CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Items 5a, 7(a,b,c), 12, 13, 15

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

52nd Session
(Virtual)
26-30 July and 3 August 2021

Comments submitted by the European Union

Agenda Item 5a

European Union Competence

European Union Vote

The European Union (EU) would like to thank to JMPR all the effort dedicated to organising an extra meeting in order to reduce the backlog of the number of new use evaluations. In addition, the EU would like to provide the following comments on section 2 of the 2019 JMPR Report:

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

The EU supports the WHO recommendation in updating Chapter 5 of the Environmental Health Criteria (240) proposing the use of the benchmark dose approach as alternative to the NOAEL as the point of departure in toxicity studies. The EU already has provided comments to WHO.

2.2 Combined exposure to multiple chemicals

The EU welcomes that further discussions on combined exposure to multiple chemicals have taken place in the context of the meeting of 17-26 September 2019 of the Joint WHO-FAO Meeting on Pesticides Residues.

The consideration of exposure to multiple chemicals during risk assessment is a priority for the EU. As part of the European Green Deal[1], in October 2020, the European Commission published its EU Chemicals Strategy for Sustainability[2] setting the framework for assessing the impact of chemical mixtures on human health and the environment. In the context of the regulatory fitness and performance programme[3] (REFIT) for the pesticide legislation, the European Commission and EFSA developed an Action Plan to accelerate the work on cumulative risk assessment (CRA)[4].

On risk assessment, EFSA developed a guidance document on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals[5], a Scientific Report on the development of a general methodology for classifying pesticides into cumulative assessment groups[6] and Scientific criteria for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals which are currently still under public consultation.[7]

In the field of pesticide residues, EFSA published in April 2020 and in January 2021 its reports on the cumulative risk assessment regarding their effects on the nervous system[8,9] and the thyroid[10]. These are pilot assessments preceding a wider implementation of cumulative risk assessments for pesticides in the EU. The nervous system and the thyroid

[1] COM(2019) 640 final
[2] COM(2020) 667 final
[3] https://ec.europa.eu/food/plant/pesticides/refit_en
[4] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_cum-risk-ass_action-plan.pdf
[5] https://www.efsa.europa.eu/en/efsajournal/pub/5634
[6] https://www.efsa.europa.eu/en/efsajournal/pub/3293
[7] https://connect.efsa.europa.eu/RM/s/publicconsultation/a0c1v00000HnXIB/pc0014
[8] https://www.efsa.europa.eu/en/efsajournal/pub/6087
[9] https://www.efsa.europa.eu/en/efsajournal/pub/6392
[10] https://www.efsa.europa.eu/en/efsajournal/pub/6088

were the selected organs for this pilot study, because they are frequent targets of pesticides and this choice allowed testing the methodologies for acute and chronic effects.

It should be noted that the current EU assessments are retrospective cumulative risk assessments, based on the actual dietary exposure (use of monitoring data) – and not prospective assessments in view of regulatory decision making. However, building on the experience gained from the retrospective assessments and in collaboration with the European Commission and EU Member States, EFSA is currently working on the methodology and the assumptions concerning the prospective scenario in the context of MRL setting.

The EU would like to offer collaborative support to FAO/WHO as the EU assessments may include elements of interest to be considered by JMPR and JECFA. During the preparation of the above mentioned reports a lot of experience has been gained addressing specific assessment assumptions in consistency with precise thresholds for regulatory consideration defined by the European risk managers.

The cumulative risks were calculated by probabilistic modelling under the assumption of dose-additivity and expressed in terms of total margin of exposure (MOET). The chemical groups used in these assessments are defined as cumulative assessment groups. They were established based on toxicological effects selected for their relevance in combined toxicity, and include substances which can act by either similar or dissimilar mode of action.

The assessments include a thorough uncertainty analysis conducted following a guidance adopted by the EFSA Scientific Committee and using weight of evidence and expert knowledge elicitation techniques. Each step of the process (hazard identification and characterisation establishment of cumulative assessment groups, cumulative exposure assessments, and cumulative risk characterisation) is reported in individual reports[11]. Recently, EFSA published the outcome of a cumulative dietary risk assessment for the Cumulative Assessment Group of acetylcholinesterase inhibition[7].

