2-16 yrs	48	1265.78	NR	NR	3	1.332	0%	-	0%
GC 0649	Rice (all commodities)	highest utilisation: polished rice (cooked)	0.1		0.400	CN	Child, 1-6 yrs	8752	1004.28	<25	NR	3	0.09 - 2.49	0% - 1%	0% - 1%	0% - 1%
GC 0655	Wild rice (all commodities)	highest utilisation: cooked/boiled	0.1		0.400	CN	Child, 1-6 yrs	129	552.59	<25	NR	3	0.44 - 1.37	0% - 0%	0% - 0%	0% - 0%
GC 0644	Job's tears (all commodities)	highest utilisation: cooked/boiled	0.04		0.300	TH	Child, 3-6 yrs	134	85.50	<25	NR	3	0.06 - 0.06	0% - 0%	0% - 0%	0% - 0%
GC 0646	Millet (common millet, proso millet) (all commodities)	highest utilisation: Total	0.04		1.000	CN	Child, 1-6 yrs	826	219.53	<25	NR	3	0.03 - 0.54	0% - 0%	0% - 0%	0% - 0%
GC 0651	Sorghum grain (Chicken corn, Dari seed, Durra, Feterita) (all commodities)	highest utilisation: cooked/boiled	0.04		0.400	CN	Gen pop, > 1 yrs	356	1348.67	<25	NR	3	0.06 - 0.41	0% - 0%	0% - 0%	0% - 0%
GC 0645	Maize (corn) (all commodities)	highest utilisation: beer	0.04		0.190	CA	Gen pop, all ages	2514	#####	NR	NR	3	0.02 - 2.05	0% - 1%	0% - 1%	0% - 0%
GC 0656	Popcorn (i.e. maize destined for popcorn preparation) (all commodities)	highest utilisation: Total	0.04		1.000	AU	Child, 2-6 yrs	120	73.67	<25	NR	3	0.12 - 0.16	0% - 0%	0% - 0%	0% - 0%

**NORFLURAZON (308)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum %ARfD:

10%  
all4%  
gen pop10%  
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	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		0.0014	1.000	CN	Child, 1-6 yrs	302	52.97	NR	NR	1	0.005	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.004	1.000	CN	Child, 1-6 yrs	302	211.87	NR	NR	1	0.053	0%	0%	0%
MF 0100	Mammalian fats (except milk fats)	Total		0.0014	1.000	PRIMO-FR	adult	P97.5	134.79	NR	NR	1	0.003	0%	0%	0%
MO 0105	Edible offal (mammalian)	Total		0.22	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	2.068	1%	1%	1%
ML 0106	Milks	Total	0.0014		1.000	PRIMO-UK	infant	P97.5	1080.70	NR	NR	3	0.174	0%	0%	0%

Annex 4

**PROFENOFOS (171)**

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

IESTI

Maximum %ARfD:

0%  
all0%  
gen pop0%  
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
SB 0716	Coffee beans (all commodities)	highest utilisation: extract (beverage)	0.02		0.180	CA	women, 15-49 yrs	2666	2088.65	NR	NR	3	0 - 0.11	0% - 0%	0% - 0%	0% - 0%

**PROPAMOCARB (148)**

Acute RfD= 2 mg/kg bw (2000 µg/kg bw)

IESTI

Maximum %ARfD:

1%

1%

0%

																	all	gen pop	child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Population group	n	Body weight (kg)	Large portion g/kg bw	Expres sed as	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	ESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	CN	Child, 1-6 yrs	302	16.14	16.414	EP	264.84	NR	NR	1	NA	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.021	1.000	CN	Child, 1-6 yrs	302	16.14	3.283	EP	52.97	NR	NR	1	0.069	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.023	1.000	CN	Child, 1-6 yrs	302	16.14	13.131	EP	211.87	NR	NR	1	0.302	0%	0%	0%
MF 0100	Mammalian fats (except milk fats)	Total		0.021	1.000	PRIMO-FR	adult	P97.5	66.40	2.030	EP	134.79	NR	NR	1	0.043	0%	0%	0%
MO 0105	Edible offal (mammalian)	Total		1.2	1.000	ZA	Gen pop, > 10 yrs	-	55.70	9.400	EP	523.58	NR	NR	1	11.280	1%	1%	0%
ML 0106	Milks	Total	0		1.000	PRIMO-UK	infant	P97.5	8.70	124.218	EP	1080.70	NR	NR	3	0.000	0%	0%	0%

**PYDIFLUMETOFEN (309)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

## IESTI

Maximum %ARfD:

20% 9% 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	all gen pop child			
													20% IESTI µg/kg bw/day	% 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	0	1.000	PRIMO-UK	adult	P97.5	1802.62	NR	NR	3	0.58 - 6.88	0% - 2%	0% - 2%	0% - 0%

**PYRACLOSTROBIN (210)**

Acute RfD= 0.7 mg/kg bw (700 µg/kg bw)

IESTI

Maximum %ARfD:

60%  
all30%  
gen pop60%  
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
FP 0226	Apple (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.012 - 0.12	0.69	1.000	CN	Child, 1-6 yrs	1314	403.39	255	3	2a	0.61 - 39.06	0% - 6%	0% - 2%	0% - 6%
FP 2220	Azarole (Mediterranean medlar) (all commodities)	highest utilisation: juice (pasteurised)	0.12	0.69	1.000	PRIMO-DE	child	P97.5	89.63	NR	NR	3	0.62 - 0.67	0% - 0%	0% - 0%	0% - 0%
FP 0227	Crab-apple (all commodities)	highest utilisation: raw with peel		0.69	1.000	CN	Gen pop, > 1 yrs	204	488.33	<25	NR	1	6.33 - 6.33	1% - 1%	1% - 1%	0% - 0%
FP 0228	Loquat (Japanese medlar) (all commodities)	highest utilisation: raw without peel		0.69	1.000	JP	Gen pop, > 1 yrs	113	326.40	49	3	2a	1.22 - 5.4	0% - 1%	0% - 1%	0% - 0%
FP 0229	Medlar (all commodities)	highest utilisation: Total		0.69	1.000	PRIMO-ES	child	P97.5	116.99	60	3	2a	4.74 - 4.74	1% - 1%	0% - 0%	1% - 1%
FP 0230	Pear (all commodities)	highest utilisation: Total	0.012 - 0.12	0.69	1.000	CA	Child, <6 yrs	175	498.28	255	3	2a	0.03 - 47.79	0% - 7%	0% - 2%	0% - 7%
FP 0307	Persimmon, Japanese (i.e. Kaki fruit) (all commodities)	highest utilisation: raw with peel (incl consumption without peel)		0.69	1.000	TH	Child, 3-6 yrs	20	264.88	228	3	2a	26.27 - 29.05	4% - 4%	1% - 2%	4% - 4%
FP 0231	Quince (all commodities)	highest utilisation: Total	0.12	0.69	1.000	PRIMO-ES	child	P97.5	169.60	301	3	2b	0 - 10.18	0% - 1%	0% - 1%	0% - 1%
FT 0305	Table olives (all commodities)	highest utilisation: Total	0.01	0.01	1.000	US	Child, < 6 yrs	132	54.38	<25	NR	1	0 - 0.04	0% - 0%	0% - 0%	0% - 0%
FI 0326	Avocado (all commodities)	highest utilisation: Total		0.104	1.000	AU	Child, 2-6 yrs	182	229.90	171	3	2a	1.6 - 3.13	0% - 0%	0% - 0%	0% - 0%
FI 0345	Mango (all commodities)	highest utilisation: raw without peel	0.11	0.35	1.000	NL	toddler, 8-20 m	11	160.43	289	3	2b	0.03 - 16.51	0% - 2%	0% - 1%	0% - 2%
FI 0353	Pineapple (all commodities)	highest utilisation: raw without peel	0.002	0.002	1.000	JP	Child, 1-6 yrs	67	499.80	1116	3	2b	0 - 0.18	0% - 0%	0% - 0%	0% - 0%
FI 0351	Passion fruit (maracuja) (all commodities)	highest utilisation: juice (pasteurised)	0.045	0.1	1.000	BR	Gen pop, > 10 yrs	2624	720.00	NR	NR	3	0.01 - 0.5	0% - 0%	0% - 0%	0% - 0%
VL 0482	Lettuce, head (all commodities)	highest utilisation: Total	9.33	19.7	1.000	PRIMO-NL	child	P97.5	140.10	290	3	2b	5.49 - 450	1% - 60%	1% - 30%	0% - 60%



**PYRACLOSTROBIN (210)**

Acute RfD= 0.7 mg/kg bw (700 µg/kg bw)

IESTI

Maximum %ARfD:

60%  
all

30%  
gen pop

60%  
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
VL 0502	Spinach (all commodities)	highest utilisation: Total	0.09	0.72 - 0.91	1.000	PRIMO-BE	toddler	P97.5	402.30	<25	NR	1	0.01 - 20.57	0% - 3%	0% - 2%	0% - 3%
VL 2832	Witloof chicory sprouts (Belgian endives) (all commodities)	highest utilisation: cooked/boiled	0.029	0.04	1.000	PRIMO-NL	child	P97.5	160.70	124	3	2a	0 - 0.89	0% - 0%	0% - 0%	0% - 0%
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds) (all commodities)	highest utilisation: Total	0.13	0.37	1.000	CA	Child, <6 yrs	261	203.31	<25	NR	1	0.2 - 5	0% - 1%	0% - 0%	0% - 1%
VP 0522	Broad bean with pods (immature pods + succulent seeds) (Vicia spp) (all commodities)	highest utilisation: Total		0.11	1.000	US	Child, < 6 yrs	221	93.96	9	NR	1	0.3 - 0.71	0% - 0%	0% - 0%	0% - 0%
VP 0542	Sword bean with pods (immature pods + succulent seeds) (Canavalia spp) (all commodities)	highest utilisation: cooked/boiled		0.11	1.000	CN	Gen pop, > 1 yrs	891	316.83	<25	NR	1	0.65 - 0.65	0% - 0%	0% - 0%	0% - 0%
VP 0063	Peas with pods (Pisum spp) immature pods + succulent seeds) (all commodities)	highest utilisation: cooked/boiled	0.075	0.12	1.000	CN	Child, 1-6 yrs	1056	290.21	6	NR	1	0.59 - 2.16	0% - 0%	0% - 0%	0% - 0%
VP 0553	Lentil with pods (immature pods + succulent seeds) (Lens spp) (all commodities)	highest utilisation: cooked/boiled		0.12	1.000	CN	Child, 1-6 yrs	371	345.76	<25	NR	1	0.69 - 2.57	0% - 0%	0% - 0%	0% - 0%
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds) (all commodities)	highest utilisation: Total	0.01	0.27	1.000	PRIMO-IE	child	P97.5	157.79	<25	NR	1	0 - 2.13	0% - 0%	0% - 0%	0% - 0%

**PYRACLOSTROBIN (210)**

Acute RfD= 0.7 mg/kg bw (700 µg/kg bw)

IESTI

Maximum %ArfD:

60%  
all30%  
gen pop60%  
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
VP 0523	Broad bean without pods (succulent seeds) (Vicia spp) (all commodities)	highest utilisation: frozen	0.01	0.01	1.000	NL	Child, 2-6 yrs	E	100.00	6	NR	1	0 - 0.05	0% - 0%	0% - 0%	0% - 0%
VP 0064	Peas without pods (Pisum spp) (succulent seeds) (all commodities)	highest utilisation: Total	0.01	0.07	1.000	PRIMO-UK	infant	P97.5	71.30	<25	NR	1	0.01 - 0.57	0% - 0%	0% - 0%	0% - 0%
VD 0072	Peas (dry) (Pisum spp) (all commodities)	highest utilisation: cooked/boiled	0.059		0.400	CN	Gen pop, > 1 yrs	268	1673.82	<25	NR	3	0.04 - 0.74	0% - 0%	0% - 0%	0% - 0%
VD 0524	Chick-pea (dry) (Cicer spp) (all commodities)	highest utilisation: canned/preserved	0.059		0.400	PRIMO-NL	child	P100	328.80	<25	NR	3	0.04 - 0.42	0% - 0%	0% - 0%	0% - 0%
VD 0533	Lentil (dry) (Lens spp) (all commodities)	highest utilisation: Total	0.059		1.000	PRIMO-UK	Child, 11-14 yrs	P97.5	321.50	<25	NR	3	0.12 - 0.4	0% - 0%	0% - 0%	0% - 0%
VD 0537	Pigeon pea (dry) (Cajanus spp)	Total	0.059		1.000	AU	Gen pop, > 2 yrs	129	95.83	<25	NR	3	0.084	0%	0%	0%
VR 0574	Beetroot (all commodities)	highest utilisation: Total	0.12	0.3	1.000	AU	Child, 2-6 yrs	53	314.08	135	3	2a	0.07 - 9.24	0% - 1%	0% - 0%	0% - 1%
VR 0575	Burdock, greater or edible	Total		0.3	1.000	JP	Child, 1-6 yrs	122	35.70	68	3	2b	1.959	0%	0%	0%
VR 0577	Carrot (all commodities)	highest utilisation: raw with skin	0.12	0.3	1.000	CN	Child, 1-6 yrs	400	234.68	300	3	2b	0.01 - 13.09	0% - 2%	0% - 1%	0% - 2%
VR 0578	Celeriac (Turnip rooted celery) (all commodities)	highest utilisation: Total	0.12	0.3	1.000	PRIMO-BE	toddler	P100	196.90	749	3	2b	0.02 - 9.96	0% - 1%	0% - 0%	0% - 1%
VR 0469	Chicory, roots (all commodities)	highest utilisation: Total	0.12	0.3	1.000	AU	Gen pop, > 2 yrs	175	26.16	48	3	2b	0.09 - 0.35	0% - 0%	0% - 0%	0% - 0%
VR 0583	Horseradish (all commodities)	highest utilisation: Total		0.3	1.000	PRIMO-DE	Gen pop	P97.5	79.50	220	3	2b	0.01 - 0.94	0% - 0%	0% - 0%	0% - 0%
VR 0587	Parsley, turnip-rooted (Hamburg roots) (all commodities)	highest utilisation: Total	0.12	0.3	1.000	PRIMO-NL	Gen pop	P97.5	96.60	140	3	2b	0.85 - 1.32	0% - 0%	0% - 0%	0% - 0%

**PYRACLOSTROBIN (210)**

Acute RfD= 0.7 mg/kg bw (700 µg/kg bw)

IESTI

Maximum %ArfD:

