CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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CODEX COMMITTEE ON PESTICIDE RESIDUES

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Comments submitted by European Union

Agenda Item 4a **CX/PR 24/55/3**

Matters arising from FAO and WHO

European Union Competence
European Union Vote

The European Union would like to thank FAO and WHO for the report they have prepared on the various activities, relevant to CCPR, that have taken place.

Agenda Item 5a **Section 2 of the 2023 JMPR Report**

Report on items of general consideration arising from the 2023 JMPR meeting

European Union Competence
European Union Vote

The European Union (EU) would like to provide the following comments on section 2 of the 2023 JMPR Report on general consideration items:

2.1 Developments in dietary exposure methodology for pesticide residues in foods

The EU welcomes the JMPR initiative to improve the long-term dietary risk assessment methodology at Codex level and to harmonise methodologies between different food domains. The EU supports the JMPR decision to explore transition from IEDI to GECDE-mean, which might give a better estimate of the expected dietary exposure of the general population and of specific population groups that may have a higher exposure than the general population.

The EU notes that for the comparison presented in the 2022 report, the results obtained with IEDI and GECDE differed significantly. Also, within a cohort (e.g. children & adolescents), the results differed significantly (e.g., difenoconazole, GECDE mean ranges from 1 to 430% of the ADI) which could give an indication that the surveys do not contain all the relevant food commodities that contribute to the dietary exposure.

The EU also acknowledges that the JMPR investigates both the implementation and modification for the GECDE-high (for the assessment of dietary exposure for chronic and shorter-than-lifetime assessment) and the degree of conservatism of IEDI and GECDE (mean and high). Based on the preliminary results provided by JMPR on GECDE-high, the EU notes that the current chronic exposure estimates are increased by at least a factor of 2, in some cases even 10 or more, compared to the IEDI. The EU suggests that JMPR presents at the next CCPR the outcome of its assessment on the degree of conservatism of IEDI and GECDE (mean and high) and its investigation of implementation options.

The EU identified several points that need to be further addressed, to allow an informed discussion at risk management level whether in future the IEDI methodology can be replaced with the GECDE-mean and whether GECDE-high would be appropriate to assess the less-than lifetime dietary exposure.

i) Points to be addressed for GECDE-mean and GECDE-high model:

- Lack of transparency of GECDE exposure calculations;
- Level of stratification of calculation of exposure assessment: definition of suitable subgroups;
- Definition of a clear protection goal;
- Validation and plausibility check of the model and the consumption data used for the calculations

ii) Additional points for GECDE-high:

- Specification of the exposure duration and/or life stage that should be addressed in a less-than-lifetime assessment;
- Appropriateness of CIFOCOss summary data for less-than-lifetime exposure calculations;
- Need to consider a consumption frequency for chronic high consumers;
- Need to consider the frequency of the use of a pesticide in the individual commodities.

A detailed discussion of these bullet points can be found in the Annex to the EU comments.

It is also noted that at EU level, work has been initiated on the modification of the methodology used for long-term exposure. The European Food Safety Authority (EFSA) is concluding a new revision of the pesticide residue intake model (PRIMo revision 4), in which calculations are performed using mean consumption of the food commodities included in the diet, averaging the consumption for the duration of the food survey. For each relevant population subgroup (country/cohort) the calculation will derive the distribution of the exposure, presenting the mean exposure of the relevant subgroups and higher percentiles (e.g. P95). The percentile that will be the basis for risk management decisions has not yet been agreed.

EFSA will prepare an impact assessment, comparing the level of conservatism of calculations with the current PRIMo methodology (using the point estimate of the mean consumption of the pertinent food commodity of the relevant subgroup of the population, normalised by body weight) and the new PRIMo version, providing the distribution of the exposure estimates for the individual diets.

In future, further modifications of the chronic risk assessment methodology are expected at EU level, aiming at an alignment of the methodology across different food domains is envisaged. Recommendations of the alignment were elaborated in a report of the European Medicines Agency (EMA) and EFSA[1]

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

The EU welcomes the development of the guidance document on the assessment and interpretation of nonlinear toxicokinetics, as being prepared by the dedicated electronic working group (eWG) of JMPR. Toxicokinetic data are helpful in the interpretation of available toxicity studies and can provide support in the design of new ones.

At EU level, hazard classification is an important element to decide on the approval of an active substance. According to the European Chemical Agency (ECHA) the kinetically-derived maximum dose (KMD) approach is not suitable/not appropriate to fulfil the legislative needs for classification and labelling; instead, the maximum tolerated dose (MTD) approach, with inclusion of the non-linear kinetics as complementary information, is considered be the most appropriate methodology to derive selection of the high dose level for toxicological studies.

The EU will welcome more detailed information on the content of the guidance, including information whether the (draft) guidance will be open for commenting.

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

The EU supports the JMPR request to submit correct chemical structures of metabolites and acknowledge the importance of this information to perform in silico analysis to predict genotoxicity.

2.4 Resolving inconsistent assessment of common metabolites.

The EU supports the JMPR request of increasing the efforts in the coordinated submission of pesticides containing common metabolites to facilitate a consistent assessment. The EU suggests the use of metabolism databases, such as

[1] https://www.ema.europa.eu/en/documents/report/ema-efsa-report-development-harmonised-approach-human-dietary-exposure_en.pdf

MetaPath[2], for identification of metabolites that could be also derived from other active substances. The database MetaPath can be updated with information related to metabolism studies for the active substances assessed by JMPR.

2.5 On the rolling submission of data

The EU fully supports the JMPR request to applicants on the correct submission of completed datasets and studies, both published and unpublished, for the toxicological and/or residue evaluations of active substances. The EU agrees with the view of JMPR that a comprehensive, state-of-knowledge assessment requires the timely submission of all relevant information. Incomplete dossiers are leading to inefficiencies, which should be avoided, considering the high workload of JMPR.

Only in 2023, there were two examples (permethrin and fluazinam) of incomplete dossiers that did not permit JMPR to perform a substantive re-evaluation. For active substances scheduled for periodic reviews, sponsors should have sufficient time to generate the necessary studies.

The EU consider that in the interest of efficiency of use of JMPR resources, the submission of incomplete dossiers needs to be avoided, since it leads to delays in the review process of setting new Codex MRLs. The EU suggests to develop an efficient procedure for cases where sponsors of substances scheduled for the periodic review program do not submit complete dossiers, precluding that existing Codex MRLs are maintained in the Codex system and avoiding that the compounds are scheduled at each Meeting, which is binding capacities at JMPR level.

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

The EU welcomes the clarifications provided and have not further comments.

2.7 Enhancement of process

The EU welcomes the feedback of the discussion with the chair of the electronic working group on the Enhancement of CCPR and JMPR Operational Procedures and have not further comments.

2.8 Strategy and timing for JMPR re-evaluation of dithiocarbamates

The EU welcomes the initiative to prioritize the periodic review of dithiocarbamates within the CCPR system and calls the sponsors to contribute with the information requested by JMPR.

