CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Items 3, 4(a), 5(a), 7(a, b), 8, 10, 11, 12 **CRD11 Rev.1**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

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

Comments submitted by the European Union

Agenda Item 3 **CX/PR 23/54/2**

Matters Referred to CCPR by CAC and/or Other Subsidiary Bodies

Mixed Competence
European Union Vote

The European Union (EU) would like to submit a number of remarks and considerations with regard to the matters referred to CCPR by CAC and/or other subsidiary bodies for information.

MATTERS ARISING FROM THE CODEX ALIMENTARIUS COMMISSION AND ITS EXECUTIVE COMMITTEE

Paragraph 3

CAC 45 noted discontinuation of discussion on the review of the IESTI equations. The EU deplores this and would like to inform that in the EU a scientific opinion of the European Food Safety Authority is expected to be published at the end of 2023. Further risk management considerations will be based on its outcome. The EU will continue to keep CCPR informed of all developments.

Paragraph 6

The EU supports the recommendation which will be further discussed under Agenda Item 8 of CCPR54.

Paragraph 7

The EU takes note of the recommendation of the CAC regarding the procedures for parallel review of new compounds, but wishes to recall that such projects have not been very successful in the past.

Paragraph 8

The EU supports the recommendation to address environmental inhibitors on a case-by-case basis within the current mandate of CCPR. This is in line with EU legislation where at least phosphonic acid and its salts (including copper salt) falls within the framework of Regulation (EC) No 1107/2009 and Regulation (EC) No 396/205

Paragraphs 16 -20

The EU is very much in favour of investigating potential mechanism to address cross-cutting, overarching and emerging issues in Codex, even if such subjects do not always yet fall naturally within the terms of reference (TOR) of existing Committees. It notes that some flexibility is proposed for dealing with such issues in the existing Committees. The EU considers that such flexibility should then also apply in other cases, such as the consideration of environmental issues of global concern when establishing CXLs (see EU comments on agenda item 4a).

Paragraph 21

The EU fully supports the establishment of a subcommittee to develop, in collaboration with the Codex secretariat, a report including a proposed blueprint for the future of Codex. This gives the opportunity to reflect on the main principles of Codex and adapt it to future new challenges.

MATTERS ARISING FROM OTHER SUBSIDIARY BODIES

Paragraph 29

The EU notes that CCFA53 agreed to remove ortho-phenylphenols (i.e., ortho-phenylphenol (ins 231) and sodium ortho-phenylphenol (ins 232)) from the General Standard for Food Additives as they were not in use as food additives. In the EU, these compounds are still used in plant protection products and MRLs are set in Regulation (EC) No 396/2009. In CCPR, for the substance (number 30) still some CXL are set, but the toxicological evaluation is outdated. The substance is scheduled for re-evaluation by JMPR in 2024 as a reserve substance, noting that only five substances are scheduled and three have a reserve status.

Paragraph 30

The EU strongly supports the request fromCCLAC22, that an updated version of CX 4-1989 "Classification of Food and Feed" was available online and that this work be prioritised by the Codex secretariat. After several years of amending the classification system, the EU considers important that now, that the work comes to an end, a consolidated version is prepared and made available on the Codex website.

Paragraph 38

Ethylene oxide is a pesticide according to European definition but not approved in the EU and never evaluated by JMPR. A joint JMPR/JECFA evaluation might be useful and the EU proposes to support this work by providing its findings and experiences to both Joint Meetings.

Paragraph 40

The EU fully supports the recommendations.

Agenda Item 4(A) **CX/PR 23/54/3**

Matters Arising from FAO and WHO

Mixed Competence
European Union Vote

The EU supports the activities of FAO and WHO to strengthen the One Health approach. Also the information about databases on individual food consumption and chemical hazards in food and about early warning alerts and responses to food safety emergencies is welcomed.

The EU notes that some documents mentioned by FAO, such as the Guidelines on Developing a Reporting System or Health and Environmental Incidents, were developed by the FAO/WHO Joint Meeting on Pesticide Management (JMPM). JMPM, similarly to JMPR and JMPS, is an advisory body to FAO and WHO on the lifecycle management of pesticide in agriculture and public health. Its activities rely on expert panels as well as key international partners, notably the United Nations Environment Programme (UNEP), that has been formally invited to join the JMPM secretariat to reflect the importance of the environmental issues in pesticide management. It also works in relation with the Rotterdam Convention and focuses its activities on highly hazardous pesticides. In this respect, the EU would welcome regular information from the FAO and/or the WHO Secretariat on the activities of the JMPM.