60%  
all

30%  
gen pop

60%  
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
VR 0588	Parsnip (all commodities)	highest utilisation: cooked/boiled (without skin)	0.12	0.3	1.000	PRIMO-NL	child	E	133.30	227	3	2b	0.68 - 6.52	0% - 1%	0% - 0%	1% - 1%
VR 0494	Radish (all commodities)	highest utilisation: Total	0.12	0.3	1.000	PRIMO-NL	child	E	64.40	172	3	2b	0.01 - 3.15	0% - 0%	0% - 0%	0% - 0%
VR 0590	Radish, black (all commodities)	highest utilisation: Total	0.12	0.3	1.000	PRIMO-NL	child	E	64.40	172	3	2b	0.01 - 3.15	0% - 0%	0% - 0%	0% - 0%
VR 0591	Radish, Japanese (Chinese radish, Daikon) (all commodities)	highest utilisation: raw without skin	0.12	0.3	1.000	CN	Child, 1-6 yrs	1187	293.37	1000	3	2b	0.01 - 16.36	0% - 2%	0% - 1%	0% - 2%
VR 0498	Salsify (Oyster plant) (all commodities)	highest utilisation: Total	0.12	0.3	1.000	PRIMO-BE	toddler	P100	99.90	75	3	2a	0.01 - 4.22	0% - 1%	0% - 0%	0% - 1%
VR 0596	Sugar beet (all commodities)	highest utilisation: composite foods; unspecified ind processed	0.12		1.000	NL	Child, 2-6 yrs	2554	168.93	NR	NR	3	0.27 - 1.1	0% - 0%	0% - 0%	0% - 0%
VR 0497	Swede (Rutabaga) (all commodities)	highest utilisation: Total	0.12	0.3	1.000	PRIMO-UK	infant	P97.5	90.00	500	3	2b	0.01 - 9.31	0% - 1%	0% - 1%	0% - 1%
VR 0506	Turnip, garden (all commodities)	highest utilisation: Total	0.12	0.3	1.000	US	Gen pop, 0-85 yrs	53	1533.22	105	3	2a	0.88 - 7.4	0% - 1%	0% - 1%	0% - 1%
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%

**PYRACLOSTROBIN (210)**

Acute RfD= 0.7 mg/kg bw (700 µg/kg bw)

IESTI

Maximum %ArfD:

60%  
all30%  
gen pop60%  
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
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%
VS 0624	Celery (all commodities)	highest utilisation: raw	0.15	0.61	1.000	CN	Child, 1-6 yrs	454	180.29	861	3	2b	0.01 - 20.45	0% - 3%	0% - 2%	0% - 3%
VS 0621	Asparagus (all commodities)	highest utilisation: Total	0.01	0.01	1.000	US	Child, < 6 yrs	23	279.99	9	NR	1	0.1 - 0.19	0% - 0%	0% - 0%	0% - 0%
GC 0649	Rice (all commodities)	highest utilisation: Total	0.195		1.000	CA	Child, <6 yrs	666	461.40	<25	NR	3	0.01 - 5.89	0% - 1%	0% - 0%	1% - 1%
GC 0650	Rice	Rice milk	0.195		0.400	AU	Child, 2-16 yrs	48	1265.78	NR	NR	3	2.598	0%	-	0%
GC 0649	Rice (all commodities)	highest utilisation: pasta/noodles (dry)	0.004 - 0.195		1.000	CA	Child, <6 yrs	40	268.35	NR	NR	3	0.07 - 3.57	0% - 1%	0% - 0%	0% - 1%
GS 0659	Sugar cane (all commodities)	highest utilisation: thick juice	0.0025 - 0.0265		1.000	CN	Gen pop, > 1 yrs	436	1817.52	NR	NR	3	0.02 - 0.9	0% - 0%	0% - 0%	0% - 0%
SO 0305	Olives for oil extraction (all commodities)	highest utilisation: oil	0.01 - 0.062		1.000	PRIMO-NL	toddler	P97.5	9.40	NR	NR	3	0 - 0.06	0% - 0%	0% - 0%	0% - 0%
SB 0715	Cocoa beans (all commodities)	highest utilisation: Total	0.01		1.000	PRIMO-FI	child 3 yrs	P97.5	49.03	<25	NR	3	0.01 - 0.03	0% - 0%	0% - 0%	0% - 0%
DT 1114	Tea, green, black (black, fermented and dried) (all commodities)	highest utilisation: Total	0.0009 - 0.965		1.000	PRIMO-IE	child	P97.5	30.60	<25	NR	3	0 - 1.48	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		0.48	1.000	CN	Child, 1-6 yrs	302	52.97	NR	NR	1	1.576	0%	0%	0%

**PYRACLOSTROBIN (210)**

Acute RfD= 0.7 mg/kg bw (700 µg/kg bw)

IESTI

Maximum %ArfD:

60%  
all30%  
gen pop60%  
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
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.052	1.000	CN	Child, 1-6 yrs	302	211.87	NR	NR	1	0.683	0%	0%	0%
MF 0100	Mammalian fats (except milk fats)	Total		0.48	1.000	PRIMO-FR	adult	P97.5	134.79	NR	NR	1	0.974	0%	0%	0%
MO 0105	Edible offal (mammalian)	Total		0.044	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	0.414	0%	0%	0%
ML 0106	Milks	Total	0.0095		1.000	PRIMO-UK	infant	P97.5	1080.70	NR	NR	3	1.180	0%	0%	0%

**SULFOXAFLOX (252)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum %ArfD:

20%  
all10%  
gen pop20%  
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
GC 0649	Rice (all commodities)	highest utilisation: Total	1.95		1.000	CA	Child, <6 yrs	666	461.40	<25	NR	3	0.11 - 58.9	0% - 20%	0% - 10%	20% - 20%
GC 0650	Rice	Rice milk	1.95		0.400	AU	Child, 2-16 yrs	48	1265.78	NR	NR	3	25.982	9%	-	9%
GC 0649	Rice (all commodities)	highest utilisation: pasta/noodles (dry)	0.2 - 1.95		1.000	CA	Child, <6 yrs	40	268.35	NR	NR	3	1.81 - 35.74	1% - 10%	1% - 8%	0% - 10%
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	0.007		0.190	CA	Gen pop, all ages	2514	#####	NR	NR	3	0 - 0.36	0% - 0%	0% - 0%	0% - 0%

**SULFOXAFLOX (252)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum %ARfD:

20%  
all10%  
gen pop20%  
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
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	0.01	1.000	TH	Child, 3-6 yrs	1383	196.99	191	3	2a	0 - 0.34	0% - 0%	0% - 0%	0% - 0%
TN 0295	Cashew nut (all commodities)	highest utilisation: raw incl roasted	0.01	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 0660	Almonds (all commodities)	highest utilisation: Total	0.01	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 0664	Chestnuts (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)	0.01	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	0.01	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	0.01	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	0.01	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	0.01	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	0.01	0.02	1.000	PRIMO-BE	toddler	P100	60.00	<25	NR	1	0 - 0.07	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	2%	1%	2%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.18	1.000	CN	Child, 1-6 yrs	302	52.97	NR	NR	1	0.591	0%	0%	0%

**SULFOXAFLOX (252)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum %ARfD:

20%  
all

10%  
gen pop

20%  
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
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.39	1.000	CN	Child, 1-6 yrs	302	211.87	NR	NR	1	5.121	2%	1%	2%
MF 0100	Mammalian fats (except milk fats)	Total		0.18	1.000	PRIMO-FR	adult	P97.5	134.79	NR	NR	1	0.365	0%	0%	0%
MO 0105	Edible offal (mammalian)	Total		0.95	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	8.930	3%	3%	3%
ML 0106	Milks	Total	0.14		1.000	PRIMO-UK	infant	P97.5	1080.70	NR	NR	3	17.391	6%	2%	6%
PM 0110	Poultry meat	Total	NA	NA	1.000	CN	Child, 1-6 yrs	175	347.00	NR	NR	1	NA	4%	2%	4%
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		0.64	1.000	CN	Child, 1-6 yrs	175	312.30	NR	NR	1	12.387	4%	2%	4%
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		0.18	1.000	CN	Gen pop, > 1 yrs	421	345.63	NR	NR	1	1.169	0%	0%	0%
PE 0112	Eggs	Total		0.07	1.000	PRIMO-UK	infant	P97.5	108.00	NR	NR	1	0.869	0%	0%	0%

**TIOXAZAFEN (311)**

Acute RfD= 0.5 mg/kg bw (500 µg/kg bw)

IESTI

Maximum %ARfD:

0%  
all0%  
gen pop0%  
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
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilisation: Total	0 - .012	0	1.000	CN	Child, 1-6 yrs	179	239.05	<25	NR	3	0 - .18	0% - 0%	0% - 0%	0% - 0%
GC 0645	Maize (corn) (all commodities)	highest utilisation: beer	0	0	0.190	CA	Gen pop, all ages	2514	21271.20	NR	NR	3	0 - 0	0% - 0%	0% - 0%	0% - 0%
SO 0691	Cotton seed (all commodities)	highest utilisation: Oil (refined)	0	0	1.000	US	Child, < 6 yrs	6354	3.13	NR	NR	3	0 - 0	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		0.02	1.000	CN	Child, 1-6 yrs	302	52.97	NR	NR	1	0.066	0%	0%	0%
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		0.025	1.000	PRIMO-FR	adult	P97.5	134.79	NR	NR	1	0.051	0%	0%	0%
MO 0105	Edible offal (mammalian)	Total		0.025	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	0.235	0%	0%	0%
ML 0106	Milks	Total	0.01		1.000	PRIMO-UK	infant	P97.5	1080.70	NR	NR	3	1.242	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		0.02	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		0.02	1.000	PRIMO-UK	infant	P97.5	108.00	NR	NR	1	0.248	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.
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## Annex 6: Livestock dietary burden

### ABAMECTIN

ESTIMATED MAXIMUM DIETARY BURDEN														MAX
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	
Bean vines	AL	0.581	HR	35	1.66			60				0.996		
Corn, sweet forage	AF/AS	0.1	HR	48	0.21			40				0.083		
Bean seed	VD	0.002	STMR	88	0.00		20				5E-04			
Cotton meal	SM	0.002	STMR	89	0.00	5	5			0.000112	1E-04			
Rice straw	AF/AS	0.001	HR	90	0.00		10		55		1E-04		6E-04	
Rice grain	GC	0.001	STMR	88	0.00	20				0.000227				
Total						25	35	100	55	0.00034	7E-04	1.079	6E-04	

ESTIMATED MEAN DIETARY BURDEN														MEAN
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	
Corn, sweet forage	AF/AS	0.056	STMR/STMR-P	48	0.12			80				0.093		
Grape pomace, wet	AB	0.01	STMR/STMR-P	15	0.07			20				0.013		
Bean seed	VD	0.002	STMR/STMR-P	88	0.00		20				5E-04			
Cotton meal	SM	0.002	STMR/STMR-P	89	0.00	5	5			0.000112	1E-04			
Rice grain	GC	0.001	STMR/STMR-P	88	0.00	20				0.000227				
Total						25	25	100		0.00034	6E-04	0.107		

DAIRY CATTLE														MAX
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	
Bean vines	AL	0.581	HR	35	1.66		20	70			0.332	1.162		
Corn, sweet forage	AF/AS	0.1	HR	48	0.21	45		30		0.09375		0.063		
Almond hulls	AM/AV	0.036	STMR	90	0.04	10				0.004				
Bean seed	VD	0.002	STMR	88	0.00		20				5E-04			
Cotton meal	SM	0.002	STMR	89	0.00	10	5			0.000225	1E-04			
Rice grain	GC	0.001	STMR	88	0.00	20				0.000227				
Total						85	45	100		0.098202	0.333	1.225		

DAIRY CATTLE														MEAN
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	
Corn, sweet forage	AF/AS	0.056	STMR/STMR-P	48	0.12	45	0	40		0.0525	0	0.047		
Grape pomace, wet	AB	0.01	STMR/STMR-P	15	0.07	0		20		0		0.013		
Almond hulls	AM/AV	0.036	STMR/STMR-P	90	0.04	10		10		0.004		0.004		
Bean seed	VD	0.002	STMR/STMR-P	88	0.00	0	20	15			5E-04	3E-04		
Cotton meal	SM	0.002	STMR/STMR-P	89	0.00	10	5	15		0.000225	1E-04	3E-04		
Rice grain	GC	0.001	STMR/STMR-P	88	0.00	20				0.000227				
Total						85	25	100		0.056952	6E-04	0.065		

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	
Bean seed	VD	0.002	STMR	88	0.00		20	70		5E-04	0.002			
Cotton meal	SM	0.002	STMR	89	0.00	20	5	10		0.000449	1E-04	2E-04		
Rice grain	GC	0.001	STMR	88	0.00	20		20		0.000227		2E-04		
Total						40	25	100		0.000677	6E-04	0.002		

POULTRY LAYER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US- CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Bean seed	VD	0.002	STMR	88	0.00		20	70		5E-04	0.002			
Cotton meal	SM	0.002	STMR	89	0.00	20	5	10		0.000449	1E-04	2E-04		
Rice grain	GC	0.001	STMR	88	0.00	20		20		0.000227		2E-04		
Total						40	25	100		0.000677	6E-04	0.002		

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	
Bean seed	VD	0.002	STMR/STMR-P	88	0.00		20	70		5E-04	0.002			
Cotton meal	SM	0.002	STMR/STMR-P	89	0.00	20	5	10		0.000449	1E-04	2E-04		
Rice grain	GC	0.001	STMR/STMR-P	88	0.00	20		20		0.000227		2E-04		
Total						40	25	100		0.000677	6E-04	0.002		

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	
Bean seed	VD	0.002	STMR/STMR-P	88	0.00		20	70		5E-04	0.002			
Cotton meal	SM	0.002	STMR/STMR-P	89	0.00	20	5	10		0.000449	1E-04	2E-04		
Rice grain	GC	0.001	STMR/STMR-P	88	0.00	20		20		0.000227		2E-04		
Total						40	25	100		0.000677	6E-04	0.002		

## CHLORFENAPYR (Australia)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace,wet	AB	4.095	STMR	20	20.48			10				2.048	
Soybean asp gr fn	SM	12	STMR	85	14.12	5				0.706			
Citrus dried pulp	AB	1.6	STMR	91	1.76	10	5	20		0.176	0.088	0.352	
Potato culls	VR	0.01	HR	20	0.05	30	30	10		0.015	0.015	0.005	
Soybean seed	VD	0.01	STMR	89	0.01	5	10	20	15	0.001	0.001	0.002	0.002
Soybean meal	SM	0.0021	STMR	92	0.00		20	10	65	5E-04	2E-04	0.001	
Total						50	65	70	80	0.897	0.104	2.407	0.003

DAIRY CATTLE													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace,wet	AB	4.095	STMR	20	20.48			10				2.048	
Citrus dried pulp	AB	1.6	STMR	91	1.76	10	20	20		0.176	0.352	0.352	
Potato culls	VR	0.01	HR	20	0.05	10	30	10		0.005	0.015	0.005	
Soybean seed	VD	0.01	STMR	89	0.01	10	10	20	10	0.001	0.001	0.002	0.001
Soybean meal	SM	0.0021	STMR	92	0.00	10	25	15	60	0.000	6E-04	3E-04	0.001
Total						40	85	75	70	0.182	0.368	2.407	0.002

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
Tomato pomace,wet	AB	4.095	STMR/STMR-P	20	20.48			10				2.048	
Soybean asp gr fn	SM	12	STMR/STMR-P	85	14.12	5				0.705882			
Citrus dried pulp	AB	1.6	STMR/STMR-P	91	1.76	10	5	20		0.175824	0.088	0.352	
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	30	30	10		0.015	0.015	0.005	
Soybean seed	VD	0.01	STMR/STMR-P	89	0.01	5	10	20	15	0.000562	0.001	0.002	0.002
Soybean meal	SM	0.0021	STMR/STMR-P	92	0.00		20	10	65	5E-04	2E-04	0.001	
Total						50	65	70	80	0.897268	0.104	2.407	0.003

DAIRY CATTLE													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace,wet	AB	4.095	STMR/STMR-P	20	20.48		0	10			0	2.048	
Citrus dried pulp	AB	1.6	STMR/STMR-P	91	1.76	10	20	20		0.175824	0.352	0.352	
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	10	30	10		0.005	0.015	0.005	
Soybean seed	VD	0.01	STMR/STMR-P	89	0.01	10	10	20	10	0.001124	0.001	0.002	0.001
Soybean meal	SM	0.0021	STMR/STMR-P	92	0.00	10	25	15	60	0.000228	6E-04	3E-04	0.001
Total						40	85	75	70	0.182176	0.368	2.407	0.002

