CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Items 5b/6

CX/PR 23/54/5-Add.1
May 2023
ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

54th Session
Beijing, P.R. China
26 June - 1 July 2023

MRLs FOR PESTICIDES IN FOOD AND FEED (AT STEPS 7 AND 4)

Comments at Step 3 in reply to CL 2023/22-PR

Comments of Australia, Brazil, Canada, Chile, Egypt, European Union (EU), Indonesia, Iraq, Kenya USA and CropLife International, International Commission for Uniform Methods of Sugar Analysis (ICUMSA)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2023/22-PR[1] issued in March 2023. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby annexed and presented in tabulated format. Part I contains comments submitted by Codex members and observers on different MRL proposals and Part II contains concern forms submitted by Codex members in relation to some proposed MRLs.

1 https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/
https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCPR

Annex

AGENDA ITEM 5(B): RESPONSES TO SPECIFIC CONCERNS RAISED BY CCPR ARISING FROM THE 2022 JMPR MEETING

COMMENT	MEMBER/OBSERVER
81 Chlorothalonil The EU acknowledges the JMPR responses to the concerns raised on chlorothalonil, and its conclusion that the exposure to the degradation product R613636 is not expected to be a safety concern. The EU does not agree with this conclusion. It is based on processing studies using unprocessed cereal products with residues much lower than the CXL, so that the exposure calculations may underestimate the exposure. Additionally, processing studies for animal products are not available, whereas CXLs are established for milk, meat, and other animal products. These products are consumed after processing and are an important component of the human diet. Additionally, the EU identified additional concerns on metabolites R182281 (SDS-3701) and R417888 on the lack of an appropriate in vivo follow-up for positive results in the mammalian gene mutation assays with both metabolites. Several in vitro gene mutation assays were available for both metabolites. JMPR considered an overall call for in vitro mammalian gene mutation as negative (considering all studies results), whereas for the EU, uncertainties over the results of in vitro mammalian gene mutation assays (inconsistent results) trigger in vivo follow-up. Therefore, the EU still expresses the same concerns, and considers that the genotoxic potential of metabolites R613636, R182281 (SDS-3701) and R417888 is inconclusive.	**EU**
167 Terbufos The EU acknowledges the JMPR responses to the concerns raised by CCPR53 on terbufos, and its conclusion that anticipating the scheduled periodic review for this substance would not be necessary. The above conclusions were derived based on an assessment of the acute neurotoxicity study used in the derivation of the toxicological reference values for terbufos. Nevertheless, the EU highlights that the concerns on the outdated toxicological assessment of terbufos were of general nature, and not restricted to the acute neurotoxicity study only, and were raised because a toxicological assessment of terbufos and metabolites expected in food is not available. In addition, the EU notes that terbufos is listed in table 2B of the priority list as no longer supported by the manufacturer. The EU invites CCPR to confirm such non-support, and taking into consideration the public health concern raised, the EU recommends withdrawing all the existing Codex MRL for terbufos and removing it from the Codex index of pesticides.	**EU**

AGENDA ITEM 6: COMMENTS ON MRL RECOMMENDATIONS ARISING FROM THE 2022 JMPR MEETING

PART I: COMMENTS ON MRLs

General Comments

COMMENT	MEMBER/OBSEVER
The Brazilian Health Regulatory Agency (ANVISA) has conducted a short-term dietary risk assessment for compounds/commodities reported on CL 2023/22-PR, regarding the proposed MRLs that correspond to Step 3 of the Codex Procedure as proposed by the 2022 JMPR Meeting. The risk assessment methodology was based on WHO/FAO guidelines. The individual food consumption and body weight of people older than 10 years were based on the Brazilian household budget survey report released in 2009. Based on the results of the short-term dietary risk assessment, Brazil has not identified cases in which ARfDs were exceeded. Thus, the MRLs proposed on CL 2023/22-PR do not present a public health concern for Brazilian consumers. Finally, Brazil kindly requests the advancement of the proposed MRL for triflumuron for soybean (0,1 mg/kg) to step 5/8.	**Brazil**
Considering that it is relevant for Codex to advance in the study and determination of MRLs for those active ingredients that are regularly used, Chile supports all the recommendations made by the JMPR as Codex's scientific advisory body for this Committee, and therefore the progress in the corresponding procedure with a view to its adoption by the CAC46.	**Chile**
General comments The EU would like to inform CCPR Members that the CXLs that were adopted by the 45th Session of the Codex Alimentarius Commission, and for which the EU had not introduced reservations during CCPR53, have now been established in the EU. It is an EU policy to align EU MRLs with Codex MRLs (CXLs) provided that: • the EU sets MRLs for the commodity under consideration; • the current EU MRL is lower than the CXL. The EU will make reservations to the advancement of the proposed Codex MRLs during the discussions on the specific substances: • if toxicological data are not available at EU level or are available but not yet assessed at EU level, and/or • if the proposed CXL is not safe for European consumers[1], and/or • if the proposed CXLs are not sufficiently supported by data as required according to the FAO manual or other agreed requirements, and/or if the CXL is not acceptable to the EU with respect to areas such as supporting data, and extrapolations, as well as environmental issues of global nature (such as the decline of pollinators or the accumulation of persistent bioaccumulative and toxic substances in the environment).	**EU**

[1] Including an assessment that the Codex residue definition ensures an equivalent level of protection.

COMMENT	MEMBER/OBSEVER
Indonesia would like to thank the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) for its excellent work reviewing pesticide residues and analytical aspects. Indonesia proposes the following comments in response to the CL 2023/22-PR for consideration. Indonesia supports the proposed MRLs for pesticides in food and feed for afidopyropen, azoxystrobin, benzovindiflupyr, benzpyrimoxan, chlormequat, difenoconazole, dimethoate/omethoate, omethoate, emamectin benzoate, fenazaquin, fluazaindolizine, fludioxonil, fluindapyr, inpyrfluxam, isoflucypram, pyridate, quinclorac, spiromesifen, sulfoxaflor and triflumuron. Indonesia also agrees to withdraw MRLS for diazinon and quintozene in food and feed. Regulations in Indonesia prohibit the use of diazinon, dimethoate, and omethoate on rice.	**Indonesia**
Agree, with regards	**Iraq**
Kenya supports the advancement of the recommendations of the JMPR for pesticide maximum residue limits corresponding step Codex Standard elaboration Process. Justification: There has been provision of new data resulting in review of existing MRLs and establishment of new MRLs thus promoting food safety and facilitating trade	**Kenya**
Why are only some things defined? For example, dw and ar are defined but there is no explanation for * or Po.	**ICUMSA**

Specific Comments

015 CHLORMEQUAT

COMMENT	MEMBER/OBSERVER
Australia supports advancement of the MRLs to Step 5/8	**Australia**
Canada acknowledges that the JMPR recommended MRLs are lower than the Canadian MRLs for the same crops based on different cGAPs.	**Canada**
The EU **supports the advancement** of the proposed draft MRLs for the following commodities: - **Milks,** - **Poultry fats,** - **Poultry meat.** The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities: - **Barley,** - **Edible offal (mammalian),** - **Eggs,** - **Mammalian fats (except milk fats),** - **Meat (from mammals other than marine mammals),** - **Poultry edible offal of,** - **Wheat.** For **edible offal (mammalian), eggs, mammalian fats (except milk fats), meat (from mammals other than marine mammals), poultry edible offal of** the result of the feeding study was rounded up to a higher MRL than necessary. Therefore, the EU invites JMPR to review these Codex MRL proposals. For **barley** and **wheat**, additional clarification on the information on the residue trials and the critical good agricultural practice (cGAP) presented in the JMPR report would be needed. Once the JMPR evaluation would be available, the EU will perform a more detailed assessment of the compound and based on the outcome, this reservation could be revised. The EU notes that the dietary burden calculations were not included in the JMPR report. Therefore, the EU invites JMPR to present all calculations in the JMPR report, in order to improve transparency.	**EU**