The EU is willing to contribute with the expertise gained on the recent MRL review of dithiocarbamates at EU level[3]

[2] https://oasis-lmc.org/products/software/metapath.aspx

[3] Review of the existing maximum residue levels for dithiocarbamates according to Article 12 of Regulation (EC) No 396/2005. https://www.efsa.europa.eu/en/efsajournal/pub/7987

Annex to EU comments on Agenda item 5a
Detailed EU comments on GECDE model

The transition towards the GECDE-mean model based on actual consumption data, instead of summary trade statistics as used in the current GEMS Food based IEDI model mirrors the deterministic methodology used in EU and in many regulatory frameworks globally. However, prior to implementation we recommend to solve some shortcomings regarding the technical procedure:

- Currently, there is lack of transparency, both in how the calculation of the model works and how the results are presented. Background documentation is required as well as a source for the model to allow all stakeholders to conduct and repeat calculations. Moreover, an output format (either electronically or as a Report Annex) sufficient to identify all input data and parameters (residue data, relevant consumption data, involved recipe data) needs to be agreed. For GECDE-mean, an EXCEL-Spreadsheet similar to the current model is considered technically feasible and it would be highly appreciated, if WHO could provide it.

- Prior to implementation, scientific agreement needs to be achieved regarding the level of stratification used in the model. Currently, IEDI focusses on 17 cluster diets from multiple countries. In theory, CIFOCOss consumption data allow consideration of single countries, certain age groups per country (e.g. children) and certain genders by country (e.g. female). When narrowing down the target population too much (e.g. female children aged 0 - 3 years versus all children or even the general population), the robustness of the data decreases due to the much lower number of consumers for each food commodity. In view of potentially 200 population subgroups from approximately 40 countries in the CIFOCOss database, the selection and interpretation of suitable sub-populations becomes challenging. For the long-term ("life-time") dietary assessment, a clear protection goal in terms of description of the desired target population (general population, vulnerable groups or even gender separation) is required by CCPR to allow a proper selection. . Thus the meeting is required to define the protection goal.

- Validation and plausibility check of the model and the underlying CIFOCOss data are required before GECDE-mean is used for decision making. If questionable consumption data are identified, the underlying survey needs to be cross-checked first to verify the values (as it was done for the JMPR IESTI-model). In parallel, the GECDE-mean model itself needs to be reviewed by third parties (e.g. Codex Member States) to ensure that it works as intended.

Regarding GECDE-high, current chronic exposure estimates are increased by at least a factor of 2, in some cases even 10 or more compared to IEDI, based on the preliminary results provided by JMPR. Some major aspects therefore have to be solved prior to implementation:

- One major objective of implementing the GECDE-high is to address potential "less-than-lifetime" dietary risks. Until now, no definition of "less-than-lifetime" was provided which would be suitable to conclude on a proper dietary model to achieve such a risk assessment. The range between the current acute (24h) and chronic (lifetime) exposure models is too broad. WHO is encouraged to specify the desired scenario in more detail in terms of exposure duration (days, week, months, seasons or life stages) and frequency (daily, weekly or longer) before the conclusion on an appropriate model can be drawn.

- The use of high percentiles for 'consumers only' in long-term assessments seems unusual and is not followed for pesticides in the EU or in any other regulatory framework so far. The CIFOCOss database only relies on summary statistics for the consumption while extrapolation of consumption survey data from a very limited number of days per individual (typically two) demands adjustment before using them in long-term assessments. The observed individual mean (OIM) is a simple method with drawbacks ("OIM is still popular because it gives conservative, i.e. too large, estimates of the upper percentiles of the usual intake distribution…", EFSA Supporting publications 2012:EN-300). Given the obvious increase in the model outcome compared to current methods, more sophisticated methodology (e.g. LNN, LNN0 or FFQ assisted methods)[5] is proposed to be explored to address high chronic consumers in sub-lifetime scenarios. If such advanced methodologies are considered scientifically necessary, CIFOCOss summary data might be unsuitable for the desired task to adequately assess less-than-lifetime risks.

- When aiming for chronic high consumers, the consumption frequency becomes a major aspect, but is still unsolved. Cited sources in the General Item[4], but also case studies in the EFSA Supporting publications[5] were based on single foods or commodity groups with a very high or even daily consumption frequency, whereas the GECDE-high approach targets single individual food commodities, many of them consumed with a frequency of less than 10 %. A similar procedure was considered by EFSA[6], when FoodEx Level 2 grouping (e.g. 'fruits', 'root and tuber vegetables' or 'meats') was successfully tested. Pesticide assessment normally deals with specific commodities (FoodEx level 4 or higher, e.g. potatoes, apples, bovine muscle). More research is required to demonstrate that the GECDE-high assumption on highest reliable percentiles ("HRP") is scientifically justified and can be applied on individual commodity level.

- When it comes to non-central long-term exposure tendencies (mean → high consumer), not only consumption aspects but also conservatism in the occurrence part has to be considered. In case of pesticides, the assumption to combine HRP-based portion sizes for 'consumers only' with median residues (STMR values) is highly conservative. In reality, detection frequencies of pesticides found on the market are very low. In the Electronic Working Group on Cumulative Risk Assessment of EU COM, it was discussed to introduce the 95th percentile of detection frequency from EU Monitoring data, which is 25 %, into prospective probabilistic risk assessments to avoid unnecessary overestimations. In GECDE-high, 100 % occurrence rates are assumed. It needs to be carefully discussed whether such a combination still reflects a conservative, but realistic scenario. For food additives such a conservative approach makes sense, as brand loyal high consumers may be exposed to the same agent on a daily basis, but for pesticides a comparable scenario appears unlikely and should not be applied unless clearly advised by risk managers as a desired protection goal. Given the low findings of pesticides in market samples, it should be discussed before GECDE-high implementation, whether IEDI or GECDE-mean already involve sufficient conservatism to cover also less-than-lifetime scenarios. The EU proposes to compare the results to higher tier exposure assessments based on realistic occurrence data (probabilistic assessments based on monitoring data or results from total diet studies).

[4] Pesticide Safety Directorate. 2004. Instructions for carrying out long term consumer risk assessment using CRD's ten consumer model.

[5] A European tool for usual intake distribution estimation in relation to data collection by EFSA. https://www.efsa.europa.eu/en/supporting/pub/en-300

[6] EFSA Guidance: Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. EFSA Journal 2011;9(3):2097

Agenda Item 5b and 6 **Agenda Item 5b: Section 3 of the 2023 JMPR Report**
Agenda Item 6: CX/PR 24/55/5 – CL 2024/44-PR

Agenda Item 5b: Report on responses to specific concerns raised by CCPR arising from the 2023 JMPR meeting

Agenda Item 6: MRLs for pesticides in food and feed (at Steps 7 and 4)

General comments
The EU would like to inform CCPR Members that the CXLs that were adopted by the 46th Session of the Codex Alimentarius Commission, and for which the EU had not introduced reservations during CCPR54, have now been established in the EU. It is an EU policy to propose a Commission Regulation for inclusion of Codex MRLs (CXLs) into EU legislation 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 the proposed CXL is not safe for European consumers[1], and/or • if toxicological data are not available at EU level or are available but not yet assessed at EU level, 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, 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). [1] Including an assessment that the Codex residue definition ensures an equivalent level of protection.
Items 5 b)
Indoxacarb (216) The EU requests that indoxacarb would be prioritized for periodic review. The EU concerns were not addressed by JMPR, and there seems to be a misunderstanding on the EFSA conclusion on the metabolite IN-JT333. The toxicological reference values derived for the parent substance are not applicable to the metabolite IN-JT333, and the JMPR residue definition should be revised to exclude it. The EU provided further detailed clarifications in writing to JMPR.
Mefentrifluconazole (320)

The EU support the advancement of the proposed draft MRL for

- **Lettuce Head**

The EU **opposes the advancement** of the proposed draft MRLs for the following commodities:

- **Leaf lettuce**
- **Spinaches**

Short-term exposure exceedances of the ARfD were indicated by JMPR.