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			
Soybean seed	VD	0.01	STMR	89	0.01	20	20	15		0.002	0.002	0.002		
Soybean meal	SM	0.0021	STMR	92	0.00	25	40	25	35	0.001	9E-04	6E-04	8E-04	
Total						45	70	40	35	0.003	0.008	0.002	8E-04	

POULTRY LAYER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Potato culls	VR	0.01	HR	20	0.05		10				0.005			
Soybean seed	VD	0.01	STMR	89	0.01	20	15	15		0.002	0.002	0.002		
Soybean meal	SM	0.0021	STMR	92	0.00	25	25	25	30	0.001	6E-04	6E-04	7E-04	
Total						45	50	40	30	0.003	0.007	0.002	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
Potato culls	VR	0.01	STMR/STMR-P	20	0.05		10				0.005		
Soybean seed	VD	0.01	STMR/STMR-P	89	0.01	20	20	15		0.00	0.002	0.002	
Soybean meal	SM	0.0021	STMR/STMR-P	92	0.00	25	40	25	35	0.00	9E-04	6E-04	8E-04
Total						45	70	40	35	0.00	0.008	0.002	8E-04

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.01	STMR/STMR-P	20	0.05		10				0.005		
Soybean seed	VD	0.01	STMR/STMR-P	89	0.01	20	15	15		0.002247	0.002	0.002	
Soybean meal	SM	0.0021	STMR/STMR-P	92	0.00	25	25	25	30	0.000571	6E-04	6E-04	7E-04
Total						45	50	40	30	0.002818	0.007	0.002	7E-04

## CHLORFENAPYR (Canada, Japan and USA)

ESTIMATED MAXIMUM DIETARY BURDEN														MAX
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	
Tomato pomace,wet	AB	4.095	STMR	20	20.48			10				2.048		
Soybean asp gr fn	SM	12	STMR	85	14.12	5				0.706				
Soybean hay	AL	3.9	HR	85	4.59			80				3.671		
Citrus dried pulp	AB	1.6	STMR	91	1.76	10	5	10		0.176	0.088	0.176		
Potato culls	VR	0.01	HR	20	0.05	30	30			0.015	0.015			
Soybean seed	VD	0.01	STMR	89	0.01	5	10		15	0.001	0.001		0.002	
Soybean meal	SM	0.0021	STMR	92	0.00		20		65	5E-04			0.001	
Total						50	65	100	80	0.897	0.104	5.894	0.003	

ESTIMATED MEAN DIETARY BURDEN														MEAN
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	
Tomato pomace,wet	AB	4.095	STMR/STMR-P	20	20.48			10				2.048		
Soybean asp gr fn	SM	12	STMR/STMR-P	85	14.12	5				0.705882				
Soybean hay	AL	1.6	STMR/STMR-P	85	1.88			80				1.506		
Citrus dried pulp	AB	1.6	STMR/STMR-P	91	1.76	10	5	10		0.175824	0.088	0.176		
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	30	30			0.015	0.015			
Soybean seed	VD	0.01	STMR/STMR-P	89	0.01	5	10		15	0.000562	0.001		0.002	
Soybean meal	SM	0.0021	STMR/STMR-P	92	0.00		20		65	5E-04			0.001	
Total						50	65	100	80	0.897268	0.104	3.729	0.003	

DAIRY CATTLE														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Tomato pomace,wet	AB	4.095	STMR	20	20.48			10				2.048		
Soybean hay	AL	3.9	HR	85	4.59	20		40		0.918		1.835		
Citrus dried pulp	AB	1.6	STMR	91	1.76	10	20	20		0.176	0.352	0.352		
Potato culls	VR	0.01	HR	20	0.05	10	30	10		0.005	0.015	0.005		
Soybean seed	VD	0.01	STMR	89	0.01	10	10	20	10	0.001	0.001	0.002	0.001	
Soybean meal	SM	0.0021	STMR	92	0.00	10	25		60	0.000	6E-04		0.001	
Total						60	85	100	70	1.100	0.368	4.242	0.002	

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Tomato pomace,wet	AB	4.095	STMR/STMR-P	20	20.48		0	10			0	2.048		
Soybean hay	AL	1.6	STMR/STMR-P	85	1.88	20		40		0.376471		0.753		
Citrus dried pulp	AB	1.6	STMR/STMR-P	91	1.76	10	20	20		0.175824	0.352	0.352		
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	10	30	10		0.005	0.015	0.005		
Soybean seed	VD	0.01	STMR/STMR-P	89	0.01	10	10	20	10	0.001124	0.001	0.002	0.001	
Soybean meal	SM	0.0021	STMR/STMR-P	92	0.00	10	25		60	0.000228	6E-04		0.001	
Total						60	85	100	70	0.558647	0.368	3.159	0.002	

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					
Soybean seed	VD	0.01	STMR	89	0.01	20	20	15		0.001	0.002	0.002				
Soybean meal	SM	0.0021	STMR	92	0.00	25	40	25	35	0.001	9E-04	6E-04	8E-04			
Total						45	70	40	35	0.003	0.008	0.002	8E-04			

POULTRY LAYER																MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)						
						US- CAN	EU	AU	JP	US-CAN	EU	AU	JP			
Soybean hay	AL	3.9	HR	85	4.59		10				0.459					
Potato culls	VR	0.01	HR	20	0.05		10				0.005					
Soybean seed	VD	0.01	STMR	89	0.01	20	15	15		0.002	0.002	0.002				
Soybean meal	SM	0.0021	STMR	92	0.00	25	25	25	30	0.001	6E-04	6E-04	7E-04			
Total						45	60	40	30	0.003	0.466	0.002	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
Potato culls	VR	0.01	STMR/STMR-P	20	0.05		10				0.005		
Soybean seed	VD	0.01	STMR/STMR-P	89	0.01	20	20	15		0.00	0.002	0.002	
Soybean meal	SM	0.0021	STMR/STMR-P	92	0.00	25	40	25	35	0.00	9E-04	6E-04	8E-04
Total						45	70	40	35	0.00	0.008	0.002	8E-04

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	1.6	STMR/STMR-P	85	1.88		10				0.188		
Potato culls	VR	0.01	STMR/STMR-P	20	0.05		10				0.005		
Soybean seed	VD	0.01	STMR/STMR-P	89	0.01	20	15	15		0.002247	0.002	0.002	
Soybean meal	SM	0.0021	STMR/STMR-P	92	0.00	25	25	25	30	0.000571	6E-04	6E-04	7E-04
Total						45	60	40	30	0.002818	0.195	0.002	7E-04

## CYANTRANILIPROLE

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
Pea vines	AL	47.07	HR	100.00	47.07		20.00	60.00		9.41	28.24		
Pea vines	AL	47.07	HR	100.00	47.07		20.00	60.00		9.41	28.24		
Soybean hay	AL	46.39	HR	100.00	46.39			40.00			18.56		
Pea hay	AL	28.54	HR	100.00	28.54		5.00			1.43			
Cabbage heads, leaves	AM/AV	1.10	HR	15.00	7.33		20.00			1.47			
Cotton gin byproducts	AM/AV	5.00	HR	90.00	5.56	5.00				0.28			
Corn, field asp gr fn	CM/CF	1.76	STMR	85.00	2.07	5.00				0.10			
Rice straw	AF/AS	0.84	HR	100.00	0.84		10.00		55.00	0.08		0.46	
Trefoil hay	AL	0.58	HR	85.00	0.68	15.00				0.10			
Vetch hay	AL	0.58	HR	85.00	0.68				5.00				0.03
Cowpea hay	AL	0.58	HR	86.00	0.67		10.00			0.07			
Alfalfa hay	AL	0.58	HR	89.00	0.65				5.00				0.03
Potato culls	VR	0.10	HR	20.00	0.50	30.00	30.00			0.15	0.15		
Clover forage	AL	0.14	HR	30.00	0.47		5.00			0.02			
Potato process waste	AB	0.05	STMR	12.00	0.38	30.00				0.12			
Corn, field stover	AF/AS	0.23	HR	83.00	0.28	15.00				0.04			
Soybean seed	VD	0.03	STMR	89.00	0.04			15.00					0.01
Corn, field milled bypds	CM/CF	0.00	STMR	85.00	0.00				5.00				0.00

ESTIMATED MEAN 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 forage	AL	15.59	STMR/STMR-P	100.00	15.59			100.00				15.59	
Soybean forage	AL	15.59	STMR/STMR-P	100.00	15.59			100.00				15.59	
Pea hay	AL	9.69	STMR/STMR-P	100.00	9.69		25.00				2.42		
Cabbage heads, leaves	AM/AV	0.56	STMR/STMR-P	15.00	3.73		20.00				0.75		
Cotton gin byproducts	AM/AV	3.10	STMR/STMR-P	90.00	3.44	5.00				0.17			
Corn, field asp gr fn	CM/CF	1.76	STMR/STMR-P	85.00	2.07	5.00				0.10			
Apple pomace, wet	AB	0.16	STMR/STMR-P	40.00	0.40		20.00				0.08		
Potato process waste	AB	0.05	STMR/STMR-P	12.00	0.38	30.00	35.00			0.12	0.13		
Potato culls	VR	0.05	STMR/STMR-P	20.00	0.23	30.00				0.07			
Rice straw	AF/AS	0.10	STMR/STMR-P	100.00	0.10				55.00				0.05
Corn, field stover	AF/AS	0.05	STMR/STMR-P	83.00	0.06	15.00				0.01			
Cotton hulls	SM	0.05	STMR/STMR-P	90.00	0.06	10.00				0.01			
Sorghum, grain stover	AF/AS	0.05	STMR/STMR-P	88.00	0.06	5.00				0.00			
Soybean seed	VD	0.03	STMR/STMR-P	89.00	0.04			15.00					0.01
Vetch hay	AL	0.02	STMR/STMR-P	85.00	0.02				5.00				0.00
Alfalfa hay	AL	0.02	STMR/STMR-P	89.00	0.02				5.00				0.00
Corn, field milled bypds	CM/CF	0.00	STMR/STMR-P	85.00	0.00				5.00				0.00
Total						100.00	100.00	200.00	85.00	0.48	3.38	31.18	0.06

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
Pea vines	AL	47.07	HR	100.00	47.07	10.00	20.00	40.00		4.71	9.41	18.83	
Soybean hay	AL	46.39	HR	100.00	46.39	10.00				4.64			
Pea hay	AL	28.54	HR	100.00	28.54		10.00	60.00			2.85	17.12	
Cabbage heads, leaves	AM/AV	1.10	HR	15.00	7.33		20.00				1.47		
Almond hulls	AM/AV	1.90	STMR	90.00	2.11	10.00				0.21			
Rice straw	AF/AS	0.84	HR	100.00	0.84		5.00		25.00		0.04		0.21
Trefoil hay	AL	0.58	HR	85.00	0.68	20.00	10.00			0.14	0.07		
Vetch hay	AL	0.58	HR	85.00	0.68				25.00				0.17
Alfalfa hay	AL	0.58	HR	89.00	0.65		35.00				0.23		
Potato culls	VR	0.10	HR	20.00	0.50	10.00				0.05			
Apple pomace, wet	AB	0.16	STMR	40.00	0.40	10.00				0.04			
Corn, field stover	AF/AS	0.23	HR	83.00	0.28	15.00				0.04			
Grass forage (fresh)	AF/AS	0.05	HR	25.00	0.21	15.00				0.03			
Grass hay	AF/AS	0.14	HR	88.00	0.16				50.00				0.08
Total						100.00	100.00	100.00	100.00	9.86	14.07	35.95	0.46

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean forage	AL	15.59	STMR/STMR-P	100.00	15.59	20.00	0.00	40.00		3.12	0.00	6.24	
Pea hay	AL	9.69	STMR/STMR-P	100.00	9.69	0.00	30.00	60.00		0.00	2.91	5.81	
Cabbage heads, leaves	AM/AV	0.56	STMR/STMR-P	15.00	3.73	0.00	20.00			0.00	0.75		
Almond hulls	AM/AV	1.90	STMR/STMR-P	90.00	2.11	10.00				0.21			
Apple pomace, wet	AB	0.16	STMR/STMR-P	40.00	0.40	10.00	10.00			0.04	0.04		
Potato process waste	AB	0.05	STMR/STMR-P	12.00	0.38	0.00	20.00			0.00	0.08		
Potato culls	VR	0.05	STMR/STMR-P	20.00	0.23	10.00	20.00			0.02	0.05		
Rice straw	AF/AS	0.10	STMR/STMR-P	100.00	0.10	0.00			25.00	0.00			0.02
Corn, field stover	AF/AS	0.05	STMR/STMR-P	83.00	0.06	15.00				0.01			
Lespedeza forage	AL	0.01	STMR/STMR-P	22.00	0.05	35.00				0.02			
Soybean seed	VD	0.03	STMR/STMR-P	89.00	0.04	0.00			10.00	0.00			0.00
Sorghum, grain forage	AF/AS	0.01	STMR/STMR-P	35.00	0.03	0.00			15.00	0.00			0.00
Corn, field forage/silage	AF/AS	0.01	STMR/STMR-P	40.00	0.03	0.00			10.00	0.00			0.00
Vetch hay	AL	0.02	STMR/STMR-P	85.00	0.02	0.00			25.00	0.00			0.01
Alfalfa hay	AL	0.02	STMR/STMR-P	89.00	0.02	0.00			15.00	0.00			0.00
Total						100.00	100.00	100.00	100.00	3.42	3.82	12.05	0.04



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	0.10	HR	20.00	0.50		10.00				0.05		
Cassava/tapioca roots	VR	0.01	HR	37.00	0.04		10.00				0.00		
Soybean seed	VD	0.03	STMR	89.00	0.04	20.00	20.00	15.00		0.01	0.01	0.01	
Cotton meal	SM	0.01	STMR	89.00	0.02	20.00	5.00	10.00		0.00	0.00	0.00	
Rice grain	GC	0.01	STMR	88.00	0.01	20.00		50.00		0.00		0.01	
Corn, field milled bypds	CM/CF	0.00	STMR	85.00	0.00	40.00	55.00			0.00	0.00		
Total						100.00	100.00	75.00		0.01	0.06	0.01	

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.05	STMR/STMR-P	20.00	0.23		10.00				0.02		
Soybean seed	VD	0.03	STMR/STMR-P	89.00	0.04	20.00	20.00	15.00		0.01	0.01	0.01	
Cassava/tapioca roots	VR	0.01	STMR/STMR-P	37.00	0.03		10.00				0.00		
Cotton meal	SM	0.01	STMR/STMR-P	89.00	0.02	20.00	5.00	10.00		0.00	0.00	0.00	
Rice grain	GC	0.01	STMR/STMR-P	88.00	0.01	20.00		50.00		0.00		0.01	
Corn, field milled bypds	CM/CF	0.00	STMR/STMR-P	85.00	0.00	40.00	55.00			0.00	0.00		
Total						100.00	100.00	75.00		0.01	0.04	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
Pea vines	AL	47.07	HR	100.00	47.07		10.00				4.71		
Cabbage heads, leaves	AM/AV	1.10	HR	15.00	7.33		5.00				0.37		
Potato culls	VR	0.10	HR	20.00	0.50		10.00				0.05		
Sorghum, grain stover	AF/AS	0.23	HR	88.00	0.26		10.00				0.03		
Rape forage	AM/AV	0.02	HR	30.00	0.07		5.00				0.00		
Cassava/tapioca roots	VR	0.01	HR	37.00	0.04		5.00				0.00		
Soybean seed	VD	0.03	STMR	89.00	0.04	20.00	15.00	15.00		0.01	0.01	0.01	
Cotton meal	SM	0.01	STMR	89.00	0.02	20.00	5.00	10.00		0.00	0.00	0.00	
Rice grain	GC	0.01	STMR	88.00	0.01	20.00		50.00		0.00		0.01	
Corn, field milled bypds	CM/CF	0.00	STMR	85.00	0.00	40.00	35.00			0.00	0.00		
Total						100.00	100.00	75.00		0.01	5.16	0.01	