022 DIAZINON

Australia does not object to the withdrawal of the MRLs noting the JMPR was unable to conclude on a residue definition for dietary risk assessment for plants and a residue definition for compliance and risk assessment for animal commodities.	**Australia**
Canada acknowledges that all MRLs are being recommended for withdrawal based on the lack of information to establish a residue definition for risk assessment.	**Canada**
The EU **supports the proposed withdrawal** of the MRLs for all commodities. In addition, the EU recommends deleting diazinon from the priority list of pesticides for evaluation.	**EU**

027 DIMETHOATE/
055 OMETHOATE

COMMENT	MEMBER/OBSERVER
Australia notes the JMPR identified an acute exposure risk associated with oranges. Australia supports advancement of the MRLs other than oranges to Step 5/8	**Australia**
Canada has no objection to the JMPR recommended MRLs for the new uses of either active ingredient.	**Canada**
Dimethoate (027) / Omethoate (055) (addendum) The EU **introduces a reservation** to the advancement of the proposed draft MRLs the following commodities due to several health concerns identified in the European Food Safety Authority peer review, including possible genotoxicity of dimethoate and its metabolite omethoate: - **Mandarins, subgroup of,** - **Avocado,** - **Brussels sprouts,** - **Tomato,** - **Yard-long bean (pods),** - **Dry beans, subgroup of (except soya bean),** - **Rape seed,** - **Wheat,** - **Edible offal (mammalian),** - **Mammalian fats (except milk fats),** - **Meat (from mammals other than marine mammals),** - **Milks,** - **Eggs,** - **Poultry fats,** - **Poultry meats,** - **Poultry, Edible offal of.** In a recent EU assessment, a genotoxicity concern could not be excluded for residues to which consumers will be exposed. In the absence of EU toxicological reference values for metabolite dimethoate and its metabolite omethoate a reliable EU risk assessment cannot be conducted. The EU **opposes the advancement** of the proposed draft MRLs for: - **Oranges, subgroup of** since a short-term exposure exceedance of the acute reference dose was indicated by JMPR.	**EU**
STMRchronic or STMR-Pchronic (mg/kg) It would be better to define chronic as a subscript, below the table.	**ICUMSA**

COMMENT	MEMBER/OBSERVER
Dimethoate(027)/Omethoate(055) FC 0004: Oranges, subgroup of (a) (a)On the basis of the information provided to the JMPR it was concluded that the estimated acute dietary exposure to residues of dimethoate and omethoate for the consumption of commodities in the subgroup of oranges may present a public health concern Comment: FMC replicated the JMPR's 2022 estimation of Dimethoate/Omethoate's short-term intake (known as International Estimate of short-Term Intake, IESTI) for orange subgroups using the JMPR IESTI Calculator (JMPR, 2018). For the Subgroup of Oranges, sweet, sour (incl orange-like hybrids) (FC0004), the highest reside (HR) input for total processing was 0.4 mg/kg as indicated in the JMPR's recommendation document (JMPR, 2022a). Using an acute reference dose (aRfD) of 0.02 mg/kg body weight/day as JMPR affirmed in the 2019 (JMPR, 2022b), Subgroup of Oranges displayed intake levels of 120% of the aRfD, indicating potential risk. JMPR determined the aRfD based on the No Observed Adverse Effect Level (NOAEL) of 2 mg/kg body weight, identified in a study of acute neurotoxicity in rats (JMPR, 2022b) and the uncertainty factor (UF) of 100, accounting for a 10-fold difference between species and a 10-fold difference within the human population. To evaluate realistic difference between rats and humans, FMC sponsored PBPK experts to develop rat and human physiologically-based pharmacokinetic/pharmacodynamic (PBPK/PD) models for dimethoate, including an extensive data collection program to measure key model parameters. These models are utilized to propose modifications to the standard uncertainty factors for interspecies extrapolation and estimated points of departure (PODs) for risk assessment. The suite of PBPK models includes an adult rat, post-natal rat, and human model. The general modelling strategy was to collect data on key parameters that influence dimethoate pharmacokinetics and AChE inhibition for both rats and humans, demonstrate the ability of the rat models to predict measured dimethoate and omethoate time courses in blood following dimethoate exposures, apply any fitting required in the rat models to the human model, and use the human model to estimate PODs for risk assessment. This PBPK study report (MRID51466401) has been submitted to U.S. EPA in 2022. The results from the PBPK modelling highlighted the robustness and accuracy of the rat models, as validated by sensitivity analysis. These models successfully demonstrate the feasibility of applying the human model for estimation of Points of Departure (PODs) in risk assessment, using the human-specific parameters incorporated within the human PBPK/PD model. Following these results, FMC proposes that a significant reduction in the standard interspecies uncertainty factor is possible, taking it from 10X down to just 1X. With this reduced UF of 10, FMC recalculated the Dimethoate/Omethoate IESTI using the JMPR calculator. This recalculation indicated that the Subgroup of Oranges exhibited only 10% of aRfD, suggesting that the Subgroup of Oranges does not pose a health risk when a realistic interspecies difference is considered in the JMPR IESTI assessment. References: World Health Organization Joint FAO/WHO Meeting on Pesticide Residues (JMPR). (2022a). Request for comments at Step 3 on the recommendations of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). World Health Organization Joint FAO/WHO Meeting on Pesticide Residues (JMPR) (2022b). Dimethoate(027) / Omethoate(055) of Dimethoate Appraisal Draft 4 (Chapter 5). World Health Organization Joint FAO/WHO Meeting on Pesticide Residues (JMPR) (2018) Joint FAO/WHO Meeting on Pesticide Residues (JMPR) IESTI Calculator ("JMPR_IESTI_calculation18_model.xls"). Reiss, R., & Loccisano, A. (2021). Physiologically-Based Pharmacokinetic/Pharmacodynamic (PBPK/PD) Models for Dimethoate (MRID No. 51466401). Exponent, Alexandria, VA. Sponsor Study/tracking No.: 2018CON-DMT4399. Sponsored by FMC Co	**CropLife International**

050 MANCOZEB (050)/
105 DITHIOCARBAMATES

COMMENT	MEMBER/OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	**Australia**
Canada has no objection to the JMPR recommended MRLs.	**Canada**
The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities pending the ongoing review of MRLs in the EU: - **Cottonseed,** - **Longan,** - **Maize,** - **Rice, husked,** - **Soya bean.** Based on the outcome of the ongoing evaluation, this reservation could be revised.	**EU**

051 METHIDATHION

Noting that the JMPR was unable to reach a conclusion on the residue definitions for compliance with the MRL and dietary risk assessment for animal commodities, Australia supports the withdrawal of MRLs for methidathion	**Australia**
Canada acknowledges that JMPR could not reach a conclusion on the residue definition for animal commodities, sufficient residue data for metabolites were not available and that no dietary risk assessment was conducted.	**Canada**
The EU **supports the proposed withdrawal** of the MRLs for the following commodities: - **Apple,** - **Cherries, Subgroup of,** - **Grapes,** - **Mandarins (including mandarin like hybrids) (subgroup),** - **Tea, green, black (black, fermented, and dried).** In addition, the EU recommends deleting methidathion from the priority list of pesticides for evaluation.	**EU**

064 QUINTOZENE

COMMENT	MEMBER/OBSERVER
Australia supports the withdrawal of the MRLs noting the JMPR was unable to conclude on a residue definition for dietary risk assessment for plants and a residue definition for compliance and risk assessment for animal commodities.	**Australia**
Canada acknowledges that JMPR was unable to establish a reside definition for compliance with MRLs for animal commodities and also unable to reach a conclusion on residue definition for dietary risk assessment for plant and animal commodities. Furthermore, exposure to some metabolites exceed the TTC for genotoxicity. Due to all these concerns, no MRLs were recommended.	**Canada**
The EU **supports the proposed withdrawal** of the MRLs for all commodities. In addition, the EU recommends deleting quintozene from the priority list of pesticides for evaluation.	**EU**

138 METALAXYL

Australia supports the advancement to step 5/8 of MRLs for pineapple and ginseng	**Australia**
Canada has no objection to the JMPR recommended MRLs for pineapple and ginseng.	**Canada**
The EU **supports the advancement** of the proposed draft MRLs for the following commodities: - **Pineapple** - **Ginseng, dried including red ginseng.**	**EU**