Metalaxyl (138)

Phosmet (103)

The EU welcomes that the periodic review of phosmet has been scheduled for 2024.

Items 6

Piperonyl butoxide (62) (R)

The EU requests to the applicant that complete and good quality dossiers should be submitted, for the good use of JMPR resources.

The EU recommends deleting the active substance completely and moving it into "Table 1. List of Pesticides Whose MRLs (CXLs) Or GLs Have Been Deleted by the Codex Alimentarius Commission and for Which No MRLs Have Been Proposed", since the last complete evaluation was more than 25 years ago, in 1995.

It should be in the future treated as a new active substance.

Pyrethrins (63) (R)

The EU requests to the applicant that complete and good quality dossiers should be submitted, for the good use of JMPR resources.

The EU recommends deleting the active substance completely and moving it into "Table 1. List of Pesticides Whose MRLs (CXLs) Or GLs Have Been Deleted by the Codex Alimentarius Commission and for Which No MRLs Have Been Proposed", since the last complete evaluation was 25 years ago, in 1999.

It should be in the future treated as a new active substance.

Carbendazim (72) (T, R)**

The EU requests to the applicant that complete and good quality dossiers should be submitted, for the good use of JMPR resources.

The EU recommends deleting the active substance completely and moving it into "Table 1. List of Pesticides Whose MRLs (CXLs) Or GLs Have Been Deleted by the Codex Alimentarius Commission and for Which No MRLs Have Been Proposed", since the last complete evaluation was more than 25 years ago, in 1995.

It should be in the future treated as a new active substance.

Thiophanate-methyl (77) (T,R)**

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodity, as the JMPR residue definition is incompatible with the EU residue definition for enforcement:

- **Almond**

Carbofuran (96) (T,R)**

The EU **supports the proposed withdrawal** of the MRLs for all commodities.

Iprodione (111) (T,R)**

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities because the genotoxicity of several metabolites is not sufficiently addressed:

- **Almond**
- **Beans with pods (Phaseolus spp) -immature pods and succulent seeds**
- **Cane berries, subgroup of**
- **Cherries, subgroup of**
- **Onion, bulb**
- **Peaches (including Nectarines and Apricots), Subgroup of**
- **Potato**

In addition, for blackberries and raspberries, an acute consumer risk has been identified for European consumers.

The EU **opposes the advancement of** the proposed draft MRLs for the following commodities:

- **Broccoli**

Since an acute consumer risk has been identified by JMPR.

The EU noted that:

- the residue definition for risk assessment proposed by JMPR for plant products covers only the parent compound while the EU could not conclude on the genotoxicity potential for several metabolites and degradation products potentially formed in processed plant products.
- several MRLs were proposed for feed products, however, for animal products, JMPR could not derive a residue definition for MRL compliance.
- JMPR did not calculate the dietary burden for livestock, although potatoes could serve as animal feed.

The EU **supports** the proposed withdrawal of the MRLs for some commodities.

Zeta-cypermethrin (118) (R)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- **Avocado**
- **Subgroup of bush berries**

An acute health risk and a long-term health risk have been identified for EU consumers with exceedances of the ARfD and the ADI

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Subgroup of bulb onions**

However, the EU notes that the Codex MRL for the subgroup of bulb onions should be 0.05 mg/kg, without an asterisk.

Permethrin (120) (T,R)**

The EU requests to the applicant that complete and good quality dossiers should be submitted, for the good use of JMPR resources.

The EU requests withdrawing the existing Codex MRLs related to pesticide use, most of them derived 30 years ago, since the last complete evaluation was 25 years ago, in 1999, and data provided as part of the periodic review was insufficient to conclude on the toxicology of permethrin and metabolites.

Diflubenzuron (130) (R)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for:

- **Tea, Black, Green, dried and fermented (subgroup).**

In processed products, the formation of the genotoxic degradation product PCA (4-chloroaniline) has been observed.

Since tea is primarily consumed as an infusion prepared from fermented/dried tea leaves with boiling water, the possible occurrence of this substance cannot be excluded based on the currently available scientific evidence.

Deltamethrin (135) (R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Papaya**

The EU notes the lack of a validation method for the alpha-R- isomer for high water commodity group.

Prochloraz (142) (T,R)**

Carbosulfan (145) (T,R)**

The EU **supports all the proposed withdrawals of** MRLs.

The EU **opposes the advancement** of the proposed draft MRLs for the following commodities:

- **Eggplant**
- **Mango**

Short-term exposure exceedances of the ARfD were indicated by JMPR.

Propiconazole (160) (R)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities based on the lack of data on the magnitude and toxicity of metabolites expected in plant and animal products that need to be considered in the dietary risk assessment. In the EU assessment, the toxicological data were found insufficient to conclude on the genotoxicity potential and the general toxicity of some of the metabolites.

- **Avocado**
- **Edible offal (mammalian)**
- **Eggs**
- **Mammalian fats (except milk fats)**
- **Meat (from mammals other than marine mammals)**
- **Milks**
- **Peanut**
- **Poultry fats**
- **Poultry meat**
- **Poultry, edible offal of**
- **Rice husked**

In addition, it is noted that the recalculation of the residues measured in avocados without pit to the whole fruit would result in a lower MRL of 0.01 mg/kg.

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 propiconazole.

Boscalid (221) (R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Pomegranate**

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:

- **Cane berries**
- **Mustard greens**
- **Radish**
- **Radish leaves**
- **Stone fruits**
- **Subgroup of maize, Cereals**
- **Sweet potato**

Based on the outcome of the ongoing evaluation, this reservation could be revised.

Additionally, for mustard greens and radish leaves, the proposed Codex MRL leads to ARfD exceedances in children for Chinese cabbage and kale respectively.

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.

Clothianidin (238) (R)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities due to the contribution of thiamethoxam and its metabolite clothianidin to the worldwide decline of pollinators:

- **Cumin seed**
- **Fruiting vegetables other than cucurbits except goji berry**
- **Goji berry**
- **Group of tree nuts**
- **Onion, bulb**
- **Subgroup of stems and petioles**

In line with the EU's announcement in the Farm to Fork Strategy and the European Green Deal, the EU takes environmental issues of global concern into account when deciding about accepting CXL.

In the case of clothianidin, this relates to its contribution to the worldwide decline of pollinators.

Fluopyram (243) (R)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities, pending the review of the dietary burden calculations in the JMPR evaluation report, once available:

- **Barley**
- **Buckwheat**
- **Oats**
- **Rye**
- **Sorghum**
- **Triticale**
- **Wheat**
- **Edible offal (mammalian)**
- **Mammalian fats (except milk fats)**
- **Meat (from mammals other than marine mammals)**
- **Eggs**
- **Milks**
- **Poultry, edible offal of**
- **Poultry fats**
- **Poultry meat**

The dietary burden calculations are not included in the Annex VI of the JMPR Report. Additionally, a chronic risk for EU consumers was identified with 331% ADI.

The EU notes that according to the new Codex food classification, CXLs should be established for “muscle” instead than for “meat”.