Reduction of pesticides use and integrated pest management, the phasing out of pesticides that are of concern for human health and/or the environment and, on the other hand, the support and facilitation of introducing low risk substances (e.g. microorganisms), as well as the issue of antimicrobial resistance in pesticides management are all very relevant topics. They are strongly related to the ongoing discussions in CCPR, in particular to the periodic review of old pesticides and the management of unsupported compounds. Therefore, the EU considers that the JMPM secretariat, including UNEP, should also be invited to CCPR sessions as a way to enhance information-sharing and foster possible ways of collaboration on cross-cutting issues.

Developments of legislation and guidelines on all these issues is currently in progress in the EU, and recently the EU, in line with the goals of its farm to fork strategy, has adopted a regulation that lowers maximum residue levels for the two neonicotinoid substances clothianidin and thiamethoxam due to environmental concerns of global nature, here the global decline of pollinators. The FAO also calls for actions to address the drivers of pollinator decline for the sake of sustainable global food production[1]. The EU considers it necessary to define harmonised measures to address environmental issues of global concern in international fora, because environmental problems that transcend national boundaries cannot be addressed by one country – or region - alone. Therefore, such issues should be considered during the establishment of Codex MRLs and included on the agenda of international cooperation and coordination activities. The EU would welcome further discussions on the possibilities to integrate such reflections also in the work of CCPR.

[1] AO. 2019. The State of the World's Biodiversity for Food and Agriculture, J. Bélanger & D. Pilling (eds.). FAO Commission on Genetic Resources for Food and Agriculture Assessments. Rome. 572 pp. **https://www.fao.org/3/CA3129EN/CA3129EN.pdf**

Agenda Item 5(a)

Report on items of general consideration arising from the 2022 JMPR meeting (Section 2 of the 2022 JMPR Report)

European Union Competence
European Union Vote

The EU would like to provide the following comments on section 2 of the 2022 JMPR Report:

2.1 Requirements for data on the impact of residues on the human intestinal microbiome

The European Union (EU) would like to thank JMPR for the efforts to take into account possible effects on the gut microbiome. The EU concurs with JMPR considerations on the potential relevance of chemicals (including pesticides and their residues) on human and animal intestinal microbiome and reckons that further developments are needed in this area to understand the importance of the microbiome in risk assessment and identify dedicated strategies and methodologies accordingly. Currently, the assessment of microbiome(s) is not part of the regulatory requirements for plant protection products and their residues in the EU and no internationally agreed guidelines are in place in the pesticide area. The EU is starting to build capacity on this subject and the European Food Safety Authority launched a thematic grant in March 2020 to collaborate with EU Member States to identify indications for future EU research agendas with a focus on specific needs from a risk assessment perspective. The EU is willing to contribute to the proposed microbiome expert working group to develop guidance for discussion and adoption by JMPR. Further information on the implementation (would the evaluation apply to only new compounds or also would it be included in periodic re-evaluations of old compounds) would be desirable.

2.2 Non-linear kinetics (KMD)

The EU welcomes the establishment of an electronic working group on the assessment

and interpretation of non-linear dispositional kinetics. The EU agrees that more guidance on assessment and interpretation of non-linear dispositional kinetics would be desirable. The guidance should more generally deal with the interpretation of non-linearity in the dispositional kinetics of pesticides. At EU level, hazard classification is an important element to decide on the approval of an active substance. According to the European Chemicals Agency (ECHA) the kinetically-derived maximum dose (KMD) approach is not appropriate to fulfil the legislative needs for classification and labelling; instead, the maximum tolerated dose (MTD approach; with inclusion of the non-liner kinetic only as a complementary information) would be the most appropriate methodology to derive selection of the high dose level for toxicological studies.

Further information on the electronic Working Group (eWG) and the progress of the activities would be desirable. The EU is willing to contribute to the critical revision of the announced guidance.

2.3 Interpretation and follow-up of positive results in in-vitro gene mutation assays

The EU welcomes JMPR clarifications on the interpretation and follow-up of positive results in in vitro gene mutation assays. The EU notes that the proposed testing strategies for follow up of positive results in in vitro gene mutation assays are not fully in line with the approaches followed in the EU:

- As a follow-up for positive *in vitro* gene mutations assays, the EU considers that routine testing for *in vivo* germ cell mutation is not necessary [2].
- As a follow-up for positive *in vitro* gene mutation results, the JMPR report states: '*However, for bacterial gene mutation caused by non-DNA reactive gene mutagens (for instance intercalating agents likely to be detected only by tester strains such as TA 1537 used in the Ames test) the in vivo alkaline comet assay is not appropriate[…]*'.
  The EU proposes to state that the *in vivo* alkaline Comet assay is not appropriate for substances that are not considered to induce single-strand breaks or double-strand breaks (SSBs or DSBs), either directly or via DNA repair intermediates, based on structural considerations and positive results in TA1537 and TA98.
- As regards clastogenicity and aneugenicity endpoints, the EU agrees with the JMPR proposal that in the case of a positive in vitro chromosomal aberration assay or in vitro micronucleus assay the recommended follow-up is the in vivo micronucleus assay. The EU suggests adding that evidence of target tissue exposure should be demonstrated in the in vivo micronucleus assay[1,3].

