CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5(a), 5(b)

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Comments on Section 2 and 3 of the 2017 JMPR Report, submitted by China, European Union and Kenya

Agenda Item 5(a) Report on items of general consideration by the 2017 JMPR

China

China appreciates the hard efforts made and enormous work accomplished by JMPR experts and the Secretariat. China notes the Field use pattern anticipated residue comparison model was described in the General Considerations Item 2.4 of the JMPR Report, which can be used to compares anticipated residues at harvest resulting from differences in application rates, retreatment intervals, and PHI. China supports the work of the JMPR in evaluating MRLs using this model, and recommends that this model could be further validated by using more databases and the relevant principle will be put forward before the formal application.

European Union

European Union Competence

European Union Vote

The European Union (EU) would like to provide the following comments on section 2 of the 2017 JMPR Report:

2.1 Harmonisation of the dietary exposure methodologies for compounds both used as pesticides and veterinary drugs - Special studies on microbiological effects of pesticide residues in foods

The EU very much welcomes the initiative of JMPR to carry out microbiological assessments of pesticides residues' adverse chronic and acute effects on the microorganisms in the human gastrointestinal tract similarly to the assessments already routinely done by JECFA for veterinary drug residues.

For chemical active substances used as pesticides, specific studies investigating the potential adverse effects of pesticide residues on the microorganisms in the human gastrointestinal tract (human microbiome) are not part of the EU data requirements. In the literature reviews which have to be submitted since 1 January 2014 in addition to the studies defined in the data requirements, adverse effects of pesticide residues on the microorganisms in the human gastrointestinal tract have not been reported so far.

The EU would welcome a wider discussion on the multidrug resistance of human pathogen fungi against substances such as triazole fungicides.

2.2. Use of historical control data

The EU welcomes the recommendation to update the document “Principles and Methods for the Risk Assessment of Chemical in Food” (EHC 240). The interpretation of statistical evaluations and historical control data often is a reason for discussion leading to divergent views of experts and it would be desirable to find a common approach.

2.3. Further consideration of the process for establishing group MRLs: Update on the use of the revised commodity classification for vegetables

As a general comment, the EU is concerned that the new approach on the establishment of group MRLs implemented by JMPR may invalidate some of the MRL decisions taken in the past and deplores that such fundamental discussions were not brought forward earlier. Such changes may lead to problems when Codex MRLs are implemented into EU legislation.

In general, the EU shares the observation of JMPR that the shape/size or surface/weight ratio of a crop is an important parameter that influences the magnitude of residues. It may be less important for systemic substances or soil applications, but for foliar uses of pesticides close to harvest an extrapolation to crops with different morphological features may lead to inappropriate MRLs.

JMPR decided that based on residue trial in tomatoes, maximum residue levels will be derived only for cherry tomatoes (VO 2700) and tomatoes (VO 0448), but not for other crops listed in the subgroup 12A 'Tomatoes', e.g. to currant tomatoes, goji berries and tomatillos. Similarly, when data are available for Bell peppers and non-Bell peppers, JMPR decided to present maximum residue levels only for VO 0051 'Subgroups of peppers', exempting okra, martynia and roselle.

In the EU, MRLs established for tomatoes are also applicable to cherry tomatoes and to a number of minor crops, such as Cape gooseberries, tomatillos, gojiberries and some other minor crops.

As regards peppers, the MRLs established for bell peppers would be equally applied to chili peppers, but not automatically to okra (okra are classified separately from peppers). However, an extrapolation from peppers to okra is allowed in the EU, provided that the same GAP applies. Roselle and marynia are not explicitly listed in the EU food classification.

The MRLs derived with the OECD calculator usually accommodate for variations, but in certain cases the MRLs might not be sufficient for small sized crops listed in the crop classification in the same category as a comparably larger crop.

The uncertainty resulting from the application of MRLs that were established for major crops like tomatoes or peppers to the related minor crops was considered acceptable in the EU by risk managers, taking into account that these commodities are usually consumed in lower amounts and that usually no specific residue trials are available that would allow to establish separate MRLs.

2.4. Field use pattern anticipated residue comparison model

JMPR developed a model/tool that estimates residues at harvest resulting for a certain GAP based on residue trials that are not exactly matching with the critical GAP, but that differ in application rates, re-treatment intervals (RTI) and pre-harvest intervals (PHI). Crop specific half-lives were estimated from a limited number of decline studies. This tool was used for deriving MRL proposals for cyclaniliprole.

The EU considers that such a model/tool can be useful to decide if results of supervised trials differing in one or several parameters are representative for the GAPs for which MRLs are requested. It might allow a more harmonised and objective evaluation of such GAPs by different assessment bodies.