Thiamethoxam (245) (R)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities due to the contribution of thiamethoxam and its metabolite clothianidin to the worldwide decline of pollinators:

- **Cumin seed**
- **Fruiting vegetables other than cucurbits except goji berry**
- **Goji berry**
- **Group of tree nuts**
- **Onion, bulb**
- **Subgroup of stems and petioles**

In line with the EU's announcement in the Farm to Fork Strategy and the European Green Deal, the EU takes environmental issues of global concern into account when deciding about accepting CXL.

In the case of thiamethoxam, this relates to its contribution to the worldwide decline of pollinators.

Acetamiprid (246) (R)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- **Soya bean (dry)**

The MRLs for Soya bean (dry) should be flagged with an asterisk indicating that residues above the LOQ are not expected.

Emamectin benzoate (247) (T)

The EU notes that in the EU, the toxicity of three of the metabolites assessed by JMPR in 2023 (L-653,649 / AB1a, L-660,599 / MFB1a, L-657,831/ FAB1a) is considered higher than the toxicity of the parent compound, while JMPR considered the metabolites are covered by the parent.

Dinotefuran (255) (R)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities pending the assessment of an import tolerance:

- **Goji berries**
- **Group of fruiting vegetables other than cucurbits (except goji berry)**

The EU notes that JMPR proposed a combined data set of residue trials on peppers and tomatoes to set the MRL of the group.

Cyantraniliprole (263) (R)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- **Beans, dry, subgroup of**
- **Peas, dry, subgroup of**
- **Grapes**
- **Olives**
- **Olives for oil production**

A lower MRL of 0.04 mg/kg is possible for soya beans in the subgroup of beans, dry.

For grapes, details of the residue decline needs to be confirmed in the JMPR evaluation report, once available, to confirm that the first application could be discarded in the residue trials.

For olives and olives for oil production, the EU assessment of the cGAP in the EU Member State Malta leads to a higher MRL of 3 mg/kg. The EU requests that the MRLs for olives and olives for oil production are maintained at Step 4 so that JMPR could review the calculations.

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Avocado**
- **Cane berries, subgroup of**
- **Eggs**
- **Tea, green, black (black, fermented and dried)**

Imazapyr (267) (R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Rice, husked**
- **Wheat**

Cyflumetofen (273) (R)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities based on the lack of metabolism studies in a commodity representative for coffee bean (classified as pulses) in line with the requirements in the FAO manual:

- **Coffee bean**

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Cucumber**
- **Hops, dried**
- **Subgroup of cherries**
- **Subgroup of peaches**

The EU notes that a more critical GAP was submitted in the EU for hops and invite the manufacturer to submit that GAP at Codex level, as the MRL derived from that GAP accurately in place in the EU is 30 mg/kg instead of 15 mg/kg.

Oxathiapiprolin (291) (R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Group of tree nuts**
- **Subgroup of bush berries**
- **Hops**

The EU introduces a reservation to the advancement of the proposed draft MRLs for the following commodity:

- **Avocados**

As the recalculation of the residues measured in avocados without pit to the whole fruit would result in a lower MRL of 0.07 mg/kg.

The EU requests the applicant to share with JMPR the EU Good Agricultural Practices and supporting trials on hops in view of aligning the Codex MRL with the EU MRL.

Tetraniliprole (324) (R)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodity based on the lack of available toxicological data at EU level:

- **Mandarins (including Mandarin-like hybrids), Subgroup of**

The EU would like to thank JMPR for consider their previous comments related to the residue trials in mandarins.

Isoflucypram (330) (T,R)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities pending the outcome of the ongoing evaluation in the EU:

- **Barley**
- **Triticale**
- **Wheat**
- **Milks**
- **Meat (from mammals other than marine mammals)**
- **Mammalian fats (except milk fats)**
- **Edible offal (mammalian)**
- **Eggs**
- **Poultry meat**
- **Poultry fats**
- **Poultry, edible offal of**

The EU notes that according to the new Codex food classification, CXLs should be established for “muscle” instead than for “meat”.

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

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Edible offal**
- **Eggs**
- **Mammalian fats**
- **Meat (from mammals other than marine mammals)**
- **Milks**
- **Potato**
- **Poultry edible offal**
- **Poultry fats**
- **Poultry meat**

The EU notes that a higher MLR will be applicable for potatoes in the second half of 2024. The EU requests the applicant to share with JMPR the EU Good Agricultural Practices and supporting trials on potatoes in view of aligning the Codex MRL with the EU MRL.

The EU notes that according to the new Codex food classification, CXLs should be established for “muscle” instead than for “meat”.

Florylpicoxamid (332) (T,R)*

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities pending the outcome of the ongoing evaluation in the EU:

- **Grapes**
- **Strawberry**
- **Banana**
- **Mango**
- **Subgroup of fruiting vegetables, cucurbits - cucumbers and summer squashes**
- **Subgroup of fruiting vegetables, cucurbits – melons, pumpkins and winter squashes**
- **Subgroup of tomatoes**
- **Peppers, chili**
- **Peppers, sweet**
- **Subgroup of eggplants**
- **Lentil (dry)**
- **Sugar beet**
- **Wheat**
- **Rape seed**
- **Edible offal (Mammalian)**
- **Eggs**
- **Mammalian fats (except milk fats)**
- **Meat (from mammals other than marine mammals)**
- **Milks**
- **Poultry fats**
- **Poultry meat**
- **Poultry, edible offal of**

The EU notes that according to the new Codex food classification, CXLs should be established for “muscle” instead than for “meat”.

The EU notes that for lentils, eggs, poultry fats, meat and edible offals, the trials indicate that no residues above the LOQ are expected and therefore MRL proposals should be flagged with an asterisk.

Fluazinam (333) (T,R)*

The EU requests to the applicant that complete and good quality dossiers should be submitted, for the good use of JMPR resources.

Isocycloseram (334) (T,R)*

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:

- **Broccoli**
- **Brussels sprouts**
- **Cabbages, head**
- **Cauliflower**
- **Coffee bean**
- **Cotton seed**
- **Cucumber**
- **Edible offal (Mammalian)**
- **Eggplant**
- **Group of pome fruits**
- **Maize**
- **Mammalian fats (except milk fats)**
- **Meat (from mammals other than marine mammals)**
- **Melons, except watermelon**
- **Milks**
- **Onion, bulb**
- **Peppers, chili**
- **Peppers, sweet**
- **Potato**
- **Soya bean (dry)**
- **Squash, summer**
- **Subgroup of cherries**
- **Subgroup of lemons and limes (including citron)**
- **Subgroup of Mandarins (including mandarin-like hybrids)**
- **Subgroup of oranges, sweet, sour (including orange- like hybrids)**
- **Subgroup of peaches (including nectarine and apricots)**
- **Subgroup of plums (including fresh Prunes)**
- **Subgroup of pummelo and grapefruits (including shaddock-like hybrids, among others grapefruit)**
- **Tomato**

The EU notes that according to the new Codex food classification, CXLs should be established for “muscle” instead than for “meat”.

Isotianil (335) (T,R)*

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities pending the assessment of an import tolerance:

- **Bananas**
- **Edible offal (Mammalian)**
- **Mammalian fats (except milk fats)**
- **Meat (from mammals other than marine mammals)**
- **Milks**
- **Poultry fats**
- **Poultry meat**
- **Poultry, edible offal of**
- **Subgroup of 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 other grapefruit)**

The EU notes that according to the new Codex food classification, CXLs should be established for “muscle” instead than for “meat”.