[2] EFSA Scientific Committee, 2011, Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment. **https://doi.org/10.2903/j.efsa.2011.2379**
[3] EFSA Scientific Committee, 2017, Clarification of some aspects related to genotoxicity assessment. **https://doi.org/10.2903/j.efsa.2017.5113**

2.4 A risk-based decision tree approach for the safety evaluation of residues of pesticides, veterinary drugs, food additives and contaminants

The EU welcomes the discussion to develop an approach for giving advice to risk managers on substances which are found in food, but for which the data are insufficient to perform a full risk assessment.

Regarding the use of the threshold of toxicological concern (TTC) approach, the EU consider that it is a pragmatic, scientifically valid methodology to assess the safety of substances of unknown toxicity found in food and the environment. However, the TTC approach should not be used for substances for which EU food/feed legislation requires the submission of toxicity data. Hence in the EU, the TTC approach is usually not applied for pesticides to waive toxicological studies defined in the legal data requirements[4].

The EU is in favour of a harmonized risk assessment approach and the elaboration of an applicable decision tree. The EU will welcome further specific information on certain details on the decision tree, such us the methodology to calculate the exposure or the subgroups of the population for which exposure estimations should be derived, and the definition of certain criteria like “meaningful margin of exposure”, “low margin of exposure” or “acceptable margin of safety”.

2.5 Unnecessary use of *in vivo* animal studies

The EU strongly supports the recommendations of JMPR to avoid unnecessary *in vivo* studies. It is highlighted that in the EU, the replacement, reduction and refinement of the use of animals for scientific studies supporting applications for pesticide approvals and MRL applications are a fundamental principle implemented in the pesticide legislation.

The EU considers that for new compounds, the respective endpoints should be addressed by appropriate *in vitro* studies. With regard to old substances that are subject to periodic re-evaluation, old *in vivo* studies can be used if their quality is still considered sufficient but should not be repeated.

The EU recommends to review the title as “*in vivo* studies”.

2.6 Establishment of MRLs for pesticides for okra

The EU appreciates the comprehensive work done by JMPR to evaluate monitoring data and to analyse the normalised initial residue concentrations measured at day 0 in different fruiting vegetables in view of identification of options for setting MRLs in okra by extrapolation. The EU agrees with the conclusion of JMPR that monitoring data are not appropriate to find representative commodities for okra, since for monitoring data usually no information is available on the treatment history. Without information on the use patterns, a meaningful interpretation of these data is not feasible.

The available data on normalised residue trials do not provide sufficient evidence that the residue behaviour in other fruiting vegetables is comparable to okra. Hence, the data do not support option 1 and option 2 on the classification of okra in the Codex food classification; option 3: introduction of a specific sub-group 12D for okra (including martynia and roselle) seems to be the only viable option at the moment.

The EU acknowledges the difficulties in generating data for the minor crop of okra and it recommends to explore if normalised residue data at day 0 in other crops show comparable residue levels with okra.

2.7 Enhancing operational procedures of JMPR to reduce the backlog

The EU supports the discussion to identify opportunities for enhancing the operational procedures of the JMPR and CCPR to reduce the backlog of evaluations. EU experiences on streamlining the assessment processes might be helpful to identify steps of the process which could be improved.

2.8. OECD Update to the Guidance on Residue Definitions

The EU encourages the active involvement of JMPR experts in OECD projects, as JMPR experts have a lot of experiences in assessments at international level and therefore they are expected to provide valuable input to the development of OECD documents.

[4] EFSA Scientific Committee, 2019, Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment. **https://doi.org/10.2903/j.efsa.2019.5708**

2.9. Information on residues in rotational crops following use on paddy rice

For European rice cultivation, crop rotation is not completely excluded, but is expected to take place only after several years of cultivation of rice. For EU assessments, a new guidance document on rotational crop assessment is under preparation. In a draft version of this guidance document, rice is considered as semi-permanent crop. Hence, primary crop uses in rice would not trigger rotational crop studies. If rotational crop studies are required due to uses in other primary crops than rice, it is not recommended to conduct rotational crop studies (confined studies and higher tier studies) with rice (crop grown as rotational crop) to investigate the uptake from residues in soil. Instead, other cereal crops should be used as test crop for rotational crop studies, as rice is considered not a crop representative for other cereals.