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean forage	AL	15.59	STMR/STMR-P	100.00	15.59		10.00				1.56		
Cabbage heads, leaves	AM/AV	0.56	STMR/STMR-P	15.00	3.73		5.00				0.19		
Potato culls	VR	0.05	STMR/STMR-P	20.00	0.23		10.00				0.02		
Sorghum, grain stover	AF/AS	0.05	STMR/STMR-P	88.00	0.06		10.00				0.01		
Soybean seed	VD	0.03	STMR/STMR-P	89.00	0.04	20.00	15.00	15.00		0.01	0.01	0.01	
Rape forage	AM/AV	0.01	STMR/STMR-P	30.00	0.03		5.00				0.00		
Cassava/tapioca roots	VR	0.01	STMR/STMR-P	37.00	0.03		5.00				0.00		
Cotton meal	SM	0.01	STMR/STMR-P	89.00	0.02	20.00	5.00	10.00		0.00	0.00	0.00	
Rice grain	GC	0.01	STMR/STMR-P	88.00	0.01	20.00		50.00		0.00		0.01	
Corn, field milled bypds	CM/CF	0.00	STMR/STMR-P	85.00	0.00	40.00	35.00			0.00	0.00		
Total						100.00	100.00	75.00		0.01	1.79	0.01	

## DIQUAT

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
Rye straw	AF/AS	26	HR	88	29.55	10	20	20		2.954545	5.909	5.909	
Barley straw	AF/AS	26	HR	89	29.21		10	80		2.921	23.37		
Pea hay	AL	25	HR	88	28.41		25			7.102			
Barley grain	GC	1.55	STMR	88	1.76	50	45		70	0.880682	0.793		1.233
Potato culls	VR	0.1	HR	20	0.50	30				0.15			
Rape meal	SM	0.19	STMR	88	0.22				15				0.032
Soybean hulls	SM	0.155	STMR	90	0.17	10				0.017222			
Soybean seed	VD	0.05	STMR	89	0.06				15				0.008
Total						100	100	100	100	4.002449	16.73	29.28	1.274

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
Pea hay	AL	16	STMR/STMR-P	88	18.18		25	100			4.545	18.18	
Rye straw	AF/AS	3.1	STMR/STMR-P	88	3.52	10	20			0.352273	0.705		
Barley straw	AF/AS	3.1	STMR/STMR-P	89	3.48		10				0.348		
Barley grain	GC	1.55	STMR/STMR-P	88	1.76	50	45		70	0.880682	0.793		1.233
Potato culls	VR	0.05	STMR/STMR-P	20	0.25	30				0.075			
Rape meal	SM	0.19	STMR/STMR-P	88	0.22				15				0.032
Soybean hulls	SM	0.155	STMR/STMR-P	90	0.17	10				0.017222			
Soybean seed	VD	0.05	STMR/STMR-P	89	0.06				15				0.008
Total						100	100	100	100	1.325177	6.391	18.18	1.274

DAIRY CATTLE													
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
Rye straw	AF/AS	26	HR	88	29.55	10	20	20	5	2.954545	5.909	5.909	1.477
Barley straw	AF/AS	26	HR	89	29.21		10			2.921			
Triticale straw	AF/AS	26	HR	90	28.89			50				14.44	
Pea hay	AL	25	HR	88	28.41	10	30	30		2.840909	8.523	8.523	
Barley grain	GC	1.55	STMR	88	1.76	45	40		40	0.792614	0.705		0.705
Potato culls	VR	0.1	HR	20	0.50	10				0.05			
Rape meal	SM	0.19	STMR	88	0.22				25				0.054
Sunflower meal	SM	0.132	STMR	92	0.14	10				0.014348			
Soybean seed	VD	0.05	STMR	89	0.06	10			10	0.005618			0.006
Soybean meal	SM	0.0425	STMR	92	0.05				20				0.009
Total						95	100	100	100	6.658034	18.06	28.88	2.251

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
Pea hay	AL	16	STMR/STMR-P	88	18.18	10	30	70		1.818182	5.455	12.73	
Rye straw	AF/AS	3.1	STMR/STMR-P	88	3.52	10	20	20	5	0.352273	0.705	0.705	0.176
Barley straw	AF/AS	3.1	STMR/STMR-P	89	3.48	0	10			0	0.348		
Triticale straw	AF/AS	3.1	STMR/STMR-P	90	3.44	0		10		0		0.344	
Barley grain	GC	1.55	STMR/STMR-P	88	1.76	45	40		40	0.792614	0.705		0.705
Potato culls	VR	0.05	STMR/STMR-P	20	0.25	10				0.025			
Rape meal	SM	0.19	STMR/STMR-P	88	0.22	0			25	0			0.054
Sunflower meal	SM	0.132	STMR/STMR-P	92	0.14	10				0.014348			
Soybean seed	VD	0.05	STMR/STMR-P	89	0.06	10			10	0.005618			0.006
Soybean meal	SM	0.0425	STMR/STMR-P	92	0.05	0			20	0			0.009
Total						95	100	100	100	3.008034	7.212	13.78	0.95

POULTRY BROILER													
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

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

Barley grain	GC	1.55	STMR	88	1.76	75	70	15	10	1.321023	1.233	0.264	0.176
Potato culls	VR	0.1	HR	20	0.50		10				0.05		
Rape meal	SM	0.19	STMR	88	0.22			5	5			0.011	0.011
Pea seed	VD	0.17	STMR	90	0.19	20	20	5		0.037778	0.038	0.009	
Sunflower meal	SM	0.132	STMR	92	0.14	5		10		0.007174		0.014	
Bean seed	VD	0.05	STMR	88	0.06			65				0.037	
Soybean meal	SM	0.0425	STMR	92	0.05				30				0.014
Total						100	100	100	45	1.365974	1.321	0.336	0.201

Barley grain	GC	1.55	STMR/STMR-P	88	1.76	75	70	15	10	1.321023	1.233	0.264	0.176
Potato culls	VR	0.05	STMR/STMR-P	20	0.25		10				0.025		
Rape meal	SM	0.19	STMR/STMR-P	88	0.22			5	5			0.011	0.011
Pea seed	VD	0.17	STMR/STMR-P	90	0.19	20	20	5		0.037778	0.038	0.009	
Sunflower meal	SM	0.132	STMR/STMR-P	92	0.14	5		10		0.007174		0.014	
Bean seed	VD	0.05	STMR/STMR-P	88	0.06			65				0.037	
Soybean meal	SM	0.0425	STMR/STMR-P	92	0.05				30				0.014
Total						100	100	100	45	1.365974	1.296	0.336	0.201

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Barley straw	AF/AS	26	HR	89	29.21		5				1.461		
Pea hay	AL	25	HR	88	28.41		10				2.841		
Barley grain	GC	1.55	STMR	88	1.76	75	85	15		1.321023	1.497	0.264	
Rape meal	SM	0.19	STMR	88	0.22			5	15			0.011	0.032
Pea seed	VD	0.17	STMR	90	0.19	20		5		0.037778		0.009	
Sunflower meal	SM	0.132	STMR	92	0.14	5		10		0.007174		0.014	
Bean seed	VD	0.05	STMR	88	0.06			65				0.037	
Soybean meal	SM	0.0425	STMR	92	0.05				15				0.007
Total						100	100	100	30	1.365974	5.799	0.336	0.039

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 hay	AL	16	STMR/STMR-P	88	18.18		10				1.818		
Barley straw	AF/AS	3.1	STMR/STMR-P	89	3.48		5				0.174		
Barley grain	GC	1.55	STMR/STMR-P	88	1.76	75	85	15		1.321023	1.497	0.264	
Rape meal	SM	0.19	STMR/STMR-P	88	0.22			5	15			0.011	0.032
Pea seed	VD	0.17	STMR/STMR-P	90	0.19	20		5		0.037778		0.009	
Sunflower meal	SM	0.132	STMR/STMR-P	92	0.14	5		10		0.007174		0.014	
Bean seed	VD	0.05	STMR/STMR-P	88	0.06			65				0.037	
Soybean meal	SM	0.0425	STMR/STMR-P	92	0.05				15				0.007
Total						100	100	100	30	1.365974	3.489	0.336	0.039

# FLUXAPYROXAD

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
Rice straw	AF/AS	48	HR	100	48.00		10	60	55		4.8	28.8	26.4
Barley forage	AF/AS	41	HR	100	41.00		20				8.2		
Oat forage	AF/AS	41	HR	100	41.00			40				16.4	
Pea vines	AL	23	HR	100	23.00		20				4.6		
Wheat asp gr fn	CM/CF	18.7	STMR	85	22.00	5				1.100			
Barley hay	AF/AS	18	HR	100	18.00	15				2.700			
Beet, sugar tops	AM/AV	17	HR	100	17.00		20				3.4		
Pea hay	AL	17	HR	100	17.00		5				0.85		
Alfalfa hay	AL	10	HR	89	11.24	15			10	1.685			1.124
Alfalfa forage	AL	2.8	HR	35	8.00		25				2		
Rice bran/pollard	CM/CF	3.55	STMR	90	3.94	10			20	0.394			0.789
Citrus dried pulp	AB	1.8	STMR	91	1.98	10				0.198			
Soybean asp gr fn	SM	1.6	STMR	85	1.88	5				0.094			
Rice grain	GC	0.94	STMR	88	1.07	20				0.214			
Barley grain	GC	0.535	STMR	88	0.61	20			15	0.122			0.091
Total						100	100	100	100	6.507	23.85	45.2	28.4

ESTIMATED MEAN 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
Wheat asp gr fn	CM/CF	18.7	STMR/STMR-P	85	22.00	5				1.1			
Grape pomace, wet	AB	16.5	STMR/STMR-P	100	16.50			20				3.3	
Pea vines	AL	12	STMR/STMR-P	100	12.00		20	60		2.4	7.2		
Pea hay	AL	11	STMR/STMR-P	100	11.00		5	20		0.55	2.2		
Beet, sugar tops	AM/AV	9.4	STMR/STMR-P	100	9.40		20			1.88			
Rice straw	AF/AS	4.2	STMR/STMR-P	100	4.20		10		55	0.42			2.31
Barley hay	AF/AS	4.1	STMR/STMR-P	100	4.10	15				0.615			
Barley straw	AF/AS	4.1	STMR/STMR-P	100	4.10		20			0.82			
Rice bran/pollard	CM/CF	3.55	STMR/STMR-P	90	3.94	10			20	0.394			0.789
Barley forage	AF/AS	3.8	STMR/STMR-P	100	3.80		25			0.95			
Citrus dried pulp	AB	1.8	STMR/STMR-P	91	1.98	10				0.198			
Soybean asp gr fn	SM	1.6	STMR/STMR-P	85	1.88	5				0.094			
Rice grain	GC	0.94	STMR/STMR-P	88	1.07	20				0.214			
Barley grain	GC	0.535	STMR/STMR-P	88	0.61	20			25	0.213			0.152
Total						100	100	100	100	2.8278	7.02	12.7	3.2509

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US- CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice straw	AF/AS	48	HR	100	48.00		5	20	25		2.4	9.6	12
Barley forage	AF/AS	41	HR	100	41.00		25	30			10.25	12.3	
Oat forage	AF/AS	41	HR	100	41.00	30		50		12.300		20.5	
Soybean forage	AL	26	HR	100	26.00	20				5.200			
Pea vines	AL	23	HR	100	23.00		20				4.6		
Beet, sugar tops	AM/AV	17	HR	100	17.00		30				5.1		
Pea hay	AL	17	HR	100	17.00		20				3.4		
Alfalfa hay	AL	10	HR	89	11.24				25				2.809
Sorghum, grain forage	AF/AS	7.1	HR	100	7.10	10			15	0.710			1.065
Carrot culls	VR	0.5	HR	12	4.17	10				0.417			
Rice bran/pollard	CM/CF	3.55	STMR	90	3.94	15			10	0.592			0.394
Corn, field forage/silage	AF/AS	3.6	HR	100	3.60	15			25	0.540			0.9
Total						100	100	100	100	19.758	25.75	42.40	17.17

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	16.5	STMR/STMR-P	100	16.50		0	20			0	3.3	
Pea vines	AL	12	STMR/STMR-P	100	12.00	10	20	40		1.2	2.4	4.8	
Pea hay	AL	11	STMR/STMR-P	100	11.00	0	10	40		0	1.1	4.4	
Beet, sugar tops	AM/AV	9.4	STMR/STMR-P	100	9.40	0	30			0	2.82		
Soybean forage	AL	7.7	STMR/STMR-P	100	7.70	10				0.77			
Rice straw	AF/AS	4.2	STMR/STMR-P	100	4.20	0	5		25	0	0.21		1.05
Barley hay	AF/AS	4.1	STMR/STMR-P	100	4.10	20				0.82			
Barley straw	AF/AS	4.1	STMR/STMR-P	100	4.10	0	25			0	1.025		
Rice bran/pollard	CM/CF	3.55	STMR/STMR-P	90	3.94	15	10		10	0.591667	0.394		0.394
Oat forage	AF/AS	3.8	STMR/STMR-P	100	3.80	10				0.38			
Sorghum, grain forage	AF/AS	3.1	STMR/STMR-P	100	3.10	35			15	1.085			0.465
Corn, field forage/silage	AF/AS	2.8	STMR/STMR-P	100	2.80	0			10	0			0.28
Alfalfa silage	AL	0.52	STMR/STMR-P	40	1.30	0			20	0			0.26
Barley grain	GC	0.535	STMR/STMR-P	88	0.61	0			20	0			0.122
Total						100	100	100	100	4.85	7.95	12.50	2.57

POULTRY BROILER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US- CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Carrot culls	VR	0.5	HR	12	4.17		10				0.417			
Rice bran/pollard	CM/CF	3.55	STMR	90	3.94	10	10	20	5	0.394	0.394	0.789	0.197	
Rice grain	GC	0.94	STMR	88	1.07	20		50		0.214		0.534		
Barley grain	GC	0.535	STMR	88	0.61	70	70		10	0.426	0.426		0.061	
Wheat milled bypdts	CM/CF	0.25	STMR	88	0.28		10				0.028			
Sorghum, grain grain	GC	0.2	STMR	86	0.23			30	55			0.07	0.128	
Corn, field grain	GC	0.01	STMR	88	0.01				30				0.003	
Total						100	100	100	100	1.034	1.265	1.393	0.389	