Mepiquat chloride (336) (T,R)*

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Cotton seed**
- **Edible offal (mammalian)**
- **Eggs**
- **Grapes**
- **Mammalian fat (except milk fats)**
- **Meat (from mammals other than marine mammals)**
- **Milk**
- **Poultry, edible offal of**
- **Poultry fats**
- **Poultry meat**

The EU notes that according to the new Codex food classification, CXLs should be established for “muscle” instead than for “meat”.

Tricyclazole (337) (T,R)**

Triflumeron

Additional comments on Agenda Item 6:

European Union Competence

European Union Vote

MAXIMUM RESIDUE LIMITS FOR PESTICIDES IN FOODS AND FEEDS
AT STEPS 7 AND 4

1. Inclusion of additional commodities in Class A and Class C.

The European Union (EU) support the new proposal for classification for:

- **Class A**, Subgroup 023C Cottonseed, SO 3149 Cottonseed, delinted,
- **Class D,** Group 069: Miscellaneous derived edible products of plant origin DM 3527 Tomato, ketchup

The EU notes that the proposed classification for AM 3604 Potato, culls in **Class C**, Subgroup 052A: Miscellaneous feed products with high water (≥20%) content (forage, beet tops) is not in line with commodities already included in this subgroup. For "potato, culls" the EU suggests to use a similar approach than for "carrot culls", which are mentioned without a code and with the addition "see Carrot, VR 0577 (the same MRL applies as the food commodity) Daucus carota L."

2. Fluazinam (306)

The EU supports the assignment of the ID number 306 to fluazinam and the assignment of the ID number 333 to another new active substance.

3. Consideration of Guideline Levels (GLs)

The EU supports to delete Part III of the list of Codex MRLs as well as to transfer of the substances into Part I at Step 4 as necessary.

The EU notes that:

- Methyl bromide is banned due to its ozone depleting properties and as such CXLs are no longer necessary.
- Guazatine is scheduled for re-evaluation by JMPR 2025 and thus can remain at step 4 in Part I and receive a new status after JMPR 2025.

4. MRLs for okra, martynia and roselle.

The EU supports the JMPR proposal implementing the decision taken in CCPR 54.

COMPOUNDS FOR ARISING FROM THE JMPR REGULAR MEETING HELD IN 2023 FOR CONSIDERATION BY CCPR53

List of the active substances maintained at steps 4 or 7

(Appendix V and VI of CCPR report 2023)

<u>MRLs retained at Step 7</u>

Metalaxyl (138) VO 0445 Peppers, sweet (including pimento or pimiento)

<u>MRLs retained at Step 4</u>

Dimethoate (027)/Omethoate (055): FC 0004 Oranges, sweet, sour (including Orange-like hybrids) (subgroup) and AB 0004 Orange, dried pulp

The EU proposes to revoke the propose MRL (currently at step 4) based on the public health concern reasons considered by JMPR in 2022.

Metalaxyl (138) FC 0004 Oranges, sweet, sour (including Orange-like hybrids) (subgroup) and OR 0004 Orange oil, edible

The EU supports the advance of the proposed MRL for Oranges, sweet, sour (including Orange-like hybrids) (subgroup) and OR 0004 Orange oil, edible to Step 8

Bifenthrin (178): VL 0482 Head lettuce

The EU proposes to revoke the propose MRL (currently at step 4) since no alternative GAP was provided to the one evaluated in 2015 for which an acute intake concern was identified.

Fipronil (202): several commodities
Flutriafol (248): GC 0649 Rice, AS 0649 Rice, hay and/or straw, AS 3570 Rice, hulls, CM

0649 Rice, husked

Mefentrifluconazol (320)

Included under Agenda item 6

Tetraniliprole (324)

Included under Agenda item 6

Agenda Item 7 **CX/PR 24/55/6 – CL 2024/45-PR**

Guidelines for monitoring the purity and stability of reference materials and related stock solutions of pesticides during prolonged storage (at Step 4)

European Union Competence
European Union Vote

The European Union (EU) would like to thank the Electronic Working Group (eWG) chaired by India and co-chaired by Argentina and Singapore for preparation of the on the Guidelines for monitoring the Purity and Stability of Reference Materials (RMs) of pesticides (CX/PR 24/55/6).

The EU generally supports the proposed guidelines with some comments in response to the Circular Letter CL 2024/45-PR.

Appendix I, CX/PR 24/55/6

- **Page 5, General criteria:** The EU suggests continuing the numeration of the paragraphs after the heading "general criteria" ("10. 1. The analysis should be conducted in an ISO/IEC 17025 accredited laboratory")

- **Page 5, paragraph 7:** The EU suggests changing the footnotes "*6,7*" to "*1,2*"

  Another study revealed the stability of pesticide reference standard up to 15 years or in stock solution up to 10 years~~*6,7*~~*1,2* **."**

- **Page 5, paragraph 8:** The EU proposes to include the option to keep the reference materials (RMs) in the refrigerator. For some RMs, standard providers recommend storage temperatures above zero; thus, refrigerator storage is also suitable. In addition, the EU propose to replace the word "better" by "more protective".

  "8. To avoid any cross contamination or degradation of RMs, the vials must be placed in airtight capped tube/sealed pouch and immediately stored in the freezer/refrigerator at conditions ~~*better*~~ more protective *than those recommended by RMPs; preferably at subzero temperature."*

- **Page 5, paragraph 8 (Also in Page 6, paragraph 16 and page 7, paragraph 25):** Since calibrated material should not be exposed to extreme temperature changes and should not be stored in the freezer or placed in the oven, the EU proposes to remove the recommendation to use volumetric flasks for storing the standard solutions:

  "8. […] The stock solutions must also be stored in airtight capped glassware ~~(preferably volumetric flask)~~."

- **Page 6, paragraph 9:** The EU considers that number of footnotes 5,6 and 5 are not correct and that only one footnote (5) should remain (same as footnote 4)

  "[…] provided the purity remains acceptable~~5,6,5.~~ "

- **Pages 6 and 7, paragraphs 12, 13 and 20:** The EU suggests adding the term "..preferably <5%" to emphasize the need for having a very small variability in measurement and to have a higher confidence in the calculated deviation between the standard solutions.

  "Perform a minimum of five replicate measurements to obtain a mean value of the peak area for the old standard with %RSD ≤ 10%, preferably <5%."

  "A minimum of five replicate measurements should be performed to obtain a mean value of percent purity and the %RSD should be ≤ 10%, preferably <5%."

- **Pages 6 and 7, paragraphs 12 and 20:** The EU considers that it is not necessary to analyse the compounds using all the techniques, therefore it is suggested to replace "and" by "or" in the following sentence:

  "(HPLC -DAD /HPLC-UV /GC -FID /LC-MS ~~and~~ or GC-MS in full scan mode"

- **Page 6, paragraph 12:** The EU suggests including the explanation of the abbreviation LC in a footnote.

Agenda Item 10 **CX/PR 24/55/9 – CL 2024/43-PR**

Establishment of Codex schedules and priority lists of pesticides for evaluation/re-evaluation by JMPR

European Union Competence
European Union Vote

The European Union (EU) would like to thank the Electronic Working Group (eWG) on Priorities chaired by Australia for the preparation of CL 2024/43-PR and its appendices, as well as the work done to incorporate the requests from members and sponsors.