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

The EU welcomes the decision of updating the guidance for the evaluation of genotoxicity of chemical substances in food. The EU has been actively involved in the development of the guidance and will remain an active contributor in the subsequent revisions.

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

The EU welcomes the publication of the WHO probabilistic acute dietary exposure assessment for 47 pesticides[12]. The study was intended to provide a benchmarking for the IESTI methodology, to inform risk managers whether the IESTI calculations are sufficiently protective for consumers. It was expected that the study would illustrate the upper tail of the exposure distributions based on representative food consumption data and monitoring data. However, the EU identified some deficiencies in the study design and the availability of representative food consumption data and monitoring data which limited the validity of the study. The EU regrets that due to these deficiencies the study does not provide a realistic exposure calculation to compare with the exposure estimates derived with the IESTI methodology.

The EU agrees with the conclusions of JMPR that a more realistic assessment of the level of protection could be made by assuming residues at the MRL for a single commodity and residues from monitoring data for other commodities. The EU would support such an assessment by providing data and scientific advice on the design of such a study. Over the last years, the EU gained considerable experience with probabilistic calculations which might be useful for this type of assessments.

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

The EU agrees with the decision of working on a guidance on toxicological interpretation based on a kinetically-derived maximum dose (KDM). Interpretation of KMD-based toxicity is needed not only in the area of pesticide residues but in general for toxicological interpretation. The EU would appreciate further discussions at OECD/WHO level. In addition, more basic research is needed for understanding the practical use that might be made of this approach.

2.6 Comments on chlorpyrifos

The EU fully supports the JMPR decision of strongly recommending chlorpyrifos to be prioritized for periodic re-evaluation. The EU is very concerned about the effects of chlorpyriphos described in the statement published by

[11] https://www.efsa.europa.eu/en/efsajournal/pub/5123
[12] https://doi.org/10.1016/j.foodcont.2020.107563

EFSA in August 2019[13]. The EU submitted a concern form on 12 March 2020 and proceeded to lower all MRLs. Similar actions were applied to the compound chlorpyrifos-methyl for which the EU is equally concerned and recommends its prioritization for periodic re-evaluation. The EU acknowledges the proposed periodic re-evaluation of chlorpyrifos in 2022 and invites all involved parties to actively participate in the project. The EU proposes to re-evaluate chlorpyrifos-methyl as soon as possible, preferably in 2023

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

The EU fully supports the JMPR view that further guidance on appropriate use of toxicological control data is needed and welcomes this activity. Available concepts should be taken into account.

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

The EU welcomes the clarifications of JMPR on the approach using monitoring data for MRL setting only in limited cases, i.e. for extraneous residue levels and for MRLs for spices, but not for dried chili peppers, for which residue trials in fresh chili peppers or in fresh bell peppers should be provided.

Agenda Item 7a,7b,7c

European Union Competence

European Union Vote

1. General Comments

The European Union (EU) would like to thank the Electronic Working Group (eWG) on the revision of the Classification of food and feed chaired by the United States of America and co-chaired by the Netherlands for the preparation of the draft on the revision of the Codex Classification of Foods and Animal Feeds. In addition, the EU would like to thank Japan for its contribution on the replacement of the term “fodder” to include more specific terms for animal feeds.

The EU acknowledges the work done by the eWG to harmonise and to check the internal coherence of various decisions taken by the CCPR in the period 2010-2021 on the revision of the classification of food and feed.

2. Specific Comments

2.1 Revised Class C

The EU contributed to the eWG in response to circular letter CL 2020/10-PR and acknowledges that most comments were included in the report CX/PR 21/52/6. The EU can agree with this document.

2.2 Revised Class D

The EU contributed to the eWG in response to circular letter CL 2020/11-PR and acknowledges that most comments were included in the report CX/PR 21/52/7. The EU can agree with this document.