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US- CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice bran/pollard	CM/CF	3.55	STMR/STMR-P	90	3.94	10	10	20	5	0.39	0.394	0.789	0.197
Rice grain	GC	0.94	STMR/STMR-P	88	1.07	20		50		0.21		0.534	
Barley grain	GC	0.535	STMR/STMR-P	88	0.61	70	70		10	0.43	0.426		0.061
Carrot culls	VR	0.06	STMR/STMR-P	12	0.50		10				0.05		
Wheat milled bypdts	CM/CF	0.25	STMR/STMR-P	88	0.28		10				0.028		
Sorghum, grain grain	GC	0.2	STMR/STMR-P	86	0.23			30	55			0.07	0.128
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				30				0.003
Total						100	100	100	100	1.033649	0.898	1.393	0.389

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POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US- CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean forage	AL	26	HR	100	26.00		10				2.6		
Beet, sugar tops	AM/AV	17	HR	100	17.00		5				0.85		
Sorghum, grain forage	AF/AS	7.1	HR	100	7.10		10				0.71		
Carrot culls	VR	0.5	HR	12	4.17		10				0.417		
Rice bran/pollard	CM/CF	3.55	STMR	90	3.94	10	5	20	20	0.394	0.197	0.789	0.789
Rice grain	GC	0.94	STMR	88	1.07	20		50		0.214		0.534	
Barley grain	GC	0.535	STMR	88	0.61	70	60			0.426	0.365		
Wheat milled bypds	CM/CF	0.25	STMR	88	0.28				10				0.028
Sorghum, grain grain	GC	0.2	STMR	86	0.23			30	55			0.07	0.13
Corn, field grain	GC	0.01	STMR	88	0.01				15				0.002
Total						100	100	100	100	1.034	5.139	1.393	0.947

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	12	STMR/STMR-P	100	12.00		10				1.2			
Beet, sugar tops	AM/AV	9.4	STMR/STMR-P	100	9.40		5				0.47			
Barley straw	AF/AS	4.1	STMR/STMR-P	100	4.10		5				0.205			
Rice bran/pollard	CM/CF	3.55	STMR/STMR-P	90	3.94	10	5	20	20	0.394444	0.197	0.789	0.789	
Sorghum, grain forage	AF/AS	3.1	STMR/STMR-P	100	3.10		5				0.155			
Rice grain	GC	0.94	STMR/STMR-P	88	1.07	20		50		0.213636		0.534		
Barley grain	GC	0.535	STMR/STMR-P	88	0.61	70	70			0.425568	0.426			
Wheat milled bypdts	CM/CF	0.25	STMR/STMR-P	88	0.28				10					0.028
Sorghum, grain grain	GC	0.2	STMR/STMR-P	86	0.23			30	55			0.070	0.13	
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				15					0.002
Total						100	100	100	100	1.033649	2.653	1.393	0.947	

## IMAZALIL

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	6.6	STMR	12	55.00	30	40	5		16.5	22	2.75	
Potato culls	VR	4.6	HR	20	23.00	30	30	10		6.9	6.9	2.3	
Wheat forage	AF/AS	0.01	HR	25	0.04		20	85		0.008	0.034		
Barley forage	AF/AS	0.01	HR	30	0.03		10			0.003			
Barley straw	AF/AS	0.01	HR	89	0.01	10				0.001124			
Total						70	100	100		23.40112	28.91	5.084	

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
Potato process waste	AB	6.6	STMR	12	55.00	10	30			5.5	16.5		
Potato culls	VR	4.6	HR	20	23.00	10	30	10		2.3	6.9	2.3	
Citrus dried pulp	AB	0.4	STMR	91	0.44			30				0.132	
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			
Total						40	90	100		7.808	23.41	2.456	

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	6.6	STMR/STMR-P	12	55.00	30	40	5		16.5	22	2.75	
Potato culls	VR	2.2	STMR/STMR-P	20	11.00	30	30	10		3.3	3.3	1.1	
Wheat forage	AF/AS	0.01	STMR/STMR-P	25	0.04		20	85		0.008	0.034		
Barley forage	AF/AS	0.01	STMR/STMR-P	30	0.03		10			0.003			
Barley straw	AF/AS	0.01	STMR/STMR-P	89	0.01	10				0.001124			
Total						70	100	100		19.80112	25.31	3.884	

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
Potato process waste	AB	6.6	STMR/STMR-P	12	55.00	10	30	0		5.5	16.5	0	
Potato culls	VR	2.2	STMR/STMR-P	20	11.00	10	30	10		1.1	3.3	1.1	
Citrus dried pulp	AB	0.4	STMR/STMR-P	91	0.44	0		30		0		0.132	
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		
Total						40	90	100		6.608	19.81	1.256	





## ISOFETAMID

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	2.7	STMR	15	18.00			20				3.6	
Apple pomace, wet	AB	0.56	STMR	40	1.40		20			0.28			
Bean seed	VD	0.01	STMR	88	0.01		20	50		0.002	0.006		
Rape meal	SM	0.0017	STMR	88	0.00		20	15	15	4E-04	3E-04	3E-04	
Total							60	85	15	0.283	3.606	3E-04	

DAIRY CATTLE													
MAX													
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	2.7	STMR	15	18.00			20				3.6	
Apple pomace, wet	AB	0.56	STMR	40	1.40	10	10			0.14	0.14		
Bean seed	VD	0.01	STMR	88	0.01		20	15		0.002	0.002		
Pea seed	VD	0.01	STMR	90	0.01			5				6E-04	
Rape meal	SM	0.0017	STMR	88	0.00		10	15	25	2E-04	3E-04	5E-04	
Total						10	40	55	25	0.14	0.142	3.603	5E-04

ESTIMATED MEAN 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	2.7	STMR/STMR-P	15	18.00			20				3.6	
Apple pomace, wet	AB	0.56	STMR/STMR-P	40	1.40		20			0.28			
Bean seed	VD	0.01	STMR/STMR-P	88	0.01		20	50		0.002	0.006		
Rape meal	SM	0.0017	STMR/STMR-P	88	0.00		20	15	15	4E-04	3E-04	3E-04	
Total							60	85	15	0.283	3.606	3E-04	

DAIRY CATTLE													
MEAN													
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	2.7	STMR/STMR-P	15	18.00		0	20			0	3.6	
Apple pomace, wet	AB	0.56	STMR/STMR-P	40	1.40	10	10			0.14	0.14		
Bean seed	VD	0.01	STMR/STMR-P	88	0.01	0	20	15		0	0.002	0.002	
Pea seed	VD	0.01	STMR/STMR-P	90	0.01	0		5		0		6E-04	
Rape meal	SM	0.0017	STMR/STMR-P	88	0.00	0	10	15	25	0	2E-04	3E-04	5E-04
Total						10	40	55	25	0.14	0.142	3.603	5E-04

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
Bean seed	VD	0.01	STMR	88	0.01		20	70			0.002	0.008	
Pea seed	VD	0.01	STMR	90	0.01	20				0.002222			
Rape meal	SM	0.0017	STMR	88	0.00			5	5			1E-04	1E-04
Total						20	20	75	5	0.002222	0.002	0.008	1E-04

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
Bean seed	VD	0.01	STMR	88	0.01		20	70			0.002	0.008	
Pea seed	VD	0.01	STMR	90	0.01	20				0.002222			
Rape meal	SM	0.0017	STMR	88	0.00		10	5	15		2E-04	1E-04	3E-04
Total						20	30	75	15	0.002222	0.002	0.008	3E-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
Bean seed	VD	0.01	STMR/STMR-P	88	0.01		20	70			0.002	0.008	
Pea seed	VD	0.01	STMR/STMR-P	90	0.01	20				0.002222			
Rape meal	SM	0.0017	STMR/STMR-P	88	0.00			5	5			1E-04	1E-04
Total						20	20	75	5	0.002222	0.002	0.008	1E-04

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
Bean seed	VD	0.01	STMR/STMR-P	88	0.01		20	70			0.002	0.008	
Pea seed	VD	0.01	STMR/STMR-P	90	0.01	20				0.002222			
Rape meal	SM	0.0017	STMR/STMR-P	88	0.00		10	5	15		2E-04	1E-04	3E-04
Total						20	30	75	15	0.002222	0.002	0.008	3E-04

## KRESOXIM-METHYL

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.8	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			
Turnip roots	VR	0.05	HR	15	0.33		20			0.067			
Barley grain	GC	0.035	STMR	88	0.04	50	50		70	0.020	0.02		0.028
Total						60	100	100	70	0.281	0.868	3.158	0.028

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	
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	70		70	0.019886	0.028		0.028
Total						60	100	100	70	0.076705	0.198	1.521	0.028

DAIRY CATTLE													
DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.8	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	
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						65	90	100	45	0.313	0.864	3.123	0.147

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
Grape pomace, wet	AB	0.8	STMR/STMR-P	15	5.33		0	20			0	1.067	
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						55	70	100	45	0.074716	0.186	1.514	0.044

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			
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													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 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	

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

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	

## LUFENURON

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
Apple pomace, wet	AB	5.192	STMR	90	5.77		20	20			1.154	1.154	
Citrus dried pulp	AB	0.01305	STMR	91	0.01	10		10		0.001		0.001	
Corn, field grain	GC	0.01	STMR	88	0.01	80	80	70	75	0.009	0.009	0.008	0.009
Total						90	100	100	75	0.011	1.163	1.163	0.009

DAIRY CATTLE													
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
Apple pomace, wet	AB	5.192	STMR	90	5.77	10	10	10		0.577	0.577	0.577	
Citrus dried pulp	AB	0.01305	STMR	91	0.01		10	20		0.001	0.003		
Corn, field grain	GC	0.01	STMR	88	0.01	45	30	20	80	0.005	0.003	0.002	0.009
Total						55	50	50	80	0.582	0.582	0.582	0.009

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	5.192	STMR/STMR-P	90	5.77		20	20			1.154	1.154	
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	30	30	10		0.015	0.015	0.005	
Citrus dried pulp	AB	0.01305	STMR/STMR-P	91	0.01	10		10		0.001434		0.001	
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	60	50	60	75	0.006818	0.006	0.007	0.009
Total						100	100	100	75	0.023252	1.174	1.167	0.009

DAIRY CATTLE													
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	5.192	STMR/STMR-P	90	5.77	10	10	10		0.576889	0.577	0.577	
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	10	30	10		0.005	0.015	0.005	
Citrus dried pulp	AB	0.01305	STMR/STMR-P	91	0.01	0	10	20		0	0.001	0.003	
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	45	30	20	80	0.005114	0.003	0.002	0.009
Total						65	80	60	80	0.587003	0.597	0.587	0.009

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	
Corn, field grain	GC	0.01	STMR	88	0.01	75	70		70	0.009	0.008		0.008	
Total						75	70		70	0.009	0.008		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
Corn, field grain	GC	0.01	STMR	88	0.01	75	70		80	0.009	0.008		0.009
Total						75	70		80	0.009	0.008		0.009

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.01	STMR/STMR-P	20	0.05		10				0.005		
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	75	70		70	0.01	0.008		0.008
Total						75	80		70	0.01	0.013		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
Potato culls	VR	0.01	STMR/STMR-P	20	0.05		10				0.005		
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	75	70		80	0.008523	0.008		0.009
Total						75	80		80	0.008523	0.013		0.009

## MANDIPROPAMID

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
Cabbage heads, leaves	AM/AV	5.8	HR	15	38.67		20			7.733			
Grape pomace, wet	AB	1.16	STMR	15	7.73			20				1.547	
Potato culls	VR	0.073	HR	20	0.37	30	30	10		0.1095	0.11	0.037	
Potato process waste	AB	0.04	STMR	12	0.33	30	40			0.1	0.133		
Total						60	90	30		0.2095	7.976	1.583	

DAIRY CATTLE													
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
Cabbage heads, leaves	AM/AV	5.8	HR	15	38.67		20			7.733			
Bean vines	AL	9.27	HR	35	26.49		20			5.297			
Grape pomace, wet	AB	1.16	STMR	15	7.73			20				1.547	
Potato culls	VR	0.073	HR	20	0.37	10	30	10		0.0365	0.11	0.037	
Potato process waste	AB	0.04	STMR	12	0.33	10	30			0.033333	0.1		
Total						20	100	30		0.069833	13.24	1.583	

ESTIMATED MEAN 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
Cabbage heads, leaves	AM/AV	3.55	STMR/STMR-P	15	23.67		20			4.733			
Grape pomace, wet	AB	1.16	STMR/STMR-P	15	7.73			20				1.547	
Potato process waste	AB	0.04	STMR/STMR-P	12	0.33	30	40			0.1	0.133		
Potato culls	VR	0.019	STMR/STMR-P	20	0.10	30	30	10		0.0285	0.029	0.01	
Total						60	90	30		0.1285	4.895	1.556	

DAIRY CATTLE													
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
Cabbage heads, leaves	AM/AV	3.55	STMR/STMR-P	15	23.67		20	0		4.733		0	
Bean vines	AL	4.35	STMR/STMR-P	35	12.43	0	20			2.486			
Grape pomace, wet	AB	1.16	STMR/STMR-P	15	7.73	0		20				1.547	
Potato process waste	AB	0.04	STMR/STMR-P	12	0.33	10	30			0.033333	0.1		
Potato culls	VR	0.019	STMR/STMR-P	20	0.10	10	30	10		0.0095	0.029	0.01	
Total						20	100	30		0.042833	7.348	1.556	

[illegible]

POULTRY LAYER																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																				
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POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.019	STMR/STMR-P	20	0.10		10				0.01		
Potato dried pulp	AB	0.019	STMR/STMR-P	88	0.02		20				0.004		
Total							30				0.014		

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	3.55	STMR/STMR-P	15	23.67	5				1.183			
Potato culls	VR	0.019	STMR/STMR-P	20	0.10	10				0.01			
Potato dried pulp	AB	0.019	STMR/STMR-P	88	0.02	15				0.003			
Total						30				1.196			



## NORFLURAZON

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
Alfalfa hay	AL	10	HR	89	11.24	15			10	1.685			1.124
Corn, field forage/silage	AF/AS	0.94	HR	40	2.35	15				0.353			
Rye straw	AF/AS	1.5	HR	88	1.70		20			0.341			
Rice straw	AF/AS	0.65	HR	90	0.72				55				0.397
Rice grain	GC	0.1	STMR	88	0.11	20		40		0.023		0.045	
Sorghum, grain grain	GC	0.04	STMR	86	0.05	20	40	60	35	0.009	0.019	0.028	0.016
Corn, field grain	GC	0.04	STMR	88	0.05	30	40			0.014	0.018		
Total						100	100	100	100	2.084	0.378	0.073	1.537

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
Alfalfa hay	AL	2.9	STMR/STMR-P	89	3.26	15			10	0.488764			0.325843
Rye straw	AF/AS	0.42	STMR/STMR-P	88	0.48	10	20			0.047727	0.095		
Corn, field forage/silage	AF/AS	0.19	STMR/STMR-P	40	0.48	5				0.02375			
Rice straw	AF/AS	0.31	STMR/STMR-P	90	0.34				55				0.189444
Rice grain	GC	0.1	STMR/STMR-P	88	0.11	20		40		0.022727		0.045	
Sorghum, grain grain	GC	0.04	STMR/STMR-P	86	0.05	20	40	60	35	0.009302	0.019	0.028	0.016279
Corn, field grain	GC	0.04	STMR/STMR-P	88	0.05	30	40			0.013636	0.018		
Total						100	100	100	100	0.605907	0.132	0.073	0.531566