178 BIFENTHRIN

Noting that the JMPR identified an acute exposure risk associated with pome fruit and peach, Australia does not support advancement of the MRLs for those commodities. We support advancement of the MRL for avocado, peanut, pomegranate, eggplant, peppers and peppers chili (dry) to Step 5/8.	**Australia**
Canada has no objection to the JMPR recommended MRL for the new uses.	**Canada**
The estimated acute dietary exposure to residues of bifenthrin for the consumption of Peaches, Subgroup of and Pome fruit, Group of (except Japanese persimmon) may present a public health concern.	**Egypt**
The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities pending the ongoing review of MRLs in the EU for certain non-approved substances for which the toxicological reference values do not comply with the current scientific standards: - **Avocados,** - **Peanuts,** - **Pomegranate,** - **Eggplant, subgroup of,** - **Peppers, Subgroup of (except okra, martynia and roselle).** The EU **opposes the advancement** of the proposed draft MRLs for - **Group of Pome fruits (except Japanese persimmon),** - **Peaches, subgroup of,** since a short-term exposure exceedance of the acute reference dose was indicated by JMPR.	**EU**

208 FAMOXADONE

COMMENT	MEMBER/OBSERVER
Australia supports advancement of the MRLs to Step 5/8	**Australia**
Canada supports the JMPR recommended MRL for caneberries and acknowledges that the recommended MRL for tomatoes is based on a different GAP.	**Canada**
The EU **supports the advancement** of the proposed draft MRLs for the following commodities: - **Hops, dried,** - **Tomato.** For the proposed MRL on **hops**, the EU notes that there is a need to check details in JMPR evaluation if the application rate (2x) was made for all individual applications and whether the other GAP parameters are matching in the residue trials. For the proposed MRL on **tomatoes**, the EU notes that there is a need to check details in JMPR evaluation on the representativeness of the residue trials supporting the GAP. The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities: - **Bulb onions, subgroup of,** - **Cane berries, subgroup of,** - **Fruiting vegetables - cucurbits, subgroup of,** - **Peppers, chili,** - **Peppers, sweet.** For the proposed MRLs on **peppers, chili** and **pepper, sweet**, an acute consumer risk has been identified for European consumers. For the proposed MRL on **fruiting vegetables, cucurbits, subgroup of**, the proposed number of residue trials for summer squashes used to derive the MRL is insufficient for major crops, according to the Information Document on the Application of the Guidance to Facilitate the Establishment of MRLs for Pesticides for Minor Crops (referred to in Annex D to the Risk Analysis Principles applied by the Codex Committee on Pesticide Residues, Codex Procedural Manual). Therefore, the EU invites JMPR to consider deriving a separate Codex MRL for cucumbers, based on the available residue trials on cucumbers, and for summer squashes, based on the available residue trials on summer squashes. The EU notes that, for **bulb onions, subgroup of,** and **cane berries, subgroup of**, the residue trials are not representative of the presented good agricultural practices (GAP).	**EU**

211 FLUDIOXONIL

COMMENT	MEMBER/OBSERVER
Australia supports advancement of the MRLs to Step 5/8	**Australia**
Canada acknowledges that the lower recommended JMPR MRLs for legume vegetables and pulses are based on a different cGPA and different data, respectively.	**Canada**
The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities, pending the outcome of the ongoing periodic re-evaluation in the EU: - **Banana,** - **Beans with pods, subgroup of,** - **Dry beans, subgroup of,** - **Dry peas, subgroup of,** - **Edible offal, mammalian,** - **Mango,** - **Mammalian fats (except milk fats),** - **Meat (from mammals other than marine mammals),** - **Milks,** - **Papaya,** - **Peas with pods, subgroup of,** - **Sugar beet**, - **Tree nuts (except Canarium nut, Chilean hazelnut, and pistachios).** Based on the outcome of the ongoing evaluation, this reservation could be revised. For tree nuts **(except Canarium nut, Chilean hazelnut, and pistachios)**, the combined data set for almonds and pecan nuts should be used for deriving the MRL. Therefore, the EU invites JMPR to review the Codex MRL proposal. This is supported by a Mann-Whitney U-Test.	**EU**

216 INDOXACARB

COMMENT	MEMBER/OBSERVER
Australia supports advancement of the MRLs to Step 5/8	**Australia**
Canada has no objection to the JMPR recommended MRLs for the new uses. Indoxacarb is not registered for use in Canada, nor have any import MRLs been established.	**Canada**
The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities: - **Bushberries, Subgroup of,** - **Beans with pods, Subgroup of (except soya bean),** - **Beans, dry, Subgroup of (except cowpea, mung bean and soya bean),** - **Beetroot,** - **Milks,** - **Edible offal (Mammalian),** - **Mammalian fats (except milk fats),** - **Meat (from mammals other than marine mammals),** - **Maize cereals, Subgroup of,** - **Tree nuts.** An acute risk with the CXL for **bushberries, beans with pods, beetroot, milks, and swine meat** was identified for EU consumers. For **beans (dry), maize cereals**, **tree nuts, mammalian edible offal, fats, and meat,** safety could not be confirmed due to the uncertainties on the toxicity and genotoxicity metabolites and degradation products (IN-P0036, KT413, IN-MP819, IN-TMG00 and IN-MK638) formed during sterilization and processing at high temperature. The EU notes that it has submitted a concern form asking for prioritization of the periodic review of indoxacarb, based on concerns with the existing toxicological reference values last evaluated in 2005.	**EU**

224 DIFENOCONAZOLE

COMMENT	MEMBER/OBSERVER
Australia supports advancement of the MRLs to Step 5/8	**Australia**
Canada has no objection to the JMPR recommended MRLs for the new uses.	**Canada**
Difenoconazole (224) R The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities pending the outcome of the ongoing periodic re-evaluation in the EU: - **Goji berry,** - **Group of fruiting vegetables,** - **other than cucurbits (except peppers, chili),** - **Group of fruiting vegetables other than cucurbits (except goji berry and pepper, chili),** - **Pencil yam,** - **Ginger, rhizome,** - **Tea, green, black (black, fermented, and dried).** Based on the outcome of the ongoing evaluation, this reservation could be revised. The EU notes that an assessment strategy for triazole derivatives metabolites (TDMs) is applicable in the EU. Residue definitions for risk assessment and toxicological reference values have been revised. The EU notes that an assessment for TDMs has not been carried out for difenoconazole.	**EU**

229 AZOXYSTROBIN

Australia supports advancement of the MRLs to Step 5/8	**Australia**
Canada has no objection to the JMPR recommended MRLs for the new uses.	**Canada**
The EU **supports the advancement** of the proposed draft MRLs for the following commodities: - **Mango** - **Papaya,** - **Sugar beet,** - **Root and tuber vegetables, Group of (except potato and sugar beet).**	**EU**

230 CHLORANTRANILIPROLE

Australia supports advancement of the MRLs to Step 5/8	**Australia**
Canada has no objection to the JMPR recommended MRLs for the new uses.	**Canada**
The EU **supports the advancement** of the proposed draft MRLs for the following commodities: - **Avocado,** - **Tea, green, black (black, fermented, and dried).**	**EU**

231 MANDIPROPAMID

COMMENT	MEMBER/OBSERVER
Australia supports advancement of the MRLs to Step 5/8	**Australia**
Canada has no objection to the JMPR recommended MRLs.	**Canada**
The EU **supports the advancement** of the proposed draft MRLs for the following commodities: - **Basil, leaves,** - **Fruiting vegetables, Cucurbits - Cucumber and Summer squashes, Subgroup of Fruiting vegetables, Cucurbits,** - **Melons, Pumpkins and Winter squashes, Subgroup of,** - **Peppers, Subgroup of (except Martynia, Okra and Roselle),** - **Tomatoes, subgroup of.** The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities: - **Bulb Onions, Subgroup of,** - **Eggplants, Subgroup of,** - **Ginseng dried including red ginseng**. For **bulb onions, Subgroup of**, and **ginseng, dried, including red ginseng**, an evaluation concerning toxicological properties of metabolites of concerns for root crops groups is currently ongoing. Based on the outcome of the ongoing evaluation, this reservation could be revised. For **eggplants**, **Subgroup of,** the EU notes that JMPR proposed the extrapolation from residue trials in sweet peppers and not from tomatoes, but this extrapolation is not in line with the Codex extrapolation rules. Therefore, the EU recommends reviewing the proposed Codex MRL. Extrapolation rules depend on representative commodities in the entire group or subgroup, i. e., one cultivar of large variety eggplant and/or tomato and one cultivar of small variety eggplant and/or tomato.	**EU**