2.10. Common pyrazole metabolites

The EU agrees with JMPR observation and consider that there is a need to harmonise the assessment of the common metabolite of pyrazole carboxamide fungicides exists. The active substances assessed by JMPR in 2022, belonging to the pyrazole class are the following: benzovindiflupyr (261), chlorantraniliprole (230), inpyrfluxam (329), isoflucypram (330) and tetraniliprole (324). However, for a number of additional active substances containing a pyrazole structure such us fenpyroximate (193), fipronil (202), pyraclostrobin (210), isopyrazam (249), fluxapyroxad (256), sedaxane (259), bixafen (262), cyantraniliprole (263), oxathiapiproline (291) and ethiprole (304) Codex MRLs are in place, and therefore, should be also considered. Harmonisation should also include the use of a unique code number for a metabolite in all the parts of a dossier.

Since this issue is not specific to pyrazole, a more general approach for assessing common metabolites should be elaborated. At EU level, for triazole derivative metabolites (TDMs) a risk assessment approach which comprises the different sources of triazole metabolites has been elaborated. A similar approach should be established for class of pyrazole pesticides.

Agenda Items 7a & b **CX/PR 23/54/6– CX/PR 23/54/7– CL 2023/34-PR**

Revision of the Classification of Food and Feed:

Class B – Primary food commodities of animal origin (all types) and
Class E - processed foods of animal origin (all types)

The development of tables on examples of selection of representative commodities for Class B and Class E Table 9 - Primary food commodities of animal origin Table 10 - processed foods of animal origin

European Union Competence
European Union Vote

The European Union (EU) would like to thank the Electronic Working Group on the Revision of the Classification of Food and Feed for the preparation of CX/PR 23/54/6 and CX/PR 23/54/7.

The EU would like to submit its comments, as instructed in CL 2023/34-PR, as follows:

a) General comments on the overall approach to the revision of Class B and Class E and the tables of representative commodities.

The EU agrees with the overall approach followed for the revision of Class B and Class E and the tables of representative commodities.

The EU highlights revised classification includes certain endangered species, notably under - but not limited to - group 044 (marine mammals). Several species are listed under annex I of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) as “threatened with extinction” (e.g., Balaenoptera bonaerensis, B. borealis, B. musculus, B. physalus, Megaptera novaeangliae).

According to article II.1 of the CITES (fundamental principles), “Trade in specimens of these species must be subject to particularly strict regulation in order not to endanger further their survival and must only be authorized in exceptional circumstances”.

The EU is concerned that the inclusion of such species in the Codex classification of foods and animal feeds, as an international food standard relevant for global trade, may contradict the CITES provisions and should therefore be avoided. By deleting those species from Appendixes I and II, Codex would sustain the global efforts made regarding biodiversity loss, in conformity with the One health approach, as well as better respond to the UN sustainable goals 12 (Ensure sustainable consumption and production patterns) and 14 (Conserve and sustainably use the oceans, seas and marine resources for sustainable development).

In addition, the EU notes that some of these species are not consumed or traded on a large scale and may not be amenable to international standardisation in any case.

Based on the above, the EU recommends the Electronic Working Group to identify and remove from classes B and E all species belonging to annex I of the CITES before presenting the revised Class B and E and the tables of representative commodities for final adoption by the CAC.

In addition, the EU recommends considering implementing some editorial changes to Appendices I and II of the document CX/PR 23/54/6. Specific comments are provided below.

b) Specific comments on Types/Groups/Subgroups of Class B and Class E and The respective Tables 9 and 10 on examples of selection of representative commodities.

The EU recommends considering the following specific comments:

Class B (CX/PR 23/54/6)

Page 4, Definition of muscle

The EU highlights that there seems to be a discrepancy with the definition of muscle, i.e., "Muscle, including adhering fatty tissues such as intramuscular, intermuscular, and subcutaneous fat from animal carcases" and the portion to which the MRL applies, which is defined as "Muscle is the skeletal tissue of an animal carcass or cuts of these tissues from an animal carcass that contains interstitial and intramuscular fat. It does not include edible offal or trimmable fat". While the definition for muscle includes subcutaneous fat, this is not included in the definition of portion to which the MRL applies. The EU also notes that subcutaneous fat is included in the definition for fat presented at page 9 "Mammalian fats, excluding milk fats are derived from the fatty tissues of animals (not processed). […] Fat is the food-based tissue that is trimmable from an animal carcass or cuts from an animal carcass. It may include subcutaneous, omental or perirenal fat. It does not include interstitial or intramuscular carcass fat or milk fat".

