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European Union Comments
CODEX COMMITTEE ON PESTICIDE RESIDUES
48th Session

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AGENDA ITEM 5 a)

**Report on items of general consideration by the 2015 JMPR
(Section 2 of the 2015 JMPR Report)**

*European Union Competence
European Union Vote*

The European Union (EU) would like to provide the following comments on section 2 of the 2015 JMPR Report:

2.1 EFSA Scientific workshop revisiting the IESTI equation, co-sponsored by WHO and FAO

Discussions on a possible revision of the IESTI equation have been ongoing in the EU for some years, albeit without any tangible results so far. The EU very much welcomes the steps undertaken recently to move ahead with these discussions taking on board the previous experiences and findings. The EU fully supports that such discussions are taken up in an international context and highly appreciates that JMPR discussed the recommendations made in the EFSA Scientific Workshop in September 2015. The final event report has been published under the following link:

<http://www.efsa.europa.eu/en/supporting/pub/907e>

Some EU Member States and Australia, coordinated by EFSA and RIVM as co-organiser of the IESTI event, are currently performing analyses comparing the outcome of the exposure calculations performed according to the current IESTI methodology and the proposed new methodology. These preliminary results will be presented during a side event at CCPR 48. To make progress, the EU proposes to CCPR to take up the work on the IESTI equation as new work and a project document and discussion paper has been prepared for discussion in CCPR 48. If the Committee agrees, an electronic WG could be set up.

2.2 Shorter than lifetime exposures

The initiative to develop models to assess exposure longer than one day but shorter than lifetime is strongly supported.

The current methodology for long-term exposure is based on the mean consumption derived for the general population and median residue concentration expected in the food consumed. However, this approach does not take into account specific periods in lifetime with different food habits (e.g. infancy and childhood), persons with regular consumption of certain food products significantly exceeding the average food consumption of the general population (e.g.

regular consumption of an apple a day), consumers that have specific preferences for certain food that is consumed only by a small percentage of the population (e.g. kiwi) or seasonal differences in consumption of products that are available only for a limited period of the year (e.g. cherries).

Thus, the methodology for less than lifetime exposure should in particular focus on food products with a big difference between the large portion (LP) used for short-term exposure assessment and the mean food consumption (averaged over the total population) used for long-term exposure assessment.

When developing such a methodology discussions should also focus on the most appropriate residue concentrations that should be used for this type of exposure assessment (STMR or any other input value?).

In addition, the discussion should address the question whether there a need to derive specific toxicological reference values for particular development or time windows that should be covered by the assessment.

Risk managers need to be involved in formulating the risk problem and defining the scope of the risk assessment.

2.3 Update on the revision of the Principles and Methods for the Risk Assessment of Chemicals in Food (EHC 240)

The recommendation to update the document “Principles and Methods for the Risk Assessment of Chemical in Food” (EHC 240) is welcome. As mentioned by JMPR, the document should reflect the outcome of the discussions on the less than lifetime exposure, but also the approach for expression of uncertainty in hazard characterisation or the TTC approach.

The EHC 240 is understood as a more generic document describing general principles for risk assessment, not only applicable for pesticides but also for other food domains. When preparing an updated version of the document, particular attention should be paid to avoid overlaps with the FAO Manual. The specific methodologies and approaches used by JMPR in its assessment should be outlined in the FAO Manual. A clear separation of the scope of the two documents will increase transparency of the risk assessment process.

2.4 Update on the report on the Joint FAO/WHO Expert Meeting on Hazards Associated with Animal Feed conducted from 12 to 15 May in Rome, Italy

The comments made by the expert group are highly appreciated. The data required by regulators are part of the current EU data requirements except residue data from biofuel production. Nevertheless, these data are currently not yet used in the EU to establish MRLs for feed. Setting realistic MRLs for food of animal origin requires a realistic dietary burden calculation, taking into account the expected residues in feed. Experts from the EU are available to discuss a possible update of the feeding tables currently in use for estimating the dietary burden with colleagues from other scientific bodies (including OECD). The OECD guidance document on residues in livestock that is the basis for the dietary burden calculation (new revision published in July 2013) contains a list of feed products that contribute to the dietary burden of livestock. It would be desirable if these (mainly processed) products are included in the Codex food classification with clear description (e.g. dry matter content). It is noted that the product explicitly mentioned (dried distillers grain soluble, DDGS) is one of feedstuffs reported in the OECD guidance document which is not covered by the Codex food classification; the list should be checked carefully whether it contains additional feed products that should be taken up in the food classification as well.

2.5 Minimum number of supervised field trials for MRL setting for minor crops

Following agreement in 2015 on the classification of major/minor crops, the minimum number of supervised field trials defined for setting MRLs for minor crops should be implemented in the MRL setting process (see also comment on General consideration, 2.6 Revision of the FAO Manual). JMPR is encouraged to highlight in their future assessments when problems are encountered by applying the agreed approach. In this respect attention should be paid to the minimum of 5 trials in category 3.

2.6 Revision of the FAO Manual on the submission and evaluation of pesticides residues data for the estimation of maximum residue levels in food and feed.

The update of the FAO manual is appreciated since it is an important reference document that illustrates in a transparent way how the MRL assessments are performed by JMPR. The new agreed concepts, such as the proportionality approach, the principles for extrapolation for maximum residue limits for pesticide commodity groups (list of representative commodities and the extrapolation to other commodities), the use of the OECD calculator, implementation of the updated feed table of the OECD guidance document (GD 73 of July 2013), the updated approach for independent trials or the minimum number of trials for minor crops agreed approach for setting group MRLs should be described in the new revision of the document.

However, approaches that are not agreed should not be included in this document (e.g. the 5-fold median approach for setting group MRLs, the approach how to take into account residues in succeeding crops or the global GAP approach).

It would be appreciated if the draft manual would be circulated for commenting before it is published.