247 EMAMECTIN BENZOATE

COMMENT	MEMBER/OBSERVER
Australia supports advancement of the MRLs to Step 5/8	**Australia**
In Canada, emamectin benzoate is regulated as a veterinary drug and is not currently registered for use as an agricultural chemical on food crops.	**Canada**
The EU **supports the advancement** of the proposed draft MRLs for the following commodities: - **Basil, leaves,** - **Brassica leafy vegetables, subgroup of,** - **Chives,** - **Mammalian fats (except milk fats),** - **Meat (from mammals other than marine mammals),** - **Edible offal (mammalian),** - **Spinach,** - **Soya bean (dry),** - **Tea, Black, Green, dried and fermented.** The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities: - **Flowerhead brassicas, subgroup of,** - **Milks.** The critical GAP in Italy is for uses authorized on broccoli and cauliflower separately, which leads to separate MRL values for broccolis (0.007 mg/kg) and cauliflowers (0.002 mg/kg). For milks, based on the results of feeding studies, a lower value of 0.001* mg/kg should be set.	**EU**

248 FLUTRIAFOL

COMMENT	MEMBER/OBSERVER
Australia supports advancement of the MRLs to Step 5/8	**Australia**
Canada has no objection to the JMPR recommended MRLs for the new uses.	**Canada**
The EU **supports the advancement** of the proposed draft MRLs for the following commodities: - **Almonds,** - **Barley,** - **Edible offal, mammalian,** - **Eggs,** - **Mammalian fats (except milk fat),** - **Meat (from mammals other than marine mammals),** - **Milks,** - **Poultry, edible offal of,** - **Poultry fats,** - **Poultry meat,** - **Rice, husked.** The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities - **Rice.** The EU notes that the proposed draft MRL is based on an Italian GAP, which is no longer supported. Therefore, the EU recommends CCPR to retain the draft MRL at step 4 and invite its members to send other GAPs supporting the proposed MRL or fallback GAPs allowing to derive a new proposal for an MRL. The EU notes that an assessment strategy for triazole derivatives metabolites (TDMs) is applicable in the EU. Residue definitions for risk assessment and toxicological reference values have been revised. The EU notes that an assessment for TDMs has not been carried out for flutriafol.	**EU**

252 SULFOXAFLOR

Australia supports advancement of the MRLs to Step 5/8.	**Australia**
Canada has no objection to the recommended JMPR MRLs for globe artichoke and subgroup of sunflower seeds.	**Canada**
Sulfoxaflor (252) The EU introduces a **reservation to the advancement** of the proposed draft MRLs pending the outcome of an ongoing evaluation in the EU for the following commodities: - **Globe artichoke,** - **Sunflower seeds, Subgroup of.** Based on the outcome of the ongoing evaluation, this reservation could be revised.	**EU**

261 BENZOVINDIFLUPYR

COMMENT	MEMBER/OBSERVER
Australia supports advancement of the MRLs to Step 5/8	**Australia**
Canada has no objection to the JMPR recommended MRLs for the new uses. The difference in MRLs for blueberries are based on a different timing of application (Canada: dormant; JMPR: pre-harvest)	**Canada**
The EU **supports the advancement** of the proposed draft MRLs for the following commodities: - **Blueberries,** - **Ginseng, dried including red ginseng,** - **Maize.**	**EU**

285 FLUPYRADIFURONE

Australia supports advancement of the MRLs to Step 5/8	**Australia**
Canada has no objection to the JMPR recommended MRLs for the new uses.	**Canada**
The EU **supports the advancement** of the proposed draft MRLs for the following commodities: - **Pineapple,** - **Sunflower seeds (subgroup),** - **Sesame seed.**	**EU**

287 QUINCLORAC

Australia supports advancement of the MRLs to Step 5/8	**Australia**
Canada acknowledges that the lower recommended JMPR MRL for canola is based on a different residue definition and different data.	**Canada**
The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities: - **Cranberries,** - **Rape seeds.** The EU reiterates the recommendation of including the metabolite quinclorac methyl ester in the residue definition for enforcement. Quinclorac methyl ester could be also a variant of the active substance used in plant protection products. If the use of quinclorac methyl ester is authorized, then more toxic methyl ester residues could be generated. Based on the available information from the JMPR evaluations it is not possible to conclude if the use of quinclorac methyl ester is authorized. The EU invites to quinclorac sponsor to clarify if the formulations placed on the market contain quinclorac methyl ester.	**EU**

294 SPIROMESIFEN

COMMENT	MEMBER/OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	**Australia**
Canada has no objection to the recommended JMPR MRLs but acknowledges that the lower MRL for dry beans subgroups is based on different data.	**Canada**
The EU **supports the advancement** of the proposed draft MRLs for the following commodities: - **Subgroup of oranges, Sweet, Sour,** - **Mango,** - **Papaya,** - **Beans with pods (Phaseolus spp.) immature pods and succulent seeds),** - **Beans without pods (Phaseolus spp.) (succulent seeds),** - **Dry beans, subgroup.**	**EU**

297 FENAZAQUIN

COMMENT	MEMBER/OBSERVER
Australia supports advancement of the MRLs to Step 5/8	**Australia**
Canada has no objection to the JMPR recommended MRLs for the new uses. The minor differences are due to a difference in application of the crop group/subgroup principle. Fenazaquin was recently registered in Canada. See PRD2022-11 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-registration-decisions/2022/fenazaquin-magister-sc-miticide-fungicide-magus.html) and RD2023-02 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates.html) for additional details.	**Canada**
The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities pending the outcome of the ongoing periodic re-evaluation in the EU, and due to diverging residue definitions: - **Lemons and Limes (inc. citron), Subgroup of,** - **Oranges, Sweet, Sour (incl.** - **orange-like hybrids), Subgroup of,** - **Pummelo and Grapefruits (incl. Shaddock-like hybrids, among other Grapefruit), Subgroup of,** - **Mandarins (incl. Mandarin-like hybrids), Subgroup of,** - **Apples,** - **Plums, Subgroup of,** - **Peaches (incl. Nectarine and Apricots), Subgroup of,** - **Cane berries, Subgroup of,** - **Bush berries, Subgroup of,** - **Small fruit vine climbing, Subgroup of,** - **Low growing berries, Subgroup of,** - **Avocado,** - **Fruiting vegetables, Cucurbits, Group of,** - **Tomatoes, Subgroup of,** - **Peppers, Subgroup of (except martynia, okra and roselle),** - **Eggplants, Subgroup of,** - **Edible offal (Mammalian),** - **Mammalian fats (except milk fats),** - **Meat (from mammals other than marine mammals),** - **Milks.** Based on the outcome of the ongoing evaluation, this reservation could be revised. The residue definition for risk assessment in the EU includes the more toxic metabolite TBPE. Additionally, an acute risk with the CXL for **peaches** was identified for EU consumers.	