The EU notes that according to CX/PR 21/52/7, rice is classified as CM 0649 (rice husked) and CM 1205 (rice polished) in the Group 058 (milled cereal products, early milling stages). The EU highlights that only husked rice (CM 0649) has a direct corresponding code in Annex I of Regulation (EC) No 396/2005 under the code 0500060 (Brown rice (husked rice), defined as rice after the removal of the hull from paddy rice). Codex MRLs established for polished rice (CM 1205) can not be implemented in the EU, unless a processing factor is available to recalculate the Codex MRL to brown rice. As it was highlighted in a recent case study published by FAO[14], the classification for rice plays an important role in terms of alignment of national legislation of Codex member countries with Codex MRLs. Due to divergences in classification, an overall low amount of alignment with Codex MRLs (23%) has been observed in this case study. However, when only the data form husked rice were compared, the level of correspondence rose to 100 percent. The EU would therefore very much welcome agreement on a common definition of the commodity to which Codex MRLs should apply or on the establishment of a reliable processing factors.

The EU notes that currently Annex I of Regulation (EC) No 396/2005 is mainly based on raw commodities and Codex MRLs for processed commodities currently can not be directly implemented in EU legislation.

The EU recommends to delete the group code DF 0175 (Group of fruit and vegetable, dried, (includes all commodities in this Group)) from the Group 055 (dried fruits) as dried vegetables are covered by the group code DV 0168 inside the Group 056.

[13] https://www.efsa.europa.eu/en/efsajournal/pub/5809

[14] FAO. 2020. *Understanding international harmonization of pesticide maximum residue limits with Codex standards: A case study on rice.* Rome. https://doi.org/10.4060/cb0463en

In Group 055 "Dried fruits" the code "DF 0001 Group of Citrus, dried (see Group 001 (Code FC 0001) for species in the group of citrus fruits)" is included twice (page 5 and 6). The EU proposes to delete the second entry on page 6.

In Group 055 “Dried fruits” the EU recommends to add the word “dried” to the entries for muscatel and pitaya (DF 2540).

2.3 Transfer of commodities from Class D to Class C

No further comments.

2.4 Tables of representative commodities for the revised Class C and Class D

No further comments.

Agenda Item 12

Mixed competence

European Union Vote

The European Union and its Member States (EUMS) would like to thank Canada, Costa Rica and Kenya for having proposed principles and procedures to enable the participation of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in parallel reviews of new compounds.

The EUMS appreciate that the proposed process contributes to accelerating the setting of Codex MRLs and further supports MRL harmonization. The EUMS welcome the establishment of a pilot project that considers the available resources at JMPR. In particular, the proposed approach should not further delay the on-going work in relation to the Priority Lists of Pesticides for Evaluation / Re-Evaluation by JMPR. The EUMS agree that the Procedural Manual should be amended to integrate the process of the JMPR parallel reviews. Discussions on the necessary amendments should start after a thorough evaluation of the pilot project.

The EUMS support that the JMPR parallel reviews build on the latest OECD guidance on definition of residues. The EUMS note that the new revision of the OECD guidance will not be finalised before the end of 2021 and may therefore not be considered in the context of the pilot project.

Agenda Item 13

European Union Competence

European Union Vote

The European Union (EU) would like to thank the Electronic Working Group (eWG) on unsupported compounds without public health concerns scheduled for periodic review chaired by Chile and co-chaired by India and the United States of America for the preparation of the discussion paper on the management of unsupported compounds without public health concerns scheduled for periodic review with reference CX/PR 21/52/17.

Generic comments:

The EU, as already indicated in its comments on CX/PR 19/51/17 and CX/PR 20/52/17 continues to support option 3, which is fully in line with the risk analysis principles.

With regard to option 2b, the EU would like to refer to its comments on Circular Letter CL 2020/40 PR from 14 September 2020:

“The EU does not support option 2b and does not agree to an amendment of the Risk Analysis Principles regarding periodic reviews. It is not a problem of the Risk Analysis Principles, but of the practical implementation of those principles for certain substances. The EU considers that the preparation of a proposal for amendment for consideration by CCPR52 (2021) exceeds the terms of reference of the current eWG. It would also divert resources from pursuing more promising ways forward.”