GENERAL COMMENTS

1) JMPR in its recent report from 2023[7] noted the following:

"In the JMPR call for data, sponsors are requested to submit all data and studies, both published and unpublished, for the toxicological and/or residue evaluations of the compounds. Several chemical dossiers submitted for evaluation were subject to multiple progressive updates and submissions over the course of evaluation (rolling submission of data). This practice causes confusion, disruption and delay in evaluation. This is particularly so when the new material is submitted close to the JMPR Meeting date. It is recommended that a single, fully complete, chemical dossier should be submitted in response to the call for data, rather than a long series 11 of updated dossiers or dossier variations over time. This issue has been the subject of previous comments by the JMPR Meetings in 2015, 2018 and 2019.

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

[7] Section 2.5: On the rolling submission of data. FAO & WHO. 2024. Report 2023: Pesticide residues in food – Joint FAO/WHO Meeting on Pesticide Residues. Rome. https://doi.org/10.4060/cc9755en

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."

The EU notes that the late submission/incomplete submission of dossiers is a recurring problem for JMPR. The EU also notes that the incomplete submission or submission of additional information after the date specified in the call for data is not in line with the procedures laid down in the Procedural Manual.[8] It seems that the procedures are not completely respected by some Members/Observers. At the same time, under agenda item 11 "Enhancement of the operational procedures of CCPR and JMPR" discussions are taking place on how to improve the work of JMPR in the short- and long-term. The EU notes that in the document provided under agenda item 11, there are no clear short- or long-term commitments for dossier submitters to improve the quality of their application or being on time with the application. Although the EU welcomes the discussions under agenda item 11, the EU would like the CCPR55 to urgently look for solutions or mechanisms for the JMPR's recurring problem which is crucial for the way to solve the long backlog of evaluations.

In addition, EU notes that especially problematic is the data submission for substances under periodic review and therefore suggests developing an efficient procedure which would for example preclude that existing Codex MRLs are maintained in the Codex system and aims to avoid that the compounds are rescheduled at each JMPR Meeting,

2) The EU would like to refer to their comment to Circular Letter CL 2023/26 PR from 16 May 2023 and invites the CCPR to consider adding more substances into periodic review in order to ensure that there are enough substances to evaluate.

"*The EU notes that although eight compounds have been listed, for several compounds it is not clear whether these will be reviewed in 2024. The EU notes that as the experience from previous years has shown that although there are always several compounds scheduled for a periodic review in that specific year, the review is often postponed or not possible to finish (e.g., ethoxyquin and guazatine) for several reasons for one or more years. Therefore, one option could be to list a certain number of substances e.g., 20 substances for the year 2024 in order to ensure that there will be a stock of substances from which a minimum of five substances[9] for 2025 could be selected for the review, plus already another 5 substances for 2026. In programming more substances at the onset, a continuous flow of periodic reviews will be ensured for the coming years.*

In addition, substances with unclear support should get a reserve status in Table 2A (Priority lists of periodic reviews – 2024 & beyond) and Table 2B (Periodic review list (compounds listed under 15-year rule but not yet scheduled or listed). Those with a reserve status will be re-evaluated once the data will become available or the reserve status should be deleted, and the compound should be deleted from the Codex List of pesticides at the latest after 25 years after last evaluation."

A. SCHEDULES AND PRIORITY LISTS 2024-2025

Paragraph 3

Chlorpyrifos

The EU notes that the 2024 CCPR Schedule of Evaluations by the Joint FAO/WHO Expert Meetings on Pesticide Residues (JMPR) is closed. However, the EU would like the CCPR55 to consider giving chlorpyrifos a reserve status until CCPR 58 (2027) and afterwards delete the active substance completely and move it into "Table 1. List of Pesticides Whose MRLs (CXLs) Or GLs Have Been Deleted by the Codex Alimentarius Commission and for Which No MRLs Have Been Proposed". In case a complete data set will be made available before the given date, the reserve status can be lifted.

[8] Codex Alimentarius Commission Procedural Manual, 28th Edition, paragraph 243 to 245 for periodic review and paragraph 229 for new uses.

[9] Report of the 49th session of the Codex Committee on Residues

Chlorpyrifos-methyl

The EU notes the 2024 CCPR Schedule of Evaluations by the Joint FAO/WHO Expert Meetings on Pesticide Residues (JMPR) is closed. The EU recalls that CCPR53 agreed to retain all the CXLs under the 4-year rule, awaiting the periodic re-evaluation by the 2024 JMPR[10]. WHO confirmed on 23 January 2024 that no toxicological data had been received so toxicological evaluation in 2024 by JMPR could not occur.

Taken all this into consideration, the EU proposes to delete all CXLs for chlorpyrifos-methyl and invites the CCPR 55 to consider following the same procedure as for chlorpyrifos i.e., give chlorpyrifos-methyl a reserve status until CCPR 58 (2027) and afterwards delete the active substance completely and move it into "Table 1. List of Pesticides Whose MRLs (CXLs) Or GLs Have Been Deleted by the Codex Alimentarius Commission and for Which No MRLs Have Been Proposed".

Phosmet

The EU notes that phosmet has been scheduled for periodic review for 2024 and that JMPR has concluded in its report[11] "*… as phosmet was last reviewed over 20 years ago and since then analytical methods have evolved and new intake estimates indicate that JMPR's ARfD could be exceeded, phosmet should be reprioritized within the CCPR periodic review scheme*.". The EU underlines the importance of the substance being reviewed as soon as possible.

B. FINALISING THE 2025 PROPOSED SCHEDULE

Paragraph 7

The EU notes that four substances (pirimicarb, hydrogen phosphide, clethodim, guazatine) are scheduled for periodic review in 2025 under the four-year rule based on the decision of CCPR52 in 2021. This means also that no prolongation is possible and periodic review is strongly recommended for these substances. If late or incomplete dossiers are provided and consequently a periodic review does not take place, these substances should be deleted and moved into "Table 1. List of Pesticides Whose MRLs (CXLs) Or GLs Have Been Deleted by the Codex Alimentarius Commission and for Which No MRLs Have Been Proposed" at CCPR56.

Guazatine

For guazatine in particular, which is one of the four substances scheduled for periodic review under four-year rule in 2021, the ADI derived in 1978 was withdrawn in 1997 and that after that no ADI or ARfD has been established. Only "guideline levels" (5 mg/kg) for citrus exist since the ADI was withdrawn in 1997. In 2022, JMPR assessed the data package received to be inadequate to estimate health-based guidance values. It is not clear whether additional information will be provided compared to the data package from 2022. As the four-year rule applies, guazatine should not have a reserve status and should be reviewed in 2025. If not reviewed, the substance with the guideline levels should be deleted and moved into "Table 1. List of Pesticides Whose MRLs (CXLs) Or GLs Have Been Deleted by the Codex Alimentarius Commission and for Which No MRLs Have Been Proposed" at CCPR56.

Advice Notes (New Use and Other Evaluations)

Paragraph 9 and 10

EU notes, that it seems necessary to include further advice to nominating Members and Observers. The EU proposes to give priorities to those uses that have already been evaluated and authorised and give those with an expected authorisation at the time of scheduling a reserve status. This might also be useful for new active substances.

C. PRIORITY LISTS 2026 AND BEYOND – TABLE 2A

The EU notes that the substance indoxacarb, for which a public health concern has been lodged, has not been added to Table 2A. In addition, this substance meets the 15-year rule. Therefore, the EU proposes to transfer indoxacarb to Table 2A.