312 AFIDOPYROPEN (312)

COMMENT	MEMBER/OBSERVER
Australia supports advancement of the MRLs to Step 5/8	**Australia**
Canada has no objection to the JMPR recommended MRLs for the new uses.	**Canada**
The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities based on the lack of available toxicological data at EU level and pending the outcome of the review by the EU of the JMPR evaluation: - **Edible offal (mammalian),** - **Eggs,** - **Mammalian fats (except milk fats),** - **Meat (from mammals other than marine mammals),** - **Milks,** - **Poultry, edible offal of,** - **Poultry, fats,** - **Poultry, meat,** - **Sorghum,** - **Strawberries.** Based on the outcome of the ongoing evaluation, this reservation could be revised. Additionally, the EU notes that the RD for enforcement should be reconsidered for **muscle/meat** and **milk**, as parent compound is considered not a valid marker substance based on livestock metabolism and feeding studies. Based on the residue trials reported, the OECD MRL calculator suggests a lower MRL of 0.15 mg/kg for **sorghum**, instead of 0.2 mg/kg, and 0.1 mg/kg for strawberries, instead of 0.15. For some feed items, the commodity description does not comply with the new classification agreed in 2021 (e.g., AL 1020 – Alfalfa, fodder, instead of Alfalfa, hay and/or straw, AL 1031 – Clover, fodder, instead of Clover, hay and/or straw, AS 0162 – Grass, hay instead of Hay and/or straw of grasses for animal feed. As regards sorghum feed, it seems more appropriate to set the CXL for sorghum stover (code AS 3561) as the MRL refers to the dry product. Hence, the commodity code should be corrected (AS 0651 refer to sorghum, forage (green)).	**EU**

315 PYRIDATE

COMMENT	MEMBER/OBSERVER
Canada acknowledges that the 2022 Meeting was unable to recommend residue definitions for dietary risk assessment for plants and animal commodities, chronic and acute dietary risk assessments could not be conducted. Pyridate was recently registered in Canada. See PRD2021-04 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-registration-decisions/2021/pyridate/document.html) and RD2021-09 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/registration-decision/2021/pyridate.html) for additional details.	**Canada**

317 TRIFLUMURON

COMMENT	MEMBER/OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	**Australia**
Canada has no objection to the JMPR recommended residue definitions and MRLs. Triflumuron is not registered for use in Canada, nor have any import MRLs been established.	**Canada**
The EU **supports the advancement** of the proposed draft MRLs for the following commodities: - **Soya bean (dry),** - **Milks,** - **Edible offal (Mammalian),** - **Meat (from mammals other than marine mammals),** - **Mammalian fats (except milk fats).** For **soya bean (dry)**, JMPR is invited to provide additional clarification on the conversion factor for M02 used in the calculation performed to obtain the STMR. For the sake of transparency, the EU invites JMPR to consider preparing an addendum to the JMPR Monograph presenting the new information on triflumuron metabolites that were assessed by JMPR in 2022.	**EU**

320 MEFENTRIFLUCONAZOLE

COMMENT	MEMBER/OBSERVER
With the exception of the MRLs for Leafy greens and Leaves of Brassicacea for which the JMPR identified acute intake concerns, Australia supports advancement of the MRLs to Step 5/8.	**Australia**
Mefentriflucoanzole (320)* Canada has no objection to the JMPR recommended ADI, ARfD, Residue Definitions and MRLs. Mefentrifluconazole was recently registered in Canada. See PRD2019-09 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-registration-decisions/2019/mefentrifluconazole/document.html) and RD2019-17 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/registration-decision/2019/mefentrifluconazole.html) for additional details.	**Canada**
In the table, row CM 0649 is duplicated. On row: AL 0541, Soya bean, hay and/or straw: the value for HR or HR-P is 12 and according to the JMPR annual report, it should be 13.	**CropLife International**

<table>
<tr><th>COMMENT</th><th>MEMBER/OBSERVER</th></tr>
<tr><td colspan="2">The EU <u>supports the advancement</u> of the proposed draft MRLs for the following commodities:</td><td rowspan="4">EU</td></tr>
<tr><td>- Lemons and Limes (including Citron), Subgroup of,
- Mandarins (including Mandarin-like hybrids), Subgroup of,
- Oranges, Sweet, Sour (including Orange-like hybrids), Subgroup of,
- Pummelo and Grapefruits (including Shaddock-like hybrids, among others Grapefruit), Subgroup of,
- Cherries, Subgroup of,
- Plums (including fresh Prunes), Subgroup of,
- Peaches (including Nectarine and Apricots), Subgroup of,
- Cane berries, Subgroup of,
- Bush berries, Subgroup of,
- Elderberries,
- Guelder rose,
- Wine grapes,
- Low growing berries, Subgroup of,
- Avocado,
- Banana,
- Mango,
- Papaya,
- Bulb Onions, Subgroup of,
- Green Onions, Subgroup of,
- Fruiting vegetables, Cucurbits - Cucumbers and Summer squashes, Subgroup of,
- Fruiting vegetables, Cucurbits – Melons, Pumpkins and Winter Squashes, Subgroup of,
- Tomatoes, Subgroup of,
- Peppers, Subgroup of (except martynia, okra and roselle),
- Eggplants, Subgroup of,</td><td>- Beans with pods, except soya bean (succulent seeds in pods), Subgroup of,
- Peas with pods, Subgroup of,
- Succulent beans without pods, except soya bean (succulent seeds), Subgroup of,
- Succulent peas without pods, Subgroup of,
- Dry beans, except soya bean (dry), Subgroup of,
- Dry peas, except lentil (dry), Subgroup of,
- Lentil (dry),
- Soya bean (dry),
- Root vegetables, except sugar beet, Subgroup of,
- Tuberous and corm vegetables, Subgroup of,
- Rye,
- Triticale,
- Wheat,
- Barley,
- Oats,
- Rice, husked,
- Millet,
- Sorghum Grain,
- Maize,
- Sweet corn (Corn-on-the-cob) (kernels plus cob with husk removed),
- Small seed oilseeds, Subgroup of,
- Sunflower seeds, Subgroup of,
- Cottonseed, Subgroup of,
- Peanut,
- Coffee bean.</td></tr>
<tr><td colspan="2">The EU notes that an assessment strategy for triazole derivatives metabolites (TDMs) is applicable in the EU. Residue definitions for risk assessment and toxicological reference values have been revised. The EU notes that an assessment for TDMs has not been carried out for mefentrifluconazole.

The EU introduces a <u>reservation to the advancement</u> of the proposed draft MRLs for the following commodities:</td></tr>
</table>

COMMENT	MEMBER/OBSERVER
- **Pome fruits except persimmon, Japanese, Group of,** - **Tree nuts, Group of,** - **Sugar cane,** - **Milks,** - **Meat (from mammals other than marine mammals),** - **Edible offal (mammalian),** - **Mammalian fats (except milk fats),** - **Eggs,** - **Poultry, edible offal,** - **Poultry, fats,** - **Poultry, meat.**	
For **pears**, an acute consumer risk has been identified for European consumers. **Pistachios** should be excluded from the tree nut group as the good agricultural practice is different from other tree nuts and the number of residue trials used to derive the MRL is insufficient, according to the Information Document on the Application of the Guidance to Facilitate the Establishment of MRLs for Pesticides for Minor Crops (referred to in Annex D to the Risk Analysis Principles applied by the Codex Committee on Pesticide Residues, Codex Procedural Manual). For **sugar cane**, no analytical method is available. The reservation could be lifted, once the JMPR evaluation could be checked concerning this item. For **animal commodities**, the EU residue definition is not compatible with JMPR's The EU **opposes the advancement** of the proposed draft MRLs for the following commodities: - **Leafy greens, Subgroup of,** - **Leaves of Brassicaceae, Subgroup of.** Short-term exposure exceedances of the ARfD were indicated by JMPR for several crops of leafy greens and leaves of brassica, subgroup of.	