DAIRY CATTLE													
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
Alfalfa forage	AL	4.4	HR	35	12.57	20				2.514			
Alfalfa hay	AL	10	HR	89	11.24		40		25	4.494			2.809
Rape forage	AM/AV	1	HR	30	3.33	10				0.333			
Wheat forage	AF/AS	0.59	HR	25	2.36	20				0.472			
Corn, field forage/silage	AF/AS	0.94	HR	40	2.35	25				0.588			
Corn, sweet forage	AF/AS	0.94	HR	48	1.96	25				0.490			
Rye straw	AF/AS	1.5	HR	88	1.70		20		5	0.341			0.085
Rice straw	AF/AS	0.65	HR	90	0.72				20				0.144
Rice grain	GC	0.1	STMR	88	0.11			20				0.023	
Sorghum, grain grain	GC	0.04	STMR	86	0.05		40	30	30	0.019	0.014	0.014	
Corn, field grain	GC	0.04	STMR	88	0.05				20				0.009
Total						100	100	50	100	4.397	4.854	0.037	3.062

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
Alfalfa forage	AL	1.9	STMR/STMR-P	35	5.43	20	0	0		1.085714	0	0	
Alfalfa hay	AL	2.9	STMR/STMR-P	89	3.26	0	40		25	0	1.303		0.814607
Rape forage	AM/AV	0.285	STMR/STMR-P	30	0.95	10				0.095			
Rye straw	AF/AS	0.42	STMR/STMR-P	88	0.48	10	20		5	0.047727	0.095		0.023864
Corn, field forage/silage	AF/AS	0.19	STMR/STMR-P	40	0.48	35				0.16625			
Corn, sweet forage	AF/AS	0.185	STMR/STMR-P	48	0.39	25				0.096354			
Rice straw	AF/AS	0.31	STMR/STMR-P	90	0.34	0			20	0			0.068889
Rice grain	GC	0.1	STMR/STMR-P	88	0.11	0		20		0		0.023	
Sorghum, grain grain	GC	0.04	STMR/STMR-P	86	0.05	0	40	30	30	0	0.019	0.014	0.013953
Corn, field grain	GC	0.04	STMR/STMR-P	88	0.05	0			20	0			0.009091
Total						100	100	50	100	1.491046	1.417	0.037	0.930404

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice grain	GC	0.1	STMR	88	0.11	20		50		0.023		0.057	
Sorghum, grain grain	GC	0.04	STMR	86	0.05	55	70	50	65	0.026	0.033	0.023	0.03
Corn, field grain	GC	0.04	STMR	88	0.05	25	30		35	0.011	0.014		0.016
Total						100	100	100	100	0.060	0.046	0.08	0.046

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice grain	GC	0.1	STMR/STMR-P	88	0.11	20		50		0.02		0.057	
Sorghum, grain grain	GC	0.04	STMR/STMR-P	86	0.05	55	70	50	65	0.03	0.033	0.023	0.030233
Corn, field grain	GC	0.04	STMR/STMR-P	88	0.05	25	30		35	0.01	0.014		0.015909
Total						100	100	100	100	0.06	0.046	0.08	0.046142

POULTRY LAYER													MAX
		Residue		DM	Residue								
Commodity	CC	(mg/kg)	Basis	(%)	dw	Diet content (%)				Residue Contribution (ppm)			
						US-	EU	AU	JP	US-CAN	EU	AU	JP
						CAN							
Wheat straw	AF/AS	1.5	HR	88	1.70		10				0.17		
Rice grain	GC	0.1	STMR	88	0.11	20		50		0.023		0.057	
Sorghum, grain grain	GC	0.04	STMR	86	0.05	55	70	50	55	0.026	0.033	0.023	0.026
Corn, field grain	GC	0.04	STMR	88	0.05	25	20		45	0.011	0.009		0.02
Total						100	100	100	100	0.060	0.212	0.08	0.046

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	0.42	STMR/STMR-P	88	0.48		10				0.048		
Rice grain	GC	0.1	STMR/STMR-P	88	0.11	20		50		0.022727		0.057	
Sorghum, grain grain	GC	0.04	STMR/STMR-P	86	0.05	55	70	50	55	0.025581	0.033	0.023	0.025581
Corn, field grain	GC	0.04	STMR/STMR-P	88	0.05	25	20		45	0.011364	0.009		0.020455
Total						100	100	100	100	0.059672	0.089	0.08	0.046036

OXATHIPIPROLIN (Parent)

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
Soybean seed	VD	0.01	STMR	89	0.01				15				0.002
Soybean meal	SM	0.01	STMR	92	0.01				10				0.001
Total						100	100	100	100	0.087	5.825	0.691	0.011

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 seed	VD	0.01	STMR/STMR-P	89	0.01				15				0.002
Soybean meal	SM	0.01	STMR/STMR-P	92	0.01				10				0.001
Total						100	100	100	100	0.047	3.984	0.613	0.011

DAIRY CATTLE													
DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Corn, field grain	GC	0.01	STMR	88	0.01	15			50	0.002			0.006
Total						100	100	100	100	0.072	5.819	12.09	0.018

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
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	15			50	0.001705			0.006
Total						100	100	100	100	0.039621	3.978	8.453	0.018

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	0.01	STMR	92	0.01	5		25	30	0.001		0.003	0.003				
Total						100	100	40	100	0.011	0.038	0.004	0.011				

POULTRY LAYER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US- CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Soybean seed	VD	0.01	STMR	89	0.01	20		15		0.002		0.002		
Soybean meal	SM	0.01	STMR	92	0.01	5		25	20	0.001		0.003	0.002	
Total						100	100	40	100	0.011	0.201	0.004	0.011	

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	5		25	30	0.00		0.003	0.003	
Total						100	100	40	100	0.01	0.017	0.004	0.011	

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		0.002247		0.002			
Soybean meal	SM	0.01	STMR/STMR-P	92	0.01	5		25	20	0.000543		0.003	0.002		
Total						100	100	40	100	0.011313	0.068	0.004	0.011		

## OXATHIPIPROLIN (metabolite)

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	0.5	STMR	15	3.33			20				0.667	
Potato process waste	AB	0.106	STMR	12	0.88	30	40			0.265	0.353		
Soybean seed	VD	0.166	STMR	89	0.19	5	10	20	15	0.009	0.019	0.037	0.028
Lupin seed meal	SM	0.12	STMR	85	0.14		20	15		0.028	0.021		
Sorghum, grain asp gr fn	CM/CF	0.12	STMR	85	0.14	5		20		0.007		0.028	
Soybean asp gr fn	SM	0.12	STMR	85	0.14	5				0.007			
Corn gluten feed	CM/CF	0.056	STMR	40	0.14	55	30		25	0.077	0.042		0.035
Bean seed	VD	0.12	STMR	88	0.14			25				0.034	
Alfalfa meal	SM	0.12	STMR	89	0.13				10				0.013
Soybean meal	SM	0.12	STMR	92	0.13				50				0.065
Total						100	100	100	100	0.365	0.442	0.787	0.142

ESTIMATED MEAN 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	0.5	STMR/STMR-P	15	3.33			20				0.667	
Kale leaves	AM/AV	0.36	STMR/STMR-P	15	2.40		20					0.48	
Sorghum, grain silage	AF/AS	0.21	STMR/STMR-P	21	1.00	15				0.15			
Potato process waste	AB	0.106	STMR/STMR-P	12	0.88	30	40			0.265	0.353		
Grass forage (fresh)	AF/AS	0.21	STMR/STMR-P	25	0.84		40	80	5	0.336	0.672	0.042	
Vetch hay	AL	0.51	STMR/STMR-P	85	0.60	15			5	0.09			0.03
Grass hay	AF/AS	0.51	STMR/STMR-P	88	0.58				35				0.203
Potato culls	VR	0.106	STMR/STMR-P	20	0.53	30				0.159			
Trefoil hay	AL	0.3	STMR/STMR-P	85	0.35	10				0.035			
Alfalfa hay	AL	0.3	STMR/STMR-P	89	0.34				5				0.017
Rice straw	AF/AS	0.18	STMR/STMR-P	90	0.20				50				0.1
Total						100	100	100	100	0.699	1.169	1.339	0.392

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.5	STMR	15	3.33			20				0.667	
Potato process waste	AB	0.106	STMR	12	0.88	10	30			0.088	0.265		
Beet, sugar ensiled pulp	AB	0.06	STMR	15	0.40		10				0.04		
Soybean seed	VD	0.166	STMR	89	0.19	10	10	20	10	0.019	0.019	0.037	0.019
Lupin seed meal	SM	0.12	STMR	85	0.14		20	15			0.028	0.021	
Peanut meal	SM	0.12	STMR	85	0.14	10				0.014			
Corn gluten feed	CM/CF	0.056	STMR	40	0.14	25	30		25	0.035	0.042		0.035
Alfalfa meal	SM	0.12	STMR	89	0.13	5		25	25	0.007		0.034	0.034
Soybean meal	SM	0.12	STMR	92	0.13				40				0.052
Corn, field grain	GC	0.102	STMR	88	0.12	40		20		0.046		0.023	
Total						100	100	100	100	0.209	0.394	0.782	0.14

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	0.5	STMR/STMR-P	15	3.33		0	20			0	0.667	
Kale leaves	AM/AV	0.36	STMR/STMR-P	15	2.40	0	20	40		0	0.48	0.96	
Sorghum, grain silage	AF/AS	0.21	STMR/STMR-P	21	1.00	40			10	0.4			0.1
Potato process waste	AB	0.106	STMR/STMR-P	12	0.88	10	30			0.088333	0.265		
Grass forage (fresh)	AF/AS	0.21	STMR/STMR-P	25	0.84	5	50	40		0.042	0.42	0.336	
Corn, field forage/silage	AF/AS	0.256	STMR/STMR-P	40	0.64	0			40	0			0.256
Lespedeza forage	AL	0.14	STMR/STMR-P	22	0.64	40				0.254545			
Vetch hay	AL	0.51	STMR/STMR-P	85	0.60	0			25	0			0.15
Grass hay	AF/AS	0.51	STMR/STMR-P	88	0.58	5			25	0.028977			0.145
Total						100	100	100	100	0.813856	1.165	1.963	0.651

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean seed	VD	0.166	STMR	89	0.19	20	20	15		0.037	0.037	0.028	
Lupin seed meal	SM	0.12	STMR	85	0.14		10	20			0.014	0.028	
Peanut meal	SM	0.12	STMR	85	0.14	25				0.035			
Corn gluten feed	CM/CF	0.056	STMR	40	0.14		10				0.014		
Bean seed	VD	0.12	STMR	88	0.14			65				0.089	
Alfalfa meal	SM	0.12	STMR	89	0.13				5				0.007
Soybean meal	SM	0.12	STMR	92	0.13		30		30		0.039		0.039
Potato dried pulp	AB	0.106	STMR	88	0.12		20				0.024		
Corn, field grain	GC	0.102	STMR	88	0.12	55	10		65	0.064	0.012		0.075
Total						100	100	100	100	0.136	0.14	0.145	0.121

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
Swede roots	VR	0.06	STMR/STMR-P	10	0.60		10				0.06		
Soybean seed	VD	0.166	STMR/STMR-P	89	0.19	20	20	15		0.04	0.037	0.028	
Cassava/tapioca roots	VR	0.06	STMR/STMR-P	37	0.16		10				0.016		
Lupin seed meal	SM	0.12	STMR/STMR-P	85	0.14		10	20			0.014	0.028	
Peanut meal	SM	0.12	STMR/STMR-P	85	0.14	25				0.04			
Corn gluten feed	CM/CF	0.056	STMR/STMR-P	40	0.14		10				0.014		
Bean seed	VD	0.12	STMR/STMR-P	88	0.14			65				0.089	
Alfalfa meal	SM	0.12	STMR/STMR-P	89	0.13				5				0.007
Soybean meal	SM	0.12	STMR/STMR-P	92	0.13		30		30		0.039		0.039
Potato dried pulp	AB	0.106	STMR/STMR-P	88	0.12		10				0.012		
Corn, field grain	GC	0.102	STMR/STMR-P	88	0.12	55			65	0.06375			0.075
Total						100	100	100	100	0.136347	0.193	0.145	0.121

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean seed	VD	0.166	STMR	89	0.19	20	15	15		0.037	0.028	0.028	
Lupin seed meal	SM	0.12	STMR	85	0.14		10	20			0.014	0.028	
Peanut meal	SM	0.12	STMR	85	0.14	25				0.035			
Corn gluten feed	CM/CF	0.056	STMR	40	0.14				10				0.014
Corn gluten meal	CM/CF	0.056	STMR	40	0.14		10				0.014		
Bean seed	VD	0.12	STMR	88	0.14		5	65			0.007	0.089	
Soybean meal	SM	0.12	STMR	92	0.13		15		30		0.02		0.039
Potato dried pulp	AB	0.106	STMR	88	0.12		15				0.018		

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	0.196	STMR/STMR-P	15	1.31		5				0.065		
Wheat forage	AF/AS	0.21	STMR/STMR-P	25	0.84		10				0.084		
Soybean silage	AL	0.186	STMR/STMR-P	30	0.62		10				0.062		
Swede roots	VR	0.06	STMR/STMR-P	10	0.60		10				0.06		
Soybean seed	VD	0.166	STMR/STMR-P	89	0.19	20	15	15		0.037303	0.028	0.028	
Cassava/tapioca roots	VR	0.06	STMR/STMR-P	37	0.16		5				0.008		
Lupin seed meal	SM	0.12	STMR/STMR-P	85	0.14		10	20			0.014	0.028	
Peanut meal	SM	0.12	STMR/STMR-P	85	0.14	25				0.035294			





# PYRACLOSTROBIN (Australia)

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
Beet, sugar tops	AM/AV	5.3	HR	23	23.04		20			4.609			
Corn, field stover	AF/AS	19	HR	83	22.89	15	25	40		3.433735	5.723	9.157	
Alfalfa hay	AL	19.83	HR	89	22.28	15		60	10	3.342135		13.37	2.228
Barley straw	AF/AS	19	HR	89	21.35		5			1.067			
Alfalfa forage	AL	6.61	HR	35	18.89		50			9.443			
Cotton gin byproducts	AM/AV	16.73	HR	90	18.59	5				0.929444			
Rice straw	AF/AS	2.69	HR	90	2.99				55				1.644
Barley grain	GC	0.345	STMR	88	0.39	50			35	0.196023			0.137
Rice bran/pollard	CM/CF	0.14	STMR	90	0.16	15				0.023333			
Total						100	100	100	100	7.92467	20.84	22.53	4.009

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
Alfalfa hay	AL	7.455	STMR/STMR-P	89	8.38	15		80	10	1.256461		6.701	0.838
Beet, sugar tops	AM/AV	1.64	STMR/STMR-P	23	7.13		20				1.426		
Alfalfa forage	AL	1.775	STMR/STMR-P	35	5.07		70	20			3.55	1.014	
Apple pomace, wet	AB	1.41	STMR/STMR-P	40	3.53		10				0.353		
Rice whole crop silage	AF/AS	0.856	STMR/STMR-P	40	2.14				5				0.107
Corn, field stover	AF/AS	1.5	STMR/STMR-P	83	1.81	15				0.271084			
Cotton gin byproducts	AM/AV	1.575	STMR/STMR-P	90	1.75	5				0.0875			
Rice straw	AF/AS	0.856	STMR/STMR-P	90	0.95				50				0.476
Barley grain	GC	0.345	STMR/STMR-P	88	0.39	50			35	0.196023			0.137
Rice bran/pollard	CM/CF	0.14	STMR/STMR-P	90	0.16	15				0.023333			
Total						100	100	100	100	1.834401	5.329	7.715	1.557