Therefore, the EU recommends amending the proposed definition for muscle, deleting subcutaneous fat.

Page 4, Muscle, portion to which the MRL applies

The EU notes that the description of the portion to which MRL applies for muscle present in CX/PR 23/54/6, i.e., "For fat-soluble pesticides a portion of adhering fat is analyzed and MRLs apply to the fat" seems to refer to the previously used definition for meat (fat and muscle) as this appears to imply that fat can still be trimmed off while, according to the new definition for muscle, trimmable fat is not included. Therefore, the EU considers that the MRL for muscle should not apply to the fat in case of fat soluble substances. Furthermore, a separate MRL for fat is provided.

Therefore, the EU recommends amending the proposed text regarding the portion of the commodity to which the MRL applies (and which is analysed) for muscle as follows: "Whole commodity (without bones, edible offal and trimmable fat)".

Page 23, Code WF 0887

Please consider adding "Snakehead, striped" after the code and before the scientific name Channa striata Bloch. The common name is missing.

Page 33, Last entry before WS 0952 Tuna

Please consider deleting all text after Southern bluefin tuna, see Tuna, WS 0952 and add the content between Tuna, skipjack … and Tuna, yellowfin … in the same way, i. e.

"Tuna, Southern bluefin, see Tuna, WS 0952

Thunnus thynnus maccoyii;

syn: Thunnus maccoyii"

in order to make the entry in line with other entries,

Page 34, Entry after WS 0942 Menhaden

Please consider deleting all text after Oil sardine, see Sardines and Sardine type fishes, WS 0130 and adding the content after Sardine, European … in the same way, i. e.

"Sardine, oil, see Sardines and Sardine type fishes, WS 0130

Sardinella spp."

to make the entry in line with other entries,

Page 35, Entries Liveroil shark and Requien shark

Please consider deleting all text after Liveroil shark and Requien shark, see Sharks, WS 0131 and add the content after Shark, blue … in the same way, i. e.

"Liveroil shark, see Sharks, WS 0131

Galeorhinus galeus L.;

other Galeorhinus spp."

and

"Requiem shark, see Sharks, WS 0131

spp. of the family Carcharinidae of the Order of Selachii"

in order to make the entries in line with other entries,

Page 38, Code WS 994 to WS 996

Please consider placing all the lines in alphabetical order.

Page 42, Subgroup 044B Fat of marine mammals

Please reconsider using the Code WM 0142 instead of the new code WM 3741. WM 0142 is the existing code for "Fat of Dolphins, Seals and Whales, unprocessed" and this are exactly the commodities mentioned in subgroup 044B. WM 0142 should than read "Subgroup of fat of marine mammals, unprocessed (includes all commodities in Subgroup 044B)".

Page 43, Last three entries before WC 0976

Please consider placing the entries in alphabetical order: the three entries on "Crab, mud", "Crab, red King" and "Crab, swimming" should shift its position before "Crab, tanner".

Page 46, Subgroup 045E Turtles, Page 52 Subgroup 048A Arachnida

Please consider adding the dividing line below the given headings which are missing.

Page 49, Entry after Scallop, New Zealand

Please consider deleting the entry "Scallop, Sea, see Scallops IM 1005" after the entry "Scallop, New Zealand". This entry is available twice and correctly included after the entry "Scallop, queen, see Scallops IM 1005".

Class E (CX/PR 23/54/6)

Page 57, Code MD 1010

Please consider editing the text after the code in bold, to be in line with the whole text.

Page 59 – 61, Subgroup headings

Please consider underlining all subgroup headings by a single line instead of a double line.

Page 59, Code IV 1000

Please consider adding the word "dried" in the line after code IV 1000, so that it reads "Clam, hort necked, dried, see IV 1000 Clams, dried".

Page 59, Code IV 1005

Please consider adding the word “dried” after Scallops to read “Scallops, dried”

Please also consider adding the word “dried” in the following line so that it reads “Scallop, sea. Dried, see IV1005 Scallops, dried”.

Page 59 and 60, Subgroup 83C

Please consider aligning the name of the Subgroup 83 C on page 59 and 50 with code IV 0160 that mentioned group 48 and thus with IN 0160 the group of insects and spiders.

Therefore, please consider renaming subgroup 83 C to “Insects and spiders dried” on page 59 and 60.

To be in line with the explanation of IV 0160 (“See Class B, Group IN 0160 …”) the two spider commodities “Araneae, dried” and “Ixodida, dried” should be added in alphabetical order.