324 TETRANILIPROLE

<table>
<tr><th>COMMENT</th><th>MEMBER/OBSERVER</th></tr>
<tr><td colspan="2">Australia supports advancement of the MRLs to Step 5/8.</td><td>Australia</td></tr>
<tr><td colspan="2">Canada has no objection to the JMPR recommended ADI, ARfD, residue definitions and MRLs. Tetraniliprole was recently registered in Canada. See PRD2019-14 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-registration-decisions/2019/tetraniliprole/document.html) and RD2020-04 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/registration-decision/2020/tetraniliprole.html) for additional details.</td><td>Canada</td></tr>
<tr><td colspan="2">The EU introduces a <u>reservation to the advancement</u> of the proposed draft MRLs for the following commodities based on the lack of available toxicological data at EU level:</td><td rowspan="3">EU</td></tr>
<tr><td>1. Cabbages, head,
2. Cherries, subgroup of,
3. Edible offal (mammalian),
4. Eggs,
5. Flowerhead Brassicas, subgroup of,
6. Fruiting vegetables, other than Cucurbits, Group of, excluding okra, martynia and roselle,
7. Leaves of Brassicaceae, Subgroup of,
8. Lemons and Limes (including Citron), Subgroup of,
9. Maize cereals, Subgroup of,
10. Mammalian fats,
11. Mandarins (including Mandarin-like hybrids), Subgroup of,
12. Meat from mammals other than marine mammals,
13. Milks,
14. Oranges, Sweet, Sour (including Orange-like hybrids), Subgroup of,</td><td>15. Peaches (including Nectarines and Apricots), Subgroup of,
16. Plums, Subgroup of,
17. Pome fruits, Group of, excluding Japanese persimmon,
18. Poultry, edible offal,
19. Poultry fat,
20. Poultry meat,
21. Pummelos and Grapefruits (including Shaddock-like hybrids, among others grapefruit), Subgroup of,
22. Rice, husked,
23. Small fruit vine climbing, Subgroup of,
24. Soya bean (dry),
25. Sweet Corn (corn-on-the-cob),
26. Tree nuts, Group of,
27. Tuberous and corm vegetables, Subgroup of,
28. Peppers, Chili, dried.</td></tr>
<tr><td colspan="2">Based on the JMPR monograph for CCPR 2021, the EU will perform a more detailed assessment of the compound and based on the outcome, this reservation could be revised.

In addition, the EU notes that for mandarins (including Mandarin-like hybrids), Subgroup of, the proposed Codex MRL is not acceptable because the number of residue trials is insufficient according to the Information Document on the Application of the Guidance to Facilitate the Establishment of MRLs for Pesticides for Minor Crops (referred to in Annex D to the Risk Analysis Principles applied by the Codex Committee on Pesticide Residues, Codex Procedural Manual).

For poultry, edible offal, poultry fat, and poultry meat, the proposed residue definition for enforcement is not acceptable as it does not include tetraniliprole-despyridyl-N-methyl-quinazolinone a major metabolite in eggs and fat that was also found in liver and muscle

For tree nuts, Group of, the OECD MRL calculator derives a lower MRL of 0.02 mg/kg.</td></tr>
</table>

325 BENZPYRIMOXAN

COMMENT	MEMBER/OBSERVER
Canada has no objection to the JMPR recommended ADI and ARfD. Benzpyrimoxan is not registered for use in Canada, nor have any import MRLs been established.	**Canada**

326 BROFLANILIDE

Australia supports advancement of the MRLs to Step 5/8	**Australia**
Canada supports the JMPR recommended ADI, residue definitions and MRLs for cereal grains. All other crop-specific MRLs are different from those established by Canada based on a different critical GAP. Broflanilide has been recently registered in Canada. See PRD2020-06 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-registration-decisions/2020/broflanilide-cimegra-teraxxa/document.html) and RD2020-16 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/registration-decision/2020/broflanilide-cimegra-teraxxa.html) for additional details.	**Canada**
According to EPA evaluation report 2022, Broflanilide is likely to be Carcinogenic in Humans, however it has not been assessed nationally due to the lack of studies and toxicity data.	**Egypt**
The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities based on the lack of available toxicological data at EU level and pending the outcome of the review by the EU of the JMPR evaluation, once available: - **Cabbages, Head,** - **Chinese cabbage, (type Pe-tsai),** - **Coffee bean, green,** - **Edible offal (mammalian),** - **Eggs,** - **Cereal grains, Group of (except rice),** - **Mammalian fats,** - **Meat (from mammals other than marine mammals),** - **Milks,** - **Radish, Japanese,** - **Poultry edible offal,** - **Poultry meat,** - **Poultry fats,** - **Tuberous and corm vegetables, Subgroup of.** Based on the outcome of the JMPR evaluation revision, this reservation could be revised.	**EU**

327 FLUAZAINDOLIZINE

<table>
<tr><th>COMMENT</th><th>MEMBER/OBSERVER</th></tr>
<tr><td colspan="2">Australia supports advancement of the MRLs to Step 5/8</td><td>Australia</td></tr>
<tr><td colspan="2">Canada has no objection to the JMPR recommended ADI, ARfD, residue definitions and MRLs. Fluazaindolizine was recently registered in Canada. See PRD2021-03 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-registration-decisions/2021/fluazaindolizine.html) and RD2021-06 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/registration-decision/2021/fluazaindolizine-salibro-nematicide.html) for additional details.</td><td>Canada</td></tr>
<tr><td colspan="2">The EU introduces a <u>reservation to the advancement</u> of the proposed draft MRLs for the following commodities based on the lack of available toxicological data at EU level:</td><td rowspan="3">EU</td></tr>
<tr><td>- Cucumbers and summer squashes, Subgroup of,
- Melons, pumpkins and winter squashes, Subgroup of,
- Tomato, Subgroup of,
- Eggplant, Subgroup of ,
- Peppers, Subgroup of (except martynia, okra, roselle),
- Carrot,
- Tuberous and corm vegetables, Subgroup of,
- Strawberries,
- Brassica vegetables, Group of (except Brassica leafy vegetables),
- Leafy vegetables, Group of (including Brassica leafy vegetables),
- Legume vegetables, Group of,
- Pulses, Group of,</td><td>- Root vegetables, Group of (except Carrot),
- Stalk and stem vegetables, Group of,
- Bulb vegetables, Group of,
- Cereal grains, Group of,
- Oilseeds and oilfruits, Group of,
- Edible offal (Mammalian),
- Mammalian fats (except milk fats),
- Meat (from mammals other than marine mammals),
- Milks,
- Poultry, Edible offal of,
- Poultry fats,
- Poultry meat.</td></tr>
<tr><td colspan="2">Once the JMPR evaluation would be available, the EU will perform a more detailed assessment of the compound and based on the outcome, this reservation could be revised.

In addition, for melons, pumpkins and winter squashes, Subgroup of the EU notes that the OECD MRL calculator derives a lower MRL.

The EU <u>notes</u> that JMPR derived a Codex MRL for several rotational crops without providing information on the residues in soil and its degradation. Moreover, for processed products the information available is not sufficient to assess whether the non-standard approach used to derive the processing factors is appropriate.</td></tr>
</table>

328 FLUINDAPYR

COMMENT	MEMBER/OBSERVER
Australia supports advancement of the MRLs to Step 5/8	**Australia**
Canada has no objection to the JMPR recommended ADI, ARfD, residue definitions and MRLs. Fluindapyr is not registered for use in Canada, nor have any import MRLs been established.	**Canada**
The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities, based on missing toxicological data at EU level and pending the outcome of the review by the EU of the JMPR evaluation, once available: - **Maize cereals, Subgroup of,** - **Sorghum Grain and Millet, Subgroup of,** - **Sweet corn (corn-on-the cob) (kernels plus cob with husk removed),** - **Tree nuts, Group of,** - **Wheat, similar grains, and pseudo cereals without husks, Subgroup of.** Based on the outcome of this review, this reservation could be revised. Additionally, the EU notes that no suitable analytical method exists to measure fluindapyr in animal commodities. Therefore, no CXLs for animal commodities are proposed, although CXLs for feed items are proposed.	**EU**

329 INPYRFLUXAM

COMMENT	MEMBER/OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	**Australia**
Canada supports the JMPR recommended ADI, ARfD and MRLs. Inpyrfluxam was recently registered in Canada. See PRD2020-10 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-registration-decisions/2020/inpyrfluxam-excalia-zeltera-fungicide/document.html) and RD2020-11 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/registration-decision/2020/inpyrfluxam-excalia-zeltera-fungicide.html) for additional details. Any differences observed in MRLs are mostly based on a difference in residue definition for enforcement or different cGAP.	**Canada**
The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities based on the lack of available toxicological data at EU level: - **Apples,** - **Soya beans,** - **Sugar beet,** - **Husked rice,** - **Maize grain,** - **Sweet corn,** - **Peanut,** - **Meat from mammals other than marine mammals,** - **Mammalian fats,** - **Edible offal (mammalian),** - **Milk,** - **Poultry meat,** - **Poultry fat,** - **Poultry edible Offal,** - **Eggs.** Once the JMPR evaluation would be available, the EU will perform a more detailed assessment of the compound and based on the outcome, this reservation could be revised	**EU**