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	5.3	HR	23	23.04		30				6.913		
Corn, field stover	AF/AS	19	HR	83	22.89	15	20	40		3.433735	4.578	9.157	
Alfalfa hay	AL	19.83	HR	89	22.28	20	40	60	25	4.45618	8.912	13.37	5.57
Barley hay	AF/AS	19	HR	88	21.59	5				1.079545			
Barley straw	AF/AS	19	HR	89	21.35		10				2.135		
Oat hay	AF/AS	19	HR	90	21.11	10				2.111111			
Rice whole crop silage	AF/AS	2.69	HR	40	6.73				55				3.699
Sorghum, grain forage	AF/AS	1.33	HR	35	3.80	10				0.38			
Apple pomace, wet	AB	1.41	STMR	40	3.53	10				0.3525			
Carrot culls	VR	0.3	HR	12	2.50	10				0.25			
Almond hulls	AM/AV	1.395	STMR	90	1.55	10				0.155			
Barley grain	GC	0.345	STMR	88	0.39	10			20	0.039205			0.078
Total						100	100	100	100	12.25728	22.54	22.53	9.347

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
Alfalfa hay	AL	7.455	STMR/STMR-P	89	8.38	20	40	60	25	1.675281	3.351	5.026	2.094
Beet, sugar tops	AM/AV	1.64	STMR/STMR-P	23	7.13	0	30			0	2.139		
Apple pomace, wet	AB	1.41	STMR/STMR-P	40	3.53	10	10	10		0.3525	0.353	0.353	
Rice whole crop silage	AF/AS	0.856	STMR/STMR-P	40	2.14	0			55	0			1.177
Corn, field stover	AF/AS	1.5	STMR/STMR-P	83	1.81	15	20	30		0.271084	0.361	0.542	
Barley hay	AF/AS	1.5	STMR/STMR-P	88	1.70	5				0.085227			
Oat hay	AF/AS	1.5	STMR/STMR-P	90	1.67	10				0.166667			
Almond hulls	AM/AV	1.395	STMR/STMR-P	90	1.55	10				0.155			
Carrot culls	VR	0.12	STMR/STMR-P	12	1.00	10				0.1			
Sorghum, grain forage	AF/AS	0.305	STMR/STMR-P	35	0.87	10				0.087143			
Barley grain	GC	0.345	STMR/STMR-P	88	0.39	10			20	0.039205			0.078
Total						100	100	100	100	2.932107	6.204	5.921	3.35

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Alfalfa forage	AL	6.61	HR	35	18.89				5				0.944
Swede roots	VR	0.3	HR	10	3.00		10				0.3		
Barley grain	GC	0.345	STMR	88	0.39	75	70	15	10	0.294034	0.274	0.059	0.039
Rice bran/pollard	CM/CF	0.14	STMR	90	0.16	10	10	20	5	0.015556	0.016	0.031	0.008
Pea seed	VD	0.059	STMR	90	0.07	15	10	5		0.009833	0.007	0.003	
Canola meal	SM	0.035	STMR	88	0.04			5				0.002	
Bean seed	VD	0.02	STMR	88	0.02			55				0.013	
Soybean meal	SM	0.01	STMR	92	0.01				35				0.004
Total						100	100	100	55	0.319423	0.597	0.108	0.995

POULTRY LAYER																	MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)							
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP				
Beet, sugar tops	AM/AV	5.3	HR	23	23.04		5				1.152						
Corn, field stover	AF/AS	19	HR	83	22.89		10				2.289						
Swede roots	VR	0.3	HR	10	3.00		10				0.3						
Barley grain	GC	0.345	STMR	88	0.39	75	75	15		0.294034	0.294	0.059					
Rice bran/pollard	CM/CF	0.14	STMR	90	0.16	10		20	20	0.015556		0.031	0.031				
Pea seed	VD	0.059	STMR	90	0.07	15		5		0.009833		0.003					
Canola meal	SM	0.035	STMR	88	0.04			5				0.002					
Bean seed	VD	0.02	STMR	88	0.02			55				0.013					
Corn, field grain	GC	0.02	STMR	88	0.02				80				0.018				
Total						100	100	100	100	0.319423	4.035	0.108	0.049				

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Alfalfa forage	AL	1.775	STMR/STMR-P	35	5.07				5				0.254
Swede roots	VR	0.12	STMR/STMR-P	10	1.20		10				0.12		
Barley grain	GC	0.345	STMR/STMR-P	88	0.39	75	70	15	10	0.294034	0.274	0.059	0.039
Rice bran/pollard	CM/CF	0.14	STMR/STMR-P	90	0.16	10	10	20	5	0.015556	0.016	0.031	0.008
Pea seed	VD	0.059	STMR/STMR-P	90	0.07	15	10	5		0.009833	0.007	0.003	
Canola meal	SM	0.035	STMR/STMR-P	88	0.04			5				0.002	
Bean seed	VD	0.02	STMR/STMR-P	88	0.02			55				0.013	
Soybean meal	SM	0.01	STMR/STMR-P	92	0.01				35				0.004
Total						100	100	100	55	0.319423	0.417	0.108	0.304

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	1.64	STMR/STMR-P	23	7.13		5				0.357		
Corn, field stover	AF/AS	1.5	STMR/STMR-P	83	1.81		10				0.181		
Swede roots	VR	0.12	STMR/STMR-P	10	1.20		10				0.12		
Barley grain	GC	0.345	STMR/STMR-P	88	0.39	75	75	15		0.294034	0.294	0.059	
Rice bran/pollard	CM/CF	0.14	STMR/STMR-P	90	0.16	10		20	20	0.015556		0.031	0.031
Pea seed	VD	0.059	STMR/STMR-P	90	0.07	15		5		0.009833		0.003	
Canola meal	SM	0.035	STMR/STMR-P	88	0.04			5				0.002	
Bean seed	VD	0.02	STMR/STMR-P	88	0.02			55				0.013	
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02				80				0.018
Total						100	100	100	100	0.319423	0.951	0.108	0.049

# PYRACLOSTROBIN

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 silage	AL	18	HR	30	60.00			80				48	
Pea silage	AL	18	HR	40	45.00		25	20		11.25		9	
Cowpea forage	AL	7	HR	30	23.33		10			2.333			
Beet, sugar tops	AM/AV	5.3	HR	23	23.04		20			4.609			
Corn, field stover	AF/AS	19	HR	83	22.89	15	25			3.433735	5.723		
Alfalfa hay	AL	19.83	HR	89	22.28	15			10	3.342135			2.228
Barley straw	AF/AS	19	HR	89	21.35		5			1.067			
Alfalfa forage	AL	6.61	HR	35	18.89		15			2.833			
Cotton gin byproducts	AM/AV	16.73	HR	90	18.59	5				0.929444			
Rice straw	AF/AS	2.69	HR	90	2.99				55				1.644
Barley grain	GC	0.345	STMR	88	0.39	50			35	0.196023			0.137
Rice bran/pollard	CM/CF	0.14	STMR	90	0.16	15				0.023333			
Total						100	100	100	100	7.92467	27.82	57	4.009

ESTIMATED MEAN 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 silage	AL	6.8	STMR/STMR-P	30	22.67			80				18.13	
Pea vines	AL	5.1	STMR/STMR-P	25	20.40		20				4.08		
Cowpea forage	AL	5.1	STMR/STMR-P	30	17.00		15	20			2.55	3.4	
Alfalfa hay	AL	7.455	STMR/STMR-P	89	8.38	15			10	1.256461			0.838
Beet, sugar tops	AM/AV	1.64	STMR/STMR-P	23	7.13		20				1.426		
Alfalfa forage	AL	1.775	STMR/STMR-P	35	5.07		35				1.775		
Apple pomace, wet	AB	1.41	STMR/STMR-P	40	3.53		10				0.353		
Rice whole crop silage	AF/AS	0.856	STMR/STMR-P	40	2.14				5				0.107
Corn, field stover	AF/AS	1.5	STMR/STMR-P	83	1.81	15				0.271084			
Cotton gin byproducts	AM/AV	1.575	STMR/STMR-P	90	1.75	5				0.0875			
Rice straw	AF/AS	0.856	STMR/STMR-P	90	0.95				50				0.476
Barley grain	GC	0.345	STMR/STMR-P	88	0.39	50			35	0.196023			0.137
Rice bran/pollard	CM/CF	0.14	STMR/STMR-P	90	0.16	15				0.023333			
Total						100	100	100	100	1.834401	10.18	21.53	1.557

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
Soybean silage	AL	18	HR	30	60.00	20		40		12		24	
Pea silage	AL	18	HR	40	45.00		30				13.5		
Peanut hay	AL	24	HR	85	28.24			20				5.647	
Bean vines	AL	8.45	HR	35	24.14			10				2.414	
Cowpea forage	AL	7	HR	30	23.33		5				1.167		
Beet, sugar tops	AM/AV	5.3	HR	23	23.04		30				6.913		
Corn, field stover	AF/AS	19	HR	83	22.89	15	20	30		3.433735	4.578	6.867	
Alfalfa hay	AL	19.83	HR	89	22.28		5		25		1.114		5.57
Barley hay	AF/AS	19	HR	88	21.59	5				1.079545			
Barley straw	AF/AS	19	HR	89	21.35		10				2.135		
Oat hay	AF/AS	19	HR	90	21.11	10				2.111111			
Rice whole crop silage	AF/AS	2.69	HR	40	6.73				55				3.699
Sorghum, grain forage	AF/AS	1.33	HR	35	3.80	10				0.38			
Apple pomace, wet	AB	1.41	STMR	40	3.53	10				0.3525			
Carrot culls	VR	0.3	HR	12	2.50	10				0.25			
Almond hulls	AM/AV	1.395	STMR	90	1.55	10				0.155			
Barley grain	GC	0.345	STMR	88	0.39	10			20	0.039205			0.078
Total						100	100	100	100	19.8011	29.41	38.93	9.347

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 silage	AL	6.8	STMR/STMR-P	30	22.67	20	0	40		4.533333	0	9.067	
Cowpea forage	AL	5.1	STMR/STMR-P	30	17.00	0	35	20		0	5.95	3.4	
Alfalfa hay	AL	7.455	STMR/STMR-P	89	8.38	0	5		25	0	0.419		2.094
Pea hay	AL	6.8	STMR/STMR-P	88	7.73	0		10		0		0.773	
Beet, sugar tops	AM/AV	1.64	STMR/STMR-P	23	7.13	0	30			0	2.139		
Apple pomace, wet	AB	1.41	STMR/STMR-P	40	3.53	10	10	10		0.3525	0.353	0.353	
Rice whole crop silage	AF/AS	0.856	STMR/STMR-P	40	2.14	0			55	0			1.177
Corn, field stover	AF/AS	1.5	STMR/STMR-P	83	1.81	15	20	20		0.271084	0.361	0.361	
Barley hay	AF/AS	1.5	STMR/STMR-P	88	1.70	5				0.085227			
Oat hay	AF/AS	1.5	STMR/STMR-P	90	1.67	10				0.166667			
Almond hulls	AM/AV	1.395	STMR/STMR-P	90	1.55	10				0.155			
Carrot culls	VR	0.12	STMR/STMR-P	12	1.00	10				0.1			
Sorghum, grain forage	AF/AS	0.305	STMR/STMR-P	35	0.87	10				0.087143			
Barley grain	GC	0.345	STMR/STMR-P	88	0.39	10			20	0.039205			0.078
Total						100	100	100	100	5.790159	9.222	13.95	3.35

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Alfalfa forage	AL	6.61	HR	35	18.89				5				0.944
Swede roots	VR	0.3	HR	10	3.00		10				0.3		
Barley grain	GC	0.345	STMR	88	0.39	75	70	15	10	0.294034	0.274	0.059	0.039
Rice bran/pollard	CM/CF	0.14	STMR	90	0.16	10	10	20	5	0.015556	0.016	0.031	0.008
Pea seed	VD	0.059	STMR	90	0.07	15	10	5		0.009833	0.007	0.003	
Canola meal	SM	0.035	STMR	88	0.04			5				0.002	
Bean seed	VD	0.02	STMR	88	0.02			55				0.013	
Soybean meal	SM	0.01	STMR	92	0.01				35				0.004
Total						100	100	100	55	0.319423	0.597	0.108	0.995

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean silage	AL	18	HR	30	60.00		10				6		
Beet, sugar tops	AM/AV	5.3	HR	23	23.04		5				1.152		
Corn, field stover	AF/AS	19	HR	83	22.89		10				2.289		
Swede roots	VR	0.3	HR	10	3.00		10				0.3		
Barley grain	GC	0.345	STMR	88	0.39	75	65	15		0.294034	0.255	0.059	
Rice bran/pollard	CM/CF	0.14	STMR	90	0.16	10		20	20	0.015556		0.031	0.031
Pea seed	VD	0.059	STMR	90	0.07	15		5		0.009833		0.003	
Canola meal	SM	0.035	STMR	88	0.04			5				0.002	
Bean seed	VD	0.02	STMR	88	0.02			55				0.013	
Corn, field grain	GC	0.02	STMR	88	0.02				80				0.018
Total						100	100	100	100	0.319423	9.996	0.108	0.049

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Alfalfa forage	AL	1.775	STMR/STMR-P	35	5.07				5				0.254
Swede roots	VR	0.12	STMR/STMR-P	10	1.20		10				0.12		
Barley grain	GC	0.345	STMR/STMR-P	88	0.39	75	70	15	10	0.294034	0.274	0.059	0.039
Rice bran/pollard	CM/CF	0.14	STMR/STMR-P	90	0.16	10	10	20	5	0.015556	0.016	0.031	0.008
Pea seed	VD	0.059	STMR/STMR-P	90	0.07	15	10	5		0.009833	0.007	0.003	
Canola meal	SM	0.035	STMR/STMR-P	88	0.04			5				0.002	
Bean seed	VD	0.02	STMR/STMR-P	88	0.02			55				0.013	
Soybean meal	SM	0.01	STMR/STMR-P	92	0.01				35				0.004
Total						100	100	100	55	0.319423	0.417	0.108	0.304

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 silage	AL	6.8	STMR/STMR-P	30	22.67		10				2.267		
Beet, sugar tops	AM/AV	1.64	STMR/STMR-P	23	7.13		5				0.357		
Corn, field stover	AF/AS	1.5	STMR/STMR-P	83	1.81		10				0.181		
Swede roots	VR	0.12	STMR/STMR-P	10	1.20		10				0.12		
Barley grain	GC	0.345	STMR/STMR-P	88	0.39	75	65	15		0.294034	0.255	0.059	
Rice bran/pollard	CM/CF	0.14	STMR/STMR-P	90	0.16	10		20	20	0.015556		0.031	0.031
Pea seed	VD	0.059	STMR/STMR-P	90	0.07	15		5		0.009833		0.003	
Canola meal	SM	0.035	STMR/STMR-P	88	0.04			5				0.002	
Bean seed	VD	0.02	STMR/STMR-P	88	0.02			55				0.013	
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02				80				0.018
Total						100	100	100	100	0.319423	3.179	0.108	0.049

## PYRIOFENONE

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.46	STMR	15	3.07			20				0.613	
Total								20				0.613	

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	0.46	STMR/STMR-P	15	3.07			20				0.613	
Total								20				0.613	

DAIRY CATTLE													
DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.46	STMR	15	3.07			20				0.613	
Total								20				0.613	

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
Grape pomace, wet	AB	0.46	STMR/STMR-P	15	3.07		0	20			0	0.613	
Total							0	20			0	0.613	

POULTRY BROILER													
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
No feed items applicable!													