[10] Report of the 53rd session of the Codex Committee on Residues

[11] Section 3.4: Phosmet. FAO & WHO. 2024. Report 2023: Pesticide residues in food – Joint FAO/WHO Meeting on Pesticide Residues. Rome. https://doi.org/10.4060/cc9755en

Paragraph 13

The EU notes that it is assumed that all Members and Observers are aware of the year of the last evaluation of the compounds. The EU would like to recall, that for all substances that meet the "25 years rule", full toxicological evaluations are then considered outdated[12] hence, these substances are of public health concern. Therefore, these substances should be immediately reviewed within a period of four years (if the four-years rule is requested) or all CXLs should be withdrawn. As for these substances a procedure is in place in the Procedural Manual therefore, these substances should not be further addressed by the eWG on Unsupported Substances without Public Health Concern.

Additional comments received

The European Union (EU) filed a concern form last year asking for a prioritisation of review of indoxacarb (last review 2005) as toxicological reference values (TRVs) are lowered in the EU (acute risks identified with current CXLs) and there is insufficient data on metabolite IN-JT333. JMPR in its report[13] stated that "The EU is invited to explain in more detail the basis for their conclusion that the NOAEL for findings in a rat developmental study is 0.5 mg/kg bw per day, and how these findings might be produced by a single dose".

As a response, the EU provided the following additional information to JMPR:

"During the Peer Review by EFSA[14], 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 ADI at Codex level is set at 0.01 mg/kg bw per day.

The previous EU 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. The JMPR ARfD is set at the level of 0.1 mg/kg bw.

The Member States experts derived an overall NOAEL for maternal toxicity at 0.5 mg/kg bw per day from a developmental toxicity study in rats (study from 2004, the same study was reported in both the JMPR and the EU revised RAR). It is acknowledged that the EU peer review reports two pilot studies and three main studies in rats, the latest one dated 2005 presented a higher maternal NOAEL at 2 mg/kg bw per day.

The 2004 study was performed according to GLP and followed the OECD TG 414 (1981) without deviations. Indoxacarb was administered by oral gavage to female rats on gestation days (GD) 6 to 20 (22 rats/dose group) at dose levels of 0, 0.5, 1.0, 2.0 and 3.5 mg/kg bw/day. In this study, maternal body weight gains were statistically significantly reduced during GD 6-8 at the dose levels of 1 mg/kg bw per day and above by more than 60% compared to control animals (France, 2017, Table B.6.6.2-14 of the RAR: -62%, -67% and -67% of control animals at 1, 2 and 3.5 mg/kg bw per day respectively). The animals recovered during the study period, and the body weight gain during GD 6-21 (corrected for gravid uterine weight) was reduced by more than 10% at 1 and 2 mg/kg bw per day, and statistically significantly reduced at 3.5 mg/kg bw per day by 27.7% compared to control animals. These findings were considered as acute adverse effects, relevant to derive the ARfD and ADI (since this represents the lowest NOAEL of the dataset).

The JMPR monograph mentions maternal toxicity based on the same adverse effects but concluded that the maternal NOAEL is 2 mg/kg bw per day.

The EU also highlighted in the concern form that the JMPR residue definition for animal products (risk assessment) covers a metabolite IN-JT333 for which it is unclear whether the TRVs derived for the parent can be applied. According to JMPR it is not genotoxic and based on the available information, is seems to be more toxic than the parent.

In its response to the concern form, JMPR acknowledged that the toxicity could not be addressed. In order to demonstrate that the metabolite is unlikely to lead to an intake concern, a conservative intake calculation was performed which should demonstrate that the exposure will not exceed the TTC for non-genotoxic compounds (Cramer class III). To underpin its argumentation that the metabolite IN-JT333 is of no concern, JMPR also referred to the EFSA

[12] Codex Alimentarius Commission Procedural Manual, 28th Edition
[13] Report 2023: Pesticide residues in food – Joint FAO/WHO Meeting on Pesticide Residues. Rome. https://doi.org/10.4060/cc9755en
[14] 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

conclusion[15] where it was stated that residues of IN-JT333 are “unlikely to be above the limit of quantitation [...]". However, it should be clarified that the sentence was taken out of the context: this conclusion was derived for the limited number of representative uses evaluated in the renewal process. EFSA also highlighted that “for any future use leading to an increase of the dietary burden calculation, the validity of these feeding studies should be reconsidered and additional data might be needed to address the toxicity and the magnitude of all compounds included in the residue definitions for risk assessment set for poultry and ruminants matrices."

EFSA notes that the use of TTC approach is normally not accepted in the EU, but acknowledges that at JMPR level, it became a tool that is regularly applied to address metabolites for which insufficient toxicological data are available to perform a full hazard characterisation. Following the explanations of JMPR, formally, it would be appropriate to revise the JMPR residue definition, excluding the metabolite IN-JT333, since the toxicological reference values derived for the parent substance are not applicable.

With regards to the health issues, the EU has identified very important risks with 27 existing CXLs with the new TRVs, up to 2188% of the ARfD which was included in the concern form the EU had sent in 2023.

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, risks were identified for 20 other 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.”

In view of these, the EU requests indoxacarb to be prioritized for review. This would give the opportunity to JMPR to review all available studies to set TRVs.

[15] 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

Agenda Item 11 **CX/PR 24/55/10 – CL 2024/48-PR**

Enhancement of the operational procedures of CCPR and JMPR

European Union Competence
European Union Vote

The European Union (EU) would like to thank the Electronic Working Group (eWG) on Enhancement of work management of CCPR and JMPR chaired by United States of America and co-chaired by Costa Rica and Uganda for the preparation of CL 2024/48-PR.

The EU would like to make the following comments:

CX/PR 24/55/10 Para 26, Appendix I Short-term/long-term approach

The EU notes based on the feedback of JMPR in its recent report from 2023[16] and under Agenda item 5a (also referred to in Circular Letter CL 2024/43-PR) that the incomplete submission of dossiers is a recurring problem for JMPR and therefore this issue should be handled in the short-term approach as a priority.

EU notes that especially problematic is the data submission for substances under periodic review (also referred to in Agenda item 5a and Agenda item 10) and therefore suggests developing an efficient procedure which would for example preclude that existing Codex MRLs are maintained in the Codex system and aims to avoid that the compounds are rescheduled at each JMPR Meeting.

As also commented on Circular Letter CL 2024/43-PR, timely submission of complete dossiers, which has been outlined in the JMPR report[17] as a problem, could be tackled already now by sponsors taking the commitment to do so. It could be further improved as part of the targeted part of the short-term approach.

In addition, the EU has additional feedback to Appendix II "Summary of comments in response to CL 2022/75-PR Request for Comments on the Need to Enhance CCPR/JMPR and the associated opportunities and challenges (For information)" that could be relevant for the future work.

CX/PR 24/55/10, Appendix II Table 1 "Summary of comments on opportunities for Enhancement to CCPR /JMPR an associated challenge

1. Table 1, Data Sponsor Dossier and Electronic Data Submission

- Bullet point 1: The EU notes that according to the last JMPR report[1], the format of dossiers is less of an issue than the completeness of original study reports and alignment of information relevant for the assessment from different sources (e.g., identical naming of common metabolites across different compounds/sponsors). Electronic submissions are usually accepted, either in the form of folders with pdf documents or container formats like Caddy XML.

- Bullet point 6: The EU supports exploring options to improve templates. In order not to add extra burden to JMPR Experts, the EU suggests tasking this issue to a third party, which may collect interviews/needs from all stakeholders (e.g., JMPR Experts, Sponsors, Editors, FAO/WHO Secretariat) and suggest a common approach.