In case only insects were meant, Code IV 0160 should be changed to “IV 0162 Subgroup of insects, dried (includes all commodities in this subgroup) (See Class B, Group IN 0162 for commodities in this subgroup)”

Page 65, Code FA 3741 and FA 0142

Subgroup 085B Processed fats from marine mammals is connected to Subgroup 044B which only mentions dolphin, seals and whale fat. Therefore, the EU is of the opinion that code FA 0142 would be sufficient to describe the subgroup and that the new code FA 3741 would not be needed.

c) Guidance on whether the revised Class B and Class E and the corresponding Tables 9 and 10 of representative commodities are ready for final adoption by the 46th Session of the Codex Alimentarius Commission

The EU recommends considering implementing the editorial changes listed above before presenting the revised Class B and Class E and the corresponding Tables 9 and 10 of representative commodities for final adoption by the 46th Session of the Codex Alimentarius Commission.

EU proposal for the revision of the foreword to Classification

FOREWORD

The Codex Classification of food and animal feed commodities moving in trade and the descriptions of the various items and groups of food and animal feedstuffs included in the present document have been developed within the framework of the Codex Committee on Pesticide Residues. It was first adopted by the 18th Session of the Codex Alimentarius Commission, (1989).

The Codex Classification includes food commodities and animal feedstuffs for which Codex maximum residue limits will not necessarily be established. The Classification is intended to be as complete a listing of food commodities in trade as possible, classified into groups on the basis of the commodity’s similar potential for pesticide residues. The Classification is not meant to contradict international agreement in other areas; the presence of species internationally recognized as endangered in the Classification is not to be considered as an attempt to facilitate trade of commodities from such species.

The Classification may also be appropriate for other purposes such as setting maximum levels for other types of residues or for other contaminants in food. The Codex Classification should be consulted in order to obtain a precise description of the food or animal feed commodities and, especially, in cases where Codex maximum residue limits have been set for groups of food and groups of animal feedstuffs. The Codex Classification is intended to promote harmonization of the terms used to describe commodities which are subject to maximum residue limits and of the approach to grouping commodities with similar potential for residue for which a common group maximum residue limit can be set.

Agenda Item 8 **CX/PR 23/54/10– CL 2023/36-PR**

Joint Electronic Working Group between CCPR and CCRVDF

Mixed Competence
European Union Vote

The European Union (EU) would like to thank the Joint Electronic Working Group (eWG) of the Codex Committee on Pesticide Residues (CCPR) and the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) for the preparation of CX/PR 23/54/10, and to thank CCRDVF26 for revising the recommendations proposed by the eWG.

The EU welcomes the efforts made by the eWG to facilitate the cooperation of CCRVDF and CCPR in view of possible harmonisation of procedures and standards. The EU would like to submit its specific comments, as instructed in CL 2023/36-PR, as follows:

i. Whether the recommendations are agreeable as proposed by the Joint EWG and revised by CCRVDF26.

The EU supports the proposed recommendations 1, 2, 3 and the revised recommendation 5. For what concerns the revised recommendation 4, the EU notes that it would be appropriate to include in the list of compounds with dual use as a pesticide and veterinary drug all those compounds for which at least one CXL has been established, or is in the step procedure either at CCPR or at CCRVDF.

ii. Whether the recommendations can be improved for completeness (please provide technical/substantive revisions only) based on the background information provided in paragraphs 8-25 of CX/PR 23/54/10. If so, please provide revised recommendation(s) in track change mode.

The EU recommends modifying the revised recommendation 4 as follows:

'4. develop a list of compounds with dual use as a pesticide and veterinary drug for which at least ~~no or only~~ one Codex MRL has been established or is in the step procedure either at CCPR or at CCRVDF and that member countries will provide the information to populate this list'.

iii. Whether there is room for additional recommendations based on the issues discussed in the Joint EWG as described in paragraphs 8-25 of CX/PR 23/54/10 and the discussions that took place at CCRVDF26 as reported in paragraphs 103-124 of REP23/RVDF26. If so, please provide additional recommendation(s).

The EU would value all additional efforts in improving the harmonisation of food descriptors used by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), as to facilitate the enforcement of the Codex standards for dual use compounds. In the view of the EU, the eWG is best suited to be tasked with the harmonisation of the relevant food descriptors for food commodities of animal origin.