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
No feed items applicable!													

POULTRY LAYER													
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
No feed items applicable!													

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
No feed items applicable!													

# SULFOXAFLOR

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
Rice straw	AF/AS	10.4	HR	90	11.56		10	60	55	1.156	6.933	6.356	
Rice hulls	CM/CF	8.8	STMR	90	9.78			5				0.489	
Beet, sugar tops	AM/AV	1.8	HR	23	7.83		20			1.565			
Cotton gin byproducts	AM/AV	4	HR	90	4.44	5				0.222			
Soybean silage	AL	1.2	HR	30	4.00			35				1.4	
Citrus dried pulp	AB	2.16	STMR	91	2.37	10	5			0.237	0.119		
Rice grain	GC	1.95	STMR	88	2.22	20				0.443			
Barley hay	AF/AS	1.8	HR	88	2.05	15				0.307			
Wheat hay	AF/AS	1.8	HR	88	2.05		10			0.205			
Barley straw	AF/AS	1.8	HR	89	2.02		10			0.202			
Soybean asp gr fn	SM	1	STMR	85	1.18	5				0.059			
Corn, field forage/silage	AF/AS	0.25	HR	40	0.63		45			0.281			
Wheat asp gr fn	CM/CF	0.53	STMR	85	0.62	5				0.031			
Beet, sugar molasses	DM	0.14	STMR	75	0.19	10				0.019			
Rape meal	SM	0.086	STMR	88	0.10				15				0.015
Barley grain	GC	0.063	STMR	88	0.07	30			30	0.021			0.021
Total						100	100	100	100	1.340	3.527	8.822	6.392

ESTIMATED MEAN 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
Rice hulls	CM/CF	8.8	STMR/STMR-P	90	9.78			5				0.489	
Kale leaves	AM/AV	0.72	STMR/STMR-P	15	4.80		20				0.96		
Citrus dried pulp	AB	2.16	STMR/STMR-P	91	2.37	10	5	30		0.237363	0.119	0.712	
Soybean silage	AL	0.67	STMR/STMR-P	30	2.23			65				1.452	
Rice grain	GC	1.95	STMR/STMR-P	88	2.22	20				0.443182			
Rice straw	AF/AS	1.5	STMR/STMR-P	90	1.67		10		55		0.167		0.917
Soybean asp gr fn	SM	1	STMR/STMR-P	85	1.18	5				0.058824			
Wheat forage	AF/AS	0.19	STMR/STMR-P	25	0.76		10				0.076		
Wheat asp gr fn	CM/CF	0.53	STMR/STMR-P	85	0.62	5				0.031			
Corn, field forage/silage	AF/AS	0.08	STMR/STMR-P	40	0.20	15	55			0.030	0.11		
Beet, sugar molasses	DM	0.14	STMR/STMR-P	75	0.19	10				0.019			
Cotton gin byproducts	AM/AV	0.15	STMR/STMR-P	90	0.17	5				0.008			
Rape meal	SM	0.086	STMR/STMR-P	88	0.10				15				0.015
Barley grain	GC	0.063	STMR/STMR-P	88	0.07	30			30	0.021			0.021
Total						100	100	100	100	0.8490	1.431	2.653	0.9528



DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice straw	AF/AS	10.4	HR	90	11.56		5	20	25		0.578	2.311	2.889
Rice hulls	CM/CF	8.8	STMR	90	9.78			10				0.978	
Beet, sugar tops	AM/AV	1.8	HR	23	7.83		30				2.348		
Kale leaves	AM/AV	0.9	HR	15	6.00			40				2.4	
Soybean silage	AL	1.2	HR	30	4.00	20		30		0.800		1.2	
Citrus dried pulp	AB	2.16	STMR	91	2.37	10	20			0.237	0.475		
Rice grain	GC	1.95	STMR	88	2.22	20				0.443			
Barley hay	AF/AS	1.8	HR	88	2.05	20				0.409			
Wheat hay	AF/AS	1.8	HR	88	2.05		15				0.307		
Barley straw	AF/AS	1.8	HR	89	2.02		10				0.202		
Almond hulls	AM/AV	0.76	STMR	90	0.84	10				0.084			
Corn, field forage/silage	AF/AS	0.25	HR	40	0.63	20	20		25	0.125	0.125		0.156
Rape meal	SM	0.086	STMR	88	0.10				25				0.02
Barley grain	GC	0.063	STMR	88	0.07				25				0.018
Total						100	100	100	100	2.099	4.034	6.889	3.087

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice hulls	CM/CF	8.8	STMR/STMR-P	90	9.78		0	10			0	0.978	
Kale leaves	AM/AV	0.72	STMR/STMR-P	15	4.80	0	20	40		0	0.96	1.92	
Citrus dried pulp	AB	2.16	STMR/STMR-P	91	2.37	10	20	30		0.237363	0.475	0.712	
Soybean silage	AL	0.67	STMR/STMR-P	30	2.23	20		20		0.446667		0.447	
Rice grain	GC	1.95	STMR/STMR-P	88	2.22	20				0.443182			
Beet, sugar tops	AM/AV	0.42	STMR/STMR-P	23	1.83	0	10			0	0.183		
Rice straw	AF/AS	1.5	STMR/STMR-P	90	1.67	0	5		25	0	0.083		0.417
Almond hulls	AM/AV	0.76	STMR/STMR-P	90	0.84	10				0.084444			
Wheat forage	AF/AS	0.19	STMR/STMR-P	25	0.76	20	15			0.152	0.114		
Corn, sweet forage	AF/AS	0.1	STMR/STMR-P	48	0.21	20				0.041667			
Corn, field forage/silage	AF/AS	0.08	STMR/STMR-P	40	0.20	0	30		25	0	0.06		0.05
Rape meal	SM	0.086	STMR/STMR-P	88	0.10	0			25	0			0.024
Barley grain	GC	0.063	STMR/STMR-P	88	0.07	0			25	0			0.018
Total						100	100	100	100	1.405322	1.875	4.057	0.509

POULTRY BROILER										MAX			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice grain	GC	1.95	STMR	88	2.22	20		50		0.443		1.108	
Carrot culls	VR	0.03	HR	12	0.25		10			0.025			
Canola meal	SM	0.088	STMR	88	0.10	15	18	5		0.015	0.018	0.005	
Rape meal	SM	0.086	STMR	88	0.10				5				0.005
Bean seed	VD	0.075	STMR	88	0.09		20	45		0.017	0.038		
Barley grain	GC	0.063	STMR	88	0.07	65	52		10	0.047	0.037		0.007
Sorghum, grain	GC	0.03	STMR	86	0.03				55				0.019
Soybean meal	SM	0.014	STMR	92	0.02				30				0.005
Total						100	100	100	100	0.505	0.097	1.151	0.036

POULTRY BROILER										MEAN			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice grain	GC	1.95	STMR/STMR-P	88	2.22	20		50		0.44		1.108	
Swede roots	VR	0.01	STMR/STMR-P	10	0.10		10				0.01		
Canola meal	SM	0.088	STMR/STMR-P	88	0.10	15	18	5		0.02	0.018	0.005	
Rape meal	SM	0.086	STMR/STMR-P	88	0.10				5				0.005
Bean seed	VD	0.075	STMR/STMR-P	88	0.09		20	45			0.017	0.038	
Barley grain	GC	0.063	STMR/STMR-P	88	0.07	65	52		10	0.05	0.037		0.007
Sorghum, grain	GC	0.03	STMR/STMR-P	86	0.03				55				0.019
Soybean meal	SM	0.014	STMR/STMR-P	92	0.02				30				0.005
Total						100	100	100	100	0.504716	0.082	1.151	0.036

POULTRY LAYER										MAX			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	1.8	HR	23	7.83		5			0.391			
Soybean silage	AL	1.2	HR	30	4.00		10			0.4			
Rice grain	GC	1.95	STMR	88	2.22	20		50		0.443		1.108	
Wheat hay	AF/AS	1.8	HR	88	2.05		10			0.205			
Carrot culls	VR	0.03	HR	12	0.25		10			0.025			
Canola meal	SM	0.088	STMR	88	0.10	15	10	5		0.015	0.01	0.005	
Rape meal	SM	0.086	STMR	88	0.10				15				0.015
Bean seed	VD	0.075	STMR	88	0.09		20	45		0.017	0.038		
Barley grain	GC	0.063	STMR	88	0.07	65	35			0.05	0.025		
Barley bran fractions	CM/CF	0.063	STMR	90	0.07				5				0.004
Sorghum, grain	GC	0.03	STMR	86	0.03				55				0.019
Soybean meal	SM	0.014	STMR	92	0.02				25				0.004
Total						100	100	100	100	0.505	1.073	1.151	0.041

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 silage	AL	0.67	STMR/STMR-P	30	2.23		10				0.223		
Rice grain	GC	1.95	STMR/STMR-P	88	2.22	20		50		0.443182		1.108	
Beet, sugar tops	AM/AV	0.42	STMR/STMR-P	23	1.83		5				0.091		
Wheat forage	AF/AS	0.19	STMR/STMR-P	25	0.76		10				0.076		
Swede roots	VR	0.01	STMR/STMR-P	10	0.10		10				0.01		
Canola meal	SM	0.088	STMR/STMR-P	88	0.10	15	10	5		0.015	0.01	0.005	
Rape meal	SM	0.086	STMR/STMR-P	88	0.10				15				0.015
Bean seed	VD	0.075	STMR/STMR-P	88	0.09		20	45			0.017	0.038	
Barley grain	GC	0.063	STMR/STMR-P	88	0.07	65	35			0.047	0.025		
Barley bran fractions	CM/CF	0.063	STMR/STMR-P	90	0.07				5				0.004
Sorghum, grain	GC	0.03	STMR/STMR-P	86	0.03				55				0.019
Soybean meal	SM	0.014	STMR/STMR-P	92	0.02				25				0.004
Total						100	100	100	100	0.504716	0.453	1.151	0.041

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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	0.17	HR	85	0.20			80				0.16	
Soybean forage	AL	0.078	HR	56	0.14			20				0.028	
Corn, field forage/silage	AF/AS	0.0081	HR	40	0.02	15	80			0.003	0.016		
Soybean meal	SM	0.017	STMR	92	0.02	5	20		65	0.001	0.004		0.012
Soybean seed	VD	0.0125	STMR	89	0.01	5			15	0.001			0.002
Cotton gin byproducts	AM/AV	0.0098	HR	90	0.01	5				0.001			
Soybean hulls	SM	0.0049	STMR	90	0.01	10				0.001			
Total						40	100	100	80	0.006	0.02	0.188	0.014

ESTIMATED MAXIMUM DIETARY BURDEN													
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	0.17	HR	85	0.20	20		40		0.040		0.08	
Corn, field forage/silage	AF/AS	0.0081	HR	40	0.02	45	60	60	50	0.009	0.012	0.012	0.01
Soybean meal	SM	0.017	STMR	92	0.02	10	25		50	0.002	0.005		0.009
Soybean seed	VD	0.0125	STMR	89	0.01	10	10			0.001	0.001		
Total						85	95	100	100	0.052	0.018	0.092	0.019

ESTIMATED MEAN 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	0.069	STMR/STMR-P	85	0.08			80				0.065	
Soybean forage	AL	0.033	STMR/STMR-P	56	0.06			20				0.012	
Soybean meal	SM	0.017	STMR/STMR-P	92	0.02	5	20		65	0.000924	0.004		0.012
Soybean seed	VD	0.0125	STMR/STMR-P	89	0.01	5	10		15	0.000702	0.001		0.002
Corn, field forage/silage	AF/AS	0.005	STMR/STMR-P	40	0.01	15	70			0.001875	0.009		
Cotton gin byproducts	AM/AV	0.0064	STMR/STMR-P	90	0.01	5				0.000356			
Soybean hulls	SM	0.0049	STMR/STMR-P	90	0.01	10				0.000544			
Total						40	100	100	80	0.004401	0.014	0.077	0.014

ESTIMATED MEAN DIETARY BURDEN													
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	0.069	STMR/STMR-P	85	0.08	20	0	40		0.016235	0	0.032	
Soybean meal	SM	0.017	STMR/STMR-P	92	0.02	10	25	15	60	0.001848	0.005	0.003	0.011
Soybean seed	VD	0.0125	STMR/STMR-P	89	0.01	10	10	20	10	0.001404	0.001	0.003	0.001
Corn, field forage/silage	AF/AS	0.005	STMR/STMR-P	40	0.01	45	60	25	30	0.005625	0.008	0.003	0.004
Total						85	95	100	100	0.025113	0.014	0.041	0.016

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	0.017	STMR	92	0.02	25	40	25	35	0.005	0.007	0.005	0.006
Soybean seed	VD	0.0125	STMR	89	0.01	20	20	15		0.003	0.003	0.002	
Total						45	60	40	35	0.007	0.01	0.007	0.006

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	0.017	STMR/STMR-P	92	0.02	25	40	25	35	0.00	0.007	0.005	0.006
Soybean seed	VD	0.0125	STMR/STMR-P	89	0.01	20	20	15		0.00	0.003	0.002	
Total						45	60	40	35	0.01	0.01	0.007	0.006

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean hay	AL	0.17	HR	85	0.20		10				0.02		
Soybean meal	SM	0.017	STMR	92	0.02	25	25	25	30	0.005	0.005	0.005	0.006
Soybean seed	VD	0.0125	STMR	89	0.01	20	15	15		0.003	0.002	0.002	
Total						45	50	40	30	0.007	0.027	0.007	0.006

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean hay	AL	0.069	STMR/STMR-P	85	0.08		10				0.008		
Soybean meal	SM	0.017	STMR/STMR-P	92	0.02	25	25	25	30	0.00462	0.005	0.005	0.006
Soybean seed	VD	0.0125	STMR/STMR-P	89	0.01	20	15	15		0.002809	0.002	0.002	
Total						45	50	40	30	0.007429	0.015	0.007	0.006

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197	Submission and evaluation of pesticide residues		

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218	Cassava Farmer Field Schools – Resource material for facilitators in sub-Saharan Africa	Ar – Arabic	Multil – Multilingual
219	Pesticide residues in food 2013 – Report, 2011 (E)	C – Chinese	* Out of print
220	Pesticide Residues in food 2013 – Evaluations – Part 1 (E)	E – English	** In preparation
221	Pesticide residues in food 2014 – Report, 2011 (E)	F – French	
222	Pesticide Residues in food 2014 – Evaluations	P – Portuguese	
223	Pesticide residues in food 2015 Joint FAO/WHO Meeting - Report 2015 (E)	S – Spanish	
224	FAO Training Manual on Evaluation of Pesticide Residues for Estimation of Maximum Residue Levels and Calculation of Dietary Intake (E, S**)	The FAO Technical Papers are available through the authorized FAO Sales Agents or directly from Sales and Marketing Group, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy.	
225	FAO Manual on the submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed (3rd edition) (E, F, S, C**)		
226	Pesticide residues in food 2015 - Joint FAO/WHO Meeting - Evaluation 2015 (E)		
227	Pesticide residues in food 2016 - Special session of the Joint FAO/WHO Meeting on Pesticide Residues. Report 2016 (E)		
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Availability: 11 December 2018



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 Berlin, Germany, from 18 to 27 September 2018. The FAO Panel of Experts had met in preparatory sessions from 13 to 17 September 2018. 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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