30 June 2021

CODEX COMMITTEE ON PESTICIDE RESIDUES

52st Session

(Virtual)

26-30 July and 3 August 2021

European Union Comments:

Report on items of general consideration arising from the 2019 JMPR extraordinary and regular meetings

(Section 2 of the 2019 JMPR Report)

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

[1] COM(2019) 640 final
[2] COM(2020) 667 final
[3] https://ec.europa.eu/food/plant/pesticides/refit_en

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 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].

[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
[11] https://www.efsa.europa.eu/en/efsajournal/pub/5123

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

[12] https://doi.org/10.1016/j.foodcont.2020.107563

chlorpyriphos described in the statement published by 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.

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