

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 5a

CRD06

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

48th Session

Chongqing, P.R. China, 25-30 April 2016

Comments on Report on items of general consideration by the 2015 JMPR, submitted by China, European Union, Ghana and African Union

China

China appreciates the hard efforts made and enormous work accomplished by JMPR experts and the Secretariat and hopes that the JMPR could continue optimizing relevant guidelines and guides, so as to promote a more science-based and uniform Codex MRL setting process and provide valuable and robust reference for pesticide management and standard-setting authorities of countries.

European Union

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.

Ghana

2.1: EFSA Workshop co-sponsored by WHO and FAO existing the IESTI equation

Position:

Ghana welcomes the proposed review of the current IESTI equation. This work has significant impact on the scientific basis of Codex standards and would contribute to providing practical approach to decision making with regards to risk management.

We look forward to participating in the activities of the proposed FAO/WHO working tasked with comparing the use of current and proposed IESTI equations. In the interest of inclusivity, participation in the FAO/WHO working group should be based on geographical representation. In addition we also recommend that the following issues should be included in the agenda for proposed working group.

- Identification of a list of commodities or classes of commodities for which a variability factor is not needed
- Support to generation of large portion data especially for developing countries for purposes of ensuring geographical representativeness of data
- Compilation of conversion and processing factors to aid in referencing.

2.2: Shorter than Lifetime Exposures

Position: Ghana supports work on developing risk assessment models for shorter than life time exposures.

Rationale: Since there is currently no internationally harmonized standard for determining human health impact from exposure to pesticides shorter than lifetime but longer than short-term, the development of an internationally acceptable model is appropriate and would address the current gap in risk assessment.

African Union

2.1: EFSA Workshop co-sponsored by WHO and FAO existing the IESTI equation

Background:

An EFSA Scientific Workshop was held in Geneva on the 8th and 9th of September 2015. The overall goal of the Workshop was to evaluate the parameters within the International Estimate of Short-Term Intake (IESTI) equations as well as the equations themselves, with the aim of harmonizing the parameters and equations between different dietary risk assessment programmes.

Position

AU appreciates the outcome of the EFSA workshop co-sponsored by FAO and WHO and welcomes the recommendation by the JMPR to have a FAO WHO working group to compare the use of current and proposed equations. Further to this recommendation, it is proposed that the workshop should critically consider the following recommendations:

- i) list of commodities be developed for which a variability factor is not needed
- ii) availability of large portion data especially for developing countries
- iii) Conversion factors and processing factors should be compiled for ease of reference.

To ensure inclusivity, the Scientific FAO/WHO working group should also ensure inclusivity of developing countries

Rationale:

The proposed revisiting of the current IESTI equation is important in providing pragmatic approach to decision making.

Justification:

The involvement of broad representation in the scientific process is important especially to developing countries, since the use of new information that may require data which is yet to be collected may have negative impact on trade.

2.2: Shorter than Lifetime Exposures

Background: Quantitative method for the estimation of risk has been developed for daily lifetime human exposure. However, a common framework for evaluating risk from less than a lifetime exposure does not exist to address this risk assessment need. As a follow-up of the 2014 report item 2.5, Characterization of risk of less-than-lifetime high exposures to pesticide residues, was discussed at the 2015 JMPR meeting and a recommendation to convene an expert working group was made.

Position:

AU welcomes the Expert Working group to look into the develop models to cover exposures longer than 1 day but shorter than lifetime.

Justification:

There is no information on the human health impact on exposure to pesticides shorter than lifetime, but longer than short-term. The development of a suitable model would therefore be useful.

2.3 Update on the revision of principles and methods for Risk Assessment of chemicals in Food (EHC 240)

Background:

Shorter than lifetime exposure

It's has been observed that the current models do not address shorter than lifetime exposure. The meeting therefore, discussed the implications of shorter than lifetime (more than 1 day) exposures on the risk characterization of residues of pesticides in food. It was proposed a group be convened to develop possible models for shorter than life time exposure. Depending on the outcome of this exercise, it might be necessary to update the relevant section of Environmental Health Criteria monograph (EHC) 240.

Consistence in risk assessment principles

During the 47th session of CCPR the meeting was informed on the standing agenda item on the update of the risk assessment principles of chemicals in foods. However, lack of consistence between the WHO core bodies i.e. JMPR and IARC on the carcinogenicity of glyphosate was sighted. The committee proposed WHO should follow on this matter. The Meeting recommended that general principles arising from this assessment should be incorporated into the relevant section of EHC 240.

Uncertainty in hazard characterization

New published guidance by WHO and EFSA on evaluating and expressing uncertainty in hazard characterization together with related activities have been developed. The meeting therefore recommended the relevant sections of EHC 240 be reviewed and revised as necessary in order to incorporate the changes in the guidance documents.

Threshold of toxicological concern

In the near future, WHO and EFSA will publish the review of the threshold of toxicological concern (TTC) approach for compounds with limited or no toxicological data. The relevant section(s) of EHC 240 should be revised to reflect the outcome of this review

Position

AU welcomes the revision of the principles and methods of risk assessment of chemicals in food (EHC 240) as needed to make transparent the criteria and approaches used to determine the quality, relevance and use of all published and proprietary studies in evaluation of compounds and its usefulness in revision in hazard characterization. AU also looks forward to the outcome of the WHO risk assessment network.

Justification:

AU recognizes the need in the spirit of harmonization to be transparent in the criterion used to evaluate data from published and proprietary studies.

2.4 Report on the Joint FAO/WHO expert meeting on hazards associated with animal feed conducted from 12 to 15 May in Rome, Italy

Background: A meeting was convened by the FAO and WHO, in line with their overall aims of securing feed and food safety and ensuring fair practices in the trade of food and feed. The objective of the meeting was to provide an updated overview of the current state of knowledge on hazards associated with feed (including use of insects, former food, food processing by-products and biofuel by-products as feed).

Position

AU welcomes the recommendation of this meeting. However, due consideration should be given to the definitions of food, animal feeds and biofuels in relation to animal feed, and how this will impact on adding additional feed items to the relevant Codex Commodity Classification and the ongoing revision of the Codex Classification of food and feed; and be in line with the Risk analysis principles used by the Codex Committee of Pesticide Residues.

Justification:

The animal feeds are used in animal feeding and may get to humans; these may give rise to food safety concerns.

2.6 Revised of the FAO manual on the submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed

Background:The JMPR continuously develops the working principles used for the evaluation of pesticide residue data, based on its practical experience and scientific developments, so as to make best use of the available information. Since the publication of the 2nd Edition of the Manual (2009) a number of important concepts have been developed. This calls for the revision of the current manual.

Position

AU welcomes the revision of the FAO Manual to incorporate new principles in the working procedures to assist in their systematic application by the CCPR.

Justification:

The revision takes into consideration the new approaches that will improve the work of the CCPR.