However, before using this approach in a regulatory decision making process, it is necessary that the model is validated to ensure that the derived MRL proposals are appropriate. The EU therefore requests that 1) a full description of the algorithms implemented in the model should be provided in the JMPR report and 2) a model validation is performed, comparing the outcome of an assessment based on trials matching the GAP with assessments based on residue trials that deviate in different parameters from the GAP to be assessed. Based on the results of the validation, a decision can be taken on the cases/scenarios where the tool can be used and the limitations of the tool (e.g. for residues with a complex degradation behaviour).

Residue decline is a complex interaction of a number of simultaneous processes. First order kinetics may often not be the best approach to describe a system as often issues are more complex than a comparably "simple" linear proportionality approach. It should be born in mind that not every decline residue study can be used. The half-life estimate for a pesticide in a certain crop is not a constant, but may vary depending on the crop development stage, e.g. for cereals the half-life at early growth stages will be significantly different from the decline rate at the last stage of the development, where the decline will be mainly influenced by the loss of moisture and increase of the dry matter content of the grain.

Further input should be sought to gain experience with the modelling tool and to help defining possible variations of parameters (e.g. PHI) and limitations for its applicability.

Given these uncertainties resulting from the lack of a model validation, the EU will reserve its position for MRL proposals that were derived with this tool for the time being. The EU is ready to provide further detailed technical comments on its analysis of the model.

2.5. Update of the IESTI model used for the calculation of dietary intake: New large portion data

The update of the IESTI model to be used for dietary exposure calculations is welcome and regular updates should be further promoted. The EU suggests to include the recommendations of the international workshop on the IESTI equation as regards the relation of consumption data to actual body weights in a future revision of the document.

The EU would like to inform the participants of the CCPR meeting that a new revision of the European model for pesticide risk assessment (EFSA PRIMo revision 3) has been recently published (available under https://www.efsa.europa.eu/en/applications/pesticides/tools). This new revision contains updated EU consumption data that could be taken into account for the IESTI model used by JMPR.

Kenya

2.1 Special studies on microbiological effects of pesticide residues in foods.

Position: Kenya appreciates the new approach in evaluating intestinal microbiota given the emerging challenges with antimicrobial resistance which is a global challenge. Some pesticide residues in food may have antimicrobial properties and there is potential exposure of intestinal microbiota following ingestion of such residues in food.

2.2 Use of historical control data

Position: Kenya supports the recommendation of 2016 JMPR on binary data on animal toxicity studies; on providing expanded guidance for these topics for EHC240.

2.3 Further consideration of the process for establishing group MRLs: Update on the use of the revised commodity classification for vegetables

Position: Kenya agrees to the fact that use of crop grouping is very important in supporting the establishment and harmonization of missing MRLs for minor crops. The approach of excluding some commodities from the crop group without due consideration of legitimate factors such as missing MRLs because it can impede trade especially in minor crops is a serious concern. We urge the CCPR to explore mechanisms to ensure that this does not set precedence on earlier agreed areas of harmonization.

2.4 Field use pattern anticipated residue comparison model

Position: Kenya notes that only one compound was evaluated, there is need for more work using other compounds and crop combinations to evaluate the usefulness of this model. The model should be robust and all inclusive to cover various compounds and crop combinations.

2.5 Update of the IESTI model used for the calculation of dietary intake: New large portion data

Position: Kenya appreciates the updated model adopted in 2003 JMPR report of the automated spread sheet for the calculation of the dietary intake, that has included more countries and look forward to the inclusion of large portion of data from Africa that will improve on the uncertainty of the outcome of short term dietary intake estimation.

Agenda Item 5(b) Report on 2017 JMPR responses to specific concerns raised by CCPR

Kenya

3.2.2.1 Update from the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

Position: Kenya supports the ongoing activities at JECFA on the updating of the guidance document on enzymes in food, development of a guidance on evaluating genotoxicology of compounds in food for human health risk assessment and best way to develop a guidance on dose-response assessment.

3.2.2.2 Harmonization of the dietary exposure methodologies for compounds used both as

Pesticides and veterinary drugs – Harmonizing/combining exposure from veterinary drug and pesticide use

Position: Kenya appreciates the ongoing work to harmonize dietary exposure methodologies for compound use for both pesticide and veterinary drug by agvet working group. There is need to develop harmonized model on the current approaches,ie international estimated daily intake (IEDI) and global estimate of chronic dietary exposure(GECDE).

3.2.2.5 Harmonization of the residue definition – determining the level of interest in a pilot project to achieve more harmonized residue definitions

Position: Kenya agrees with the position to establish an active substance dialogue between national regulators and international organizations in order to come up with a non-binding harmonized residue definition. Different residue definitions by national governments and international organizations normally results into different dietary exposure conclusions and enforcement requirement and hence the need for harmonization.