Specific Comments:

TOR(ii)

The EU supports the collaboration activities suggested in the discussion paper for unsupported compounds.

Additionally, in this context, the EU would also welcome further discussions/reflections on how to support Codex Members, in particular developing countries, in moving gradually towards the use of lower risk substances. These discussions/reflections could take place within a future mandate of this or a new working group.

The EU notes that the eWG of unsupported compounds could be functioning permanently as proposed in paragraph 21 of Appendix I. The EU believes that the three eWGs on Unsupported Compounds, on the National Registration Database and on Priorities are closely interlinked. Therefore, the EU proposes merging the eWG on Unsupported Compounds with the one on the National Registration Database. The merged eWG could also be tasked to contribute to the eWG on Priorities by preparing suggestions for the substances to be included into the tables of the priority list. This division of responsibilities should be reflected in the mandate of a future joint eWG on unsupported compounds and on the National Registration Database.

TOR(iv)

The EU supports the additional practices suggested in the discussion paper.

As regards paragraph 49, the EU would like to refer to its comments on Circular Letter CL 2020/40 PR (rev) from 14 September 2020 on paragraph 27:

"The EU agrees with the proposal of the eWG, and suggests that the eWG recommends to explore whether the platform "forum.codex-alimentarius.net" could be used for this purpose."

Agenda Item 15

Mixed competence

European Union Vote

The European Union and its Member States (EUMS) 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.

B. FINALISING THE 2022 PROPOSED SCHEDULE

Paragraph 5 and 6

The EUMS agree with the proposed schedule.

Paragraph 7

The EUMS support the seven compounds and one reserve compound that are listed for periodic review in 2022.

The EUMS acknowledges that efforts were made to increase the number of substances for the periodic review. However, this does not solve the general problem with a steady increasing backlog of substances for which the last review was done more than 25 years ago.

The EUMS regret that the re-evaluation for chlorpyrifos is deferred to 2023 as based on the information available from the European Food Safety Authority serious human health concerns have been identified and therefore public health concerns were submitted in 13 March 2020.

It is not clear whether an evaluation could take place for carbendazim, based on the comments in Column E on commodities in the respective Excel worksheet. The EUMS seek for clarification how to proceed with carbendazim, which toxicology is outdated as the last full toxicological evaluation was in 1995 with an evaluation for acute effects in 2005.

The EUMS acknowledges that the periodic re-evaluation for dithiocarbamates will likely be more complex than other evaluations, due to the different active substances contributing to dithiocarbamate residues.

F. PUBLICH HEALTH CONCERNS

Paragraph 13

The EUMS note that the substances propiconazole, chlorothalonil and chlorpropham, for which a public health concern have been lodged, have not been added to Table 2A. In addition, the substances propiconazole and chlorpropham meet the 15-year rule. Therefore, the EUMS propose to transfer propiconazole, chlorothalonil and chlorpropham to Table 2A.

G. PERIODIC REVIEWS (UNSUPPORTED COMPOUNDS)

Paragraph 14

The EUMS are in favour of deleting compounds from the CCPR pesticides list that are no longer supported by a manufacturer and for which a public health concern has been identified. The withdrawal of the corresponding CXLs will reduce the number of substances for which a periodic review is needed. Therefore, the EUMS support the removal of related CXLs from the CCPR pesticides list for amitraz PHC (122), bromopropylate PHC (070), fenarimol PHC (192), dicloran PHC (083), bromide ion (047) and fenbutatin oxide.

The EUMS consider that maintaining CXLs that are not supported by submission of toxicology, residue and other relevant data, and also do not have a corresponding registration listed in the National Registration Database, violates the requirements laid down in the Risk Analysis Principles applied by the Codex Committee on Pesticide Residues. The EUMS acknowledge the work on a discussion paper concerning the management of unsupported compounds. Nevertheless, the respective discussion should not jeopardise or counteract the aim to perform a periodic re-evaluation of active substances as required. An extension of the period in case an existing evaluation will be outdated, i.e. beyond 25 years, is not acceptable.