330 ISOFLUCYPRAM

Canada acknowledges that a conclusion could not be reached on the residue definition for risk assessment for plant and animal commodities and thus MRLs could not be recommended. Isofluypram is not registered for use in Canada, nor have any import MRLs been established.	**Canada**

PART II: CONCERN FORMS

103 Phosmet

Submitted by: *The European Union (RMS Spain)*

Date: *May 2023*

Pesticide/Pesticide Code Number	*Food/Food Code Number*	*CXL (mg/kg)*
103 Phosmet	**All commodities with CXLs:**	**All CXLs**
	Apricot	10 mg/kg
	Blueberries	10 mg/kg
	Cattle meat	1 mg/kg
	Citrus fruits (group)	3 mg/kg
	Cotton seed	0.05 mg/kg
	Cranberry	3 mg/kg
	Grapes	10 mg/kg
	Milks	0.02 mg/kg
	Nectarine	10 mg/kg
	Peach	10 mg/kg
	Pome fruits (group)	10 mg/kg
	Potato	0.05 mg/kg
	Tree nuts (group)	0.2 mg/kg

Is this a concern? *Yes*

The concern relates to which prioritization criterion/criteria (Specific statement of concern)

Phosmet was originally evaluated by the JMPR in 1976 and then several times up to 2014 and was evaluated under the periodic review in 1994 for toxicity and in 1997 for residues. It was evaluated for toxicology in 1994 and 1998 by JMPR (ADI of 0-0.01 mg/kg bw) and for residues in 1997, 2002, 2003, 2007and 2014. The ADI of 0.01 mg/kg bw was established in 1994. The ARfD of 0.2 mg/kg bw was established in 2003. Existing residue definitions for phosmet were set at the 1997 JMPR Meeting. For plant and animal commodities, the residue definition for enforcement and dietary risk assessment is phosmet.

In the EU, during the 2020 Peer Review and 2022 review of MRLs under Article 12 of Regulation (EC) No 396/2005 by the European Food Safety Authority (EFSA) concerns were identified:

- The toxicological reference values were substantially lowered. The new ADI of phosmet is 0.001 mg/kg bw/day based on the NOAEL of 1 mg/kg bw/day based on RBC AChE inhibition from the two-generation reproduction study in the rat and supported by the short-term rat and dog studies and long-term rat studies, by applying an uncertainty factor (UF) of 1000. An additional UF of 10 was applied on the basis of the lack of a developmental neurotoxicity (DNT) study. Based on neurotoxicity results (decreased ChE activity (RBC, plasma, and brain)), and since epidemiological evidence was available from organophosphates (in general), the experts agreed that the developmental neurotoxicity of phosmet should have been further investigated. The ARfD, the AOEL and AAOEL are also 0.001 mg/kg bw (per day), on the same basis as the ADI. The previous toxicological reference values were ADI 0.01 mg/kg bw/day, ARfD 0.045 mg/kg bw and AOEL 0.02 mg/kg bw/day.
- Considering the metabolism studies and the toxicological data available, during the peer review, the residue definition for risk assessment was proposed by EFSA as phosmet, phosmet-oxon and phthalic acid. This residue definition is provisional pending further information on residue occurrence and a toxicological evaluation of phthalic acid and phosmet-oxon, for which a conclusion on the toxicological relevance could not be drawn (EFSA, 2021). It differs from the residue definition set by the JMPR, as phosmet only (FAO, 1998).
- Serious chronic and acute risks were identified for EU consumers, with very high exceedances of the ADI (up to 880 % for Portugal population) and the ARfD (up to 67083 % for table grapes). Therefore, a risk to consumers was identified for the CXLs of phosmet in all citrus fruits, wine and table grapes, coconuts, blueberries, cranberries, kumquats, and potatoes, and even the proposed LOQ of 0.01 mg/kg for potatoes and oranges would not provide a satisfactory level of protection for consumers. Nonetheless, the LOQ of 0.005 mg/kg achievable according to the EURLs, would provide sufficient protection. For the remaining CXLs (tree nuts, except coconuts, and cotton seeds), safety could not be proven due to the data gap on the toxicity and genotoxicity of the metabolite phosmet-oxon.

Therefore, it is considered that a re-evaluation for toxicology and residues of phosmet and all its CXLs is highly necessary, and this task should be prioritized on the JMPR calendar. It was noted that aspects of epidemiology should be included.

Is supporting data being provided? Yes
Data/Information: EFSA (European Food Safety Authority), 2022. *Review of the existing maximum residue levels for phosmet according to Article 12 of Regulation (EC) No 396/2005*. EFSA Journal 2022;20(7):7448 DOI 10.2903/j.efsa.2022.7448 EFSA (European Food Safety Authority), 2021. *Peer review of the pesticide risk assessment of the active substance phosmet.* EFSA Journal 2021;19(3):6237 DOI: 10.2903/j.efsa.2021.6237 EFSA
Is this a continuing concern? No
Outline ongoing concern and provide supporting data

138 Metalaxyl

Submitted by: Ministry of Food and Drug Safety (MFDS), *Republic of Korea*			
Date: 2023. May. 23			
Pesticide/ Pesticide Code Number	***Food/Food Code Number***	***MRL (mg/kg)***	***Present Step***
Metalaxyl	Ginseng	**0.03***	REP22/PR53 Step 5/8 _ adopted at CAC
	Ginseng, dried including red ginseng	**0.06***	included in CL2023/22-PR (Step 3)
	Ginseng, extracts	~~0.2~~ misevaluated ⇒ **0.08**	?
Is this a request for clarification? *YES*			
Request for clarification (Specific statement of clarification requested) Current status of evaluating and setting MRL for 'Ginseng, extracts'			
Is this a concern?			
Is this a continuing concern?			
Concern (Specific statement of reason for concern to the advancementof the proposed MRL) Within the REP22/PR53 of paragraph 56, it stated that "CCPR noted that JMPR would reconsider processing data for ginseng based on data to be submitted by the Republic of Korea ". Since, our submission for *2018 JMPR call for data* made at the end of Dec. 2017 contains 'Ginseng, extracts' as well as 'Ginseng' and 'Ginseng, dried including red ginseng', we - ROK delegates - thought 2022 JMPR report and its relevant CL would cover omitted information, however, we could find only 'Ginseng, dried including red ginseng' in process. We kindly ask you to let us know that there is any specific reason why 'Ginseng, extracts' is excluded.			
Do you wish this concern to be noted in the CCPR Report?			
Data/Information (Description of each separate piece of data/information which will be provided to the appropriate JMPR secretary within one month of the CCPR meeting)			

216 Indoxacarb

Submitted by: *The European Union (RMS France)*		
Date: *May 2023*		
Pesticide/ Pesticide Code Number	***Food/Food Code Number***	***CXL (mg/kg)***
216 Indoxacarb	**All commodities with CXLs:**	**All CXLs**
	Alfalfa fodder	60
	Apple	0.5
	Broccoli	0.2
	Cabbages, head	3
	Cauliflower	0.2
	Chick-pea (dry)	0.2
	Cotton fodder, dry	20
	Cotton seed	1
	Cowpea (dry)	0.1
	Cranberry	1
	Edible offal (mammalian)	0.05
	Egg plant	0.5
	Eggs	0.02
	Fruiting vegetables, cucurbits (group)	0.5
	Grape, dried (= Currants, Raisins, and Sultanas)	5
	Grapes	2
	Lettuce, head	7
	Lettuce, leaf	3
	Maize fodder (dry)	25
	Meat (from mammals other than marine mammals)	2
	Milk fats	2
	Milks	0.1
	Mints	15
	Mung bean (dry)	0.2
	Peanut	0.02
	Peanut fodder	50
	Pear	0.2
	Peppers (subgroup)	0.3
	Potato	0.02
	Poultry meat	0.01
	Poultry, edible offal of	0.01
	Prunes	3
	Soya bean (dry)	0.5
	Stone fruits (group)	1
	Sweet corn (corn-on-the-cob)	0.02
	Tea, green, black (black, fermented, and dried)	5
	Tomato	0.5

Is this a concern? *Yes*

The concern relates to which prioritization criterion/criteria (Specific statement of concern)

Indoxacarb was originally evaluated by the JMPR in 2005 for toxicology and residues data and then several times up to 2022 for residues data only. In 2005 an ADI of 0.01 mg/kg bw and an ARfD of 0.1 mg/kg bw were proposed by JMPR. Existing residue definitions for indoxacarb were also set by JMPR in 2005.