Therefore, the EU recommends adding the following recommendation:

'6. Examine the classification of commodities of animal origin in both CCPR and CCRVDF as to identify and list food descriptors that would need to be harmonised, and recommend on a case-by-case basis, a single, harmonized food descriptor for the relevant commodity(ies)), i. e., the part of the commodity to which the CXL applies'.

iv. Where there is agreement to task the Joint EWG with an additional task on harmonization of food descriptors to be used by JECFA and JMPR based on the discussions held at CCRVDF26 and the background information provided in paragraph 29 of CX/PR 23/54/10

The EU agrees to task the present the Joint EWG with the harmonization of food descriptors to be used by JECFA and JMPR based on the discussions held at CCRVDF26 and the background information provided in paragraph 29 of CX/PR 23/54/10.

The additional recommendation proposed by the EU is added under point iii).

Agenda Item 10 **CX/PR 23/54/12**

National registrations of pesticides

Mixed Competence
European Union Vote

The European Union and its Member States (EUMS) would like to thank the Electronic Working Group (eWG) chaired Germany and co-chaired by Australia for the preparation of the document on the national registrations of pesticides-state of the work (CX/PR 23/54/12).

The EUMS support the approach and the timelines provided in the document.

Agenda Item 11 **CX/PR 23/54/13**

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 Australia for the preparation of the schedules and priority lists of pesticides as well as the work done to incorporate the requests from members and sponsors.

General comments:

The EU notes that there might be compounds from previous years for which the evaluation was not completed and therefore no further nominations to the 2024 schedule can be accepted.

The EU also notes, that "Table 2A" worksheet lists up to 15 compounds which meet "25-year rule" and "Table 2B" worksheet lists approximately 60 compounds which meet the "15-year rule" but have not yet been listed for periodic review.

The EU notes that in 2022, JMPR reviewed only three compounds (diazinon, methidathion, quintozene) within the context of the periodic review. For these compounds, all CXLs were recommended to withdraw. These are the examples of using significant capacities of JMPR without resulting in firmly supported CXL proposals.

Therefore, the EU proposes significantly increase the list of periodic review substances (e.g., 20 substances) for 2025 and onwards. This would ensure that that among those, a minimum of five substances[5] could be reviewed each year. In addition, every year new compounds should be added to the list for the review.

On the one hand this would give interested parties the time to prepare the information needed and on the other hand this would ensure that there will be enough compounds for periodic review. In general, this approach would accelerate the overall periodic review process.

Although the discussion on the enhancement of the operational procedures of CCPR and JMPR are ongoing, some improvements could be done already now to avoid that listed substance cannot be assessed due to incomplete dossiers during the periodic review. One possibility would be to have a thorough data package check made by JMPR right at the beginning as this could avoid problems at the later stage because of missing information.

In addition, the Procedural Manual should be applied consistently. Compounds, after the first announcement for re-evaluation, should be moved to Table 1 of CX/PR 18/50/5[6] within one to four years' time (e.g., depending on a concern form lodged, whether the 25 years have been reached etc.) if no data is provided on time.

The EU believes that much more efforts are needed by all interested parties to speed up the periodic review process and that repeatedly postponing periodic reviews or keeping unsupported compounds in the system, cannot continue if there is a serious intention to reduce this backlog. The EU believes that sponsors of active substances are key in this process. The EU is grateful that the relevant sponsors have initiated the discussion on the enhancement of the operational procedures of CCPR and JMPR. This is important as it will help to address the problems. However, the EU is of the view, that more efforts are needed to come forward with complete supporting dossiers in time for the scheduled periodic reviews.

Specific comments:

B. FINALISING THE 2024 PROPOSED SCHEDULE

Paragraph 8

[5] Report of the 49th session of the Codex Committee on Residues
[6] List of pesticides whose MRLs (CXLs) or GLs have been deleted by the Codex Alimentarius Commission and for which no MRLs have been proposed

The sponsor for ethoxyquin has confirmed that they are able to provide a data package for JMPR 2023, the application of the 4-year rule is therefore not necessary.

Paragraph 9

The EU notes that the "2024 Periodic Review" worksheet lists parathion-methyl and chlorpyrifos-methyl for re-evaluation but same time no support has been indicated for those substances. Therefore, if no support will be given during the CCPR 54th (2023), the revocation of CXLs and moving those substances to the Table 1 of CX/PR 18/50/5[2] should be considered during the CCPR 55th (2024).

Paragraph 12

The EU proposes to delete the word "2022" from the first sentence.

"*Should more than 20 compound nominations on the ~~2022~~ Schedule meet the registered use / formulation …*"

E. TABLE 2B

Paragraph 18

The decision on unsupported compounds should be taken in CCPR 54. The EU notes that 2-phenylphenol has been listed as an unsupported compound. However, the EU has received information from a sponsor who supports the compound and intends to submit data for the periodic review in 2024.