- Bullet point 9: The EU supports the comment, however the provision of the same data submitted to national authorities represents the minimum. The data considered, may differ as well as assessment practice. The EU emphasizes that JMPR requests all data available in relation to the setting of HBGV and consideration of GAPs.

[16] Section 2.5: On the rolling submission of data. FAO & WHO. 2024. Report 2023: Pesticide residues in food – Joint FAO/WHO Meeting on Pesticide Residues. Rome. https://doi.org/10.4060/cc9755en
[17] Section 2.5: On the rolling submission of data. FAO & WHO. 2024. Report 2023: Pesticide residues in food – Joint FAO/WHO Meeting on Pesticide Residues. Rome. https://doi.org/10.4060/cc9755en

2. Table 1 CCPR Processes and Procedures, Schedule and Priority List

- The EU notes that increasing the number of uses in addition to a full evaluation of a new substances might be too big of a burden for one expert to evaluate within one year.

3. Table 1 CCPR Processes and Procedures, Criteria for Periodic Reviews

- Bullet point 1, 2. sentence: The EU notes that the claim that CXLs can be retained if GAPs remain unchanged is confusing. The idea of a periodic review is a renewed assessment according to the current state of scientific knowledge, which has usually improved significantly in the meantime. Although maintaining a CXL is desirable, many aspects have changed such as the criteria for defining the residue, HBGV or use of the OECD MRL Calculator, which alters the outcome.

- Bullet point 2: The EU notes that the extension of the period will not reduce the number of periodic reviews but will stretch the interval. In the next few years, less reviews become necessary but, in the end, the number of compounds to be assessed remains the same.

4. Table 1 CCPR Processes and Procedures, Pesticide MRL Database

- The EU encourages Codex Secretariat not only to provide a Codex MRL database but an up-to-date commodity database including adopted recommendations for representative group commodities and minor commodity classifications.

Table 1, JMPR Evaluation Process and Procedures, Working Procedures

- Bullet point 1: The EU notes that in this section it is stated that the main bottlenecks are the capacity and limited number of experts rather than the processes and procedures within the JMPR. The EU would like to outline that an increase in experts would not lead to an increased number of substances that can be discussed during the JMPR Meeting. Their agendas are already fully booked, and extension of the two-week meeting is not desirable.
- Last bullet point: Given the complexity in finding a residue definition, as currently seen in the process of updating the OECD Guidance Document on residue definitions, residue, and toxicological assessment work hand in hand nowadays. Relevance of metabolites relies both on hazard and occurrence in parallel. By shifting toxicology to another year than the residue assessment, re-discussion will become necessary afterwards and de-facto two years will be required by the WHO group.

CX/PR 24/55/10, Appendix II Table 2, Summary of Comments on Opportunities for Major Reform to CCPR/JMPR and Associated Challenges

Table 2, Other Areas of Reform, Scope of Evaluations and Default MRLs

- Bullet point 1: The EU notes that the range of affected commodities is given by the GAP and the supporting residue data. Especially for the mentioned feed commodities, an assessment would anyway become necessary to estimate the dietary burden of livestock and residues in animal commodities. By narrowing the scope of commodities to be considered, the importance of Codex MRLs for trade and as safety values in terms of consumer protections would be then weakened.

Agenda Item 12 **CX/PR 24/55/11 – CL 2024/49-PR**

Coordination of work between CCPR and CCRVDF: *Joint CCPR/CCRVDF Working Group on Compounds for Dual Use* – Status of Work

Mixed Competence
European Union Vote

The European Union and its Member States (EUMS) would like to thank the chair and co-chairs of the joint electronic working group between the CCRVDF and CCPR for the work carried out.

The EUMS:

i. Express support to the Joint CCRVDF-CCPR EWG
ii. Endorse scheduling a virtual Joint Physical Working Group
iii. Support the encouragement of CCPR delegations to participate in the virtual Joint Physical Working Group

Agenda Item 14

Other Business

European Union Competence
European Union Vote

The European Union (EU) would like to take this opportunity to propose some issues it considers relevant under this agenda item.

The EU requests clarification on the publication date for the announced comprehensive document comprising the new Revision of the Classification for food and feed.

It is also recommended:

- In line with the decision of CAC46 (2023), to update the *Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Pesticides to Commodity Groups, CXG 84-2012* (last modified in 2017), including the agreed extrapolations for Class B, C, D and E.

- to revoke, as soon as possible, the Codex Classification of foods and animal feeds of 1993, which is still available on the Codex Alimentarius website[18].

Furthermore, the EU would like to seek clarification on the implementing plan of the new food classification for plant and animal products.

For animal products, the EU noted several discrepancies with previous decisions during the evaluation of the JMPR report 2023. For example, the new codes for animal products were not used consistently and MRL proposals were still derived for 'meat (from mammals other than marine mammals)', and not for the new commodity 'muscle (from mammals other than marine mammals)'.

The EU would like to ask clarifications if the existing Codex MRLs for meat will be reconsidered and replaced by new MRLs for muscle.

In addition, clarifications are required if the new commodity classification 'muscle (from mammals other than marine mammals)' will have an impact on the policy of setting Codex MRLs for fat soluble substances. Under the old classification, Codex MRLs for 'meat (from mammals other than marine mammals)' were flagged with the suffix (fat), indicating that the MRLs refer to fat. The 'fat-soluble' status determines the nature of a sample that should be taken for enforcement analysis. For fat soluble pesticides a portion of carcass fat is analysed and MRLs apply to carcass fat, and not to the meat. For non-fat soluble substances, the MRLs referred to meats (muscular tissue, including adhering fatty tissue, from animal carcasses prepared for wholesale distribution.).

[18] Codex Alimentarius Volume 2 Pesticide residues in food (second edition), Section 2 : Codex classification of Foods and Animal Feeds. Rome 1993.
https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXA%2B4-1989%252FCXA_004e.pdf

It is not yet clear if JMPR will maintain the current practice and will propose MRLs for fat soluble substances for muscle, flagged with the suffix "(fat)" or whether different MRLs would be set for muscle and fat.

The EU also would like to get further information whether the existing Codex MRLs with obsolete (old) codes (which were replaced with new codes) will remain unchanged, or whether the old codes will be replaced with the new codes. Keeping old codes might cause confusion. If the old codes will be replaced by the new codes, it would be necessary to check the impact of the new commodity classification on those MRLs set for commodity groups that will have a different composition compared to the old commodity groups.

Some examples of cases where a commodity was moved from one group/subgroup to another group or subgroup are listed below:

- "Azaroles": old code: FB 0280, classified in the group of "berries and other small fruits"; new code FP 2220, classified in the group of "pome fruit".

- "Japanese persimmon": old code: FT 0307, classified in the group "assorted tropical and sub-tropical fruits – edible peel"; new code FP 0307 classified in the group of "pome fruit".

- "Chives": old code HH 0727, classified in the group of "herbs", new code VA 2605, classified in the group of "bulb vegetables".

In certain cases, a reassessment of MRLs by JMPR would be required to ensure that CXLs are not lost for certain commodities (e.g., if a CXL for "herbs" is applicable to "chives") and that the CXL for the new crop group is appropriated for certain commodities (e.g., if a CXL for "bulb vegetables" is appropriate for "chives").

An update of the FAO manual reflecting the new food classification would be also desirable.