Residue Definitions

The JMPR residue definition for enforcement is "*Sum of indoxacarb and its R-enantiomer*". The residue definition is the same in the EU for plant commodities, however for animal commodities, the EU residue definition also includes the metabolite IN-JT33.

The JMPR residue definition for dietary risk assessment is "sum of indoxacarb and its R-enantiomer" for plant commodities, and "sum of indoxacarb, its R-enantiomer and IN-JT33 expressed as indoxacarb" for animal commodities. In the EU, metabolites KT413, IMMK638, INMK638, IN-P0036, IN MP819 and IN-TMG00 are included for processed commodities of plant origin. For animal commodities, additional metabolites are also included for poultry: IN-JT333, metabolite 'F' (tentatively identified as compound IN-VRN79), IN-KG433 and 5-OH-IN-JT333, and for milk: IN-MP819.

There is insufficient data on the metabolite IN-JT333 included in the JMPR residue definition for risk assessment. The JMPR report does not clearly report whether the metabolite is covered by the TRVs established for the parent. The metabolite is acutely more toxic than indoxacarb, it gave negative results in an adequate battery of genotoxicity studies in vitro and in vivo.

Toxicological reference values

During the Peer Review by the European Food Safety Authority (EFSA, 2018), the EU replaced the previous ADI of 0.006 mg/kg bw per day by a new ADI of 0.005 mg/kg bw per day, based on the NOAEL of 0.5 mg/kg bw per day for maternal toxicity in a developmental toxicity study in rats, and applying an UF of 100.

The previous ARfD of 0.125 mg/kg bw (based on an acute rat neurotoxicity study) was replaced by a new ARfD of 0.005 mg/kg bw, based on the same point of departure as the ADI and applying an UF of 100.

Risk assessment

Acute risks were identified for the following CXLs proposed in 2023 using the new EU TRVs:

- Beetroot: 251% of ARfD
- Milk (cattle): 174% of ARfD
- Currants (red, black, and white): 164% of ARfD
- Beans with pods: 135% of ARfD
- Blueberries: 190% of ARfD
- Gooseberries: 122% of ARfD
- Swine meat: 111% of ARfD
- Processed products:
    - Currants/juice: 331% of ARfD
    - Beetroot/boiled: 195% of ARfD
    - Beans with pods/boiled: 148% of ARfD

Furthermore, EFSA screened the existing CXLs considering the new EU TRVs (EFSA, 2022). Regarding the acute exposure, acute risks were identified for 20 existing CXLs: apples, pears, apricots, cherries, peaches, plums, table and wine grapes, tomatoes, peppers, aubergines, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, broccoli, cauliflower, and lettuce, with exposure exceeding up to 2 188% of the ARfD.

Regarding chronic exposure, chronic risks were identified, with exposure exceeding up to 128% of the ADI.

- Considering that the last toxicological assessment of indoxacarb by JMPR was in 2005, i.e. 18 years ago, and in view of the acute and chronic risks identified by the EU, a re-evaluation for toxicology and residues of indoxacarb and all its CXLs is highly necessary, and this task should be prioritized by JMPR.

Is supporting data being provided? Yes

Data/Information:

EFSA (European Food Safety Authority), 2018. *Peer review of the pesticide risk assessment of the active substance indoxacarb.* EFSA-Q-2015-00023. DOI: 10.2903/j.efsa.2018.5140

EFSA (European Food Safety Authority), 2022. *Targeted Review of the maximum residue levels for indoxacarb*.; EFSA-Q-2022-00178. DOI: 10.2903/j.efsa.2022.7527

Is this a continuing concern? No

Outline ongoing concern and provide supporting data

320 Mefentrifluconazole

Submitted by: USA/ BASF

Date: May 16, 2023

Pesticide/ Pesticide Code Number	Commodity/ Commodity Code Number	MRL (mg/kg)			Present Step
		US	Current CXL	Requested CXL	
Mefentrifluconazole / 320	Lettuce, head / VL 0482	5	--	5	4, but as part of the subgroup of leafy greens (CXL 30) with a footnote indicating the acute exposure may present a public health concern

Is this a Request for Clarification? Yes

Is this a Concern? Yes

Is this a Continuing Concern? No

Concern (Specific statement of reason for concern to the advancement of the proposed MRL).

BASF requested a CXL for head lettuce alone. No request was made for the subgroup of leafy vegetables. JMPR only considered the subgroup including the higher residues for leaf lettuce and spinach, resulting in an exceedance of the acute reference dose. No CXL proposal was made for head lettuce.

Request for Clarification (Specific statement of clarification requested).

BASF is pleased that The Meeting explored the possibility of estimating a subgroup maximum residue level for mefentrifluconazole. However, when this approach resulted in a dietary risk assessment exceeded the acute reference dose, clarification is requested as to why Meeting did not propose a CXL for head lettuce alone, as was requested by BASF?

Do you wish this Concern to be Noted in the CCPR Report? Yes

Data/Information (Description of each separate piece of data/information which is attached or will be provided to the appropriate JMPR secretary within one month of the CCPR meeting.)

BASF requested a Codex MRL for head lettuce for the fungicide mefentrifluconazole based on the US gap. Despite having extensive residue data on the other leafy vegetables, we were aware that only the head lettuce would pass the acute dietary risk assessment of JMPR. The residues in head lettuce are significantly lower than the other leafy lettuce varieties – in fact, both the HR and the median residue values are not within the 5X range preferred by EPA or JMPR for including in a crop group. However, in the recent evaluation, JMPR decided to propose the subgroup of leafy vegetables based on the residues in spinach, thus leading to an exceedance of the acute risk assessment for all leafy vegetables. A comment was submitted requesting consideration of only head lettuce to support at least some of the lettuce growers in the US; however, given the size of the submission and the limited time available to the reviewers, the reviewer likely did not have enough time to consider the request.

From page 28 of the draft appraisal for mefentrifluconazole:

Subgroup of leaft greens

Mefentrifluconazole residues in head lettuce with wrapper leaves, in ranked order were (n = 8): 0.12, 0.27, 0.32, 0.89, 1.30, 1.50, 2.1 and 2.2 mg/kg. Residues in head lettuce without wrapper leaves were <0.01, 0.05, 0.09 and 1.6 mg/kg

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

Mefentrifluconazole in one sample of cos lettuce was 2.3 mg/kg.

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

The Meeting noted that the GAP in the USA covers the subgroup of leafy vegetables and decided to explore the possibility of estimating a subgroup maximum residue level for mefentrifluconazole. The median residues in head lettuce with wrapper leaves, leaf lettuce and spinach differed by more than 5-fold and from the Kruskal-Wallis test, the datasets were not shown to be from the same residue population. Therefore, the Meeting used the spinach dataset to estimate a maximum residue level of 30 mg/kg, an STMR of 8.1 mg/kg and an HR of 18 mg/kg (based on the highest residue of replicate samples) for the Subgroup of leafy greens.

And from the 2022 JMPR Annual Report (mefentrifluconazole - page 473 and 637/640):

The Meeting noted that the acute dietary exposure assessment showed that residues in leafy greens exceeded the ARfD of 0.3 mg/kg bw, at 140 percent for each amaranth leaves, chicory leaves and edible leaved chrysanthemums for Belgian toddlers, 130 percent for raw endive for Dutch children, 240 percent for cooked/boiled endive for Dutch toddlers, 140 percent for head lettuce for Dutch children and 120 percent for leaf lettuce for Dutch children. No alternative GAP was available.

VL 2050	Leafy greens, Subgroup of [a]	30		8.1	18
VL 0054	Leaves of Brassicaceae, Subgroup of [a]	30		6.65	12

[a] **On the basis of the information provided to the JMPR it was concluded that the estimated acute dietary exposure to residues of mefentrifluconazole for the consumption of commodities from the subgroups of Leafy greens and Leaves of Brassicaceae may present a public health concern**