Agenda Item 12 **CX/PR 23/54/14 and CL 2023/38-PR**

Monitoring the purity and stability of certified reference material of multi-class pesticides during prolonged storage

European Union Competence
European Union Vote

The European Union (EU) would like to thank the Electronic Working Group (eWG) on the Guidelines for monitoring the Purity and Stability of Reference Materials (RMs) of pesticides chaired by India and co-chaired by Argentina and Iran for the preparation of the Discussion Paper with reference CX/PR 23/54/14. The EU would like to submit its comments in the format instructed in CL 2023/38-PR, as follows:

(i) With consideration to Appendix I, the EU considers that it provides sufficient data/information that support the development of a guidance on monitoring the stability and purity of reference material of pesticides during prolonged storage.

In addition, the EU would like to provide comments as regards the current information, as follows:

Comment No I-1:

Appendix I, paragraph 1: The EU suggests providing clarification of the term "multi-class pesticide", possibly in section of definitions in the Annex of the document.

Comment No I-2:

Appendix I, paragraph 2: The EU suggests modifying the sentence

"Their stability can be assessed by creating quality control charts, comparing the certified values of expired RMs with fresh RMs, and through satisfactory performance in proficiency testing (Linsinger, 2019)" as follows:

"Their stability can be assessed by creating quality control charts and by comparison of the certified values of expired RMs with fresh RMs (Linsinger, 2019).

The reason is that satisfactory performance in proficiency tests is supporting evidence of the stability of the analytical standards, but not a proof.

Comment No I-3:

Appendix I, paragraph 3: The EU suggests deleting the whole paragraph, as the purpose of the proposed guidance document is to continue using the expired certified analytical standards for quantification of the samples. Thus, it is not relevant if the aforementioned standards can be used to demonstrate repeatability.

Comment No I-4:

Appendix I, paragraph 5: The EU suggests deleting the whole paragraph, as verification of the purity of Certified Reference Materials (CRMs) by participation in proficiency tests is not an appropriate approach. At most, questionable or unacceptable z scores might indicate problems with the analytical standard solutions, but not necessarily related to the purity of the (CRM).

Comment No I-5:

Appendix I, paragraph 8: The EU suggests deleting the whole paragraph, as proficiency tests are not relevant with regard to the evaluation of the purity of RMs.

(ii) (a) With reference to Appendix II, the EU acknowledges the need and the purpose of new work on this matter as a means to contribute to analytical cost reduction and to facilitate the work of analytical laboratories.

(b) Regarding Appendix III, the EU would like to provide more specific comments as follows:

Comment No III-1:

Considering the current wording of the title of the proposed guidance, the EU suggests clarifying whether the proposed guidance concerns the monitoring only of the stability or also of the purity of reference material, even though paragraphs 6 to 9 of the document suggest that the purity of reference material is also included.

Comment No III-2:

Appendix III, paragraph 5: the EU suggests modifying the whole sentence as follows: "To minimize the degradation of RMs, the vials must be placed in airtight capped tube/sealed pouch and immediately stored in the freezer at at ≤ -18°C with the aim to reach even lower temperature (Sharma et al. 2020).

The reason is that in certain cases, degradation cannot be avoided, but can be minimised. In addition, freezers that work at -25°C are not so common, but most freezers reach temperatures of -18°C.

Comment No III-3:

Appendix III, paragraph 6: the EU suggests deleting paragraph 6 and proposes using the procedure explained in document SANTE/11312/2021[7] under "Testing and replacement of standards" (paragraphs F8-F11).

Comment No III-4:

Appendix III, paragraph 6, footnote 9: the EU suggests replacing "mass chromatography" with "mass spectrometry".

Comment No III-5:

Appendix III, paragraph 8: the EU suggests modifying the sentence "If the deviation in the purity of the RM after expiration is found within 5%, the analyte [...]" as follows: "If the deviation in the purity of the RM after expiration is found within 10%, the analyte [...]", as 5 % is very low and does not take into account the instrumental repeatability.

Comment No III-6:

Appendix III, paragraph 8: the EU suggests correcting the sentence "[…] acceptable and therefore be considered for continued use as a RM" as follows: "[…] acceptable and therefore can be considered for continued use as a RM."

(c) the EU agrees with the proposal to establish an eWG to prepare guidance on monitoring the stability of reference material purity of pesticides during prolonged storage based on the outline provided in Appendix III for consideration by CCPR55.

[7] https://food.ec.europa.eu/system/files/2022-02/pesticides_mrl_guidelines_wrkdoc_2021-11312.pdf