

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 8

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

Thirty-eighth Session

Hotel Vila Galé, Fortaleza, Brazil, 3 - 8 April 2006

COMMENTS ON THE DRAFT RISK ANALYSIS PRINCIPLES APPLIED BY THE COMMITTEE ON PESTICIDE RESIDUES AT STEP 6

ARGENTINA

Argentina believes that it would be appropriate to include a footnote in paragraph 10, on the phrase “other legitimate factors...”, with the following wording: “in accordance with the **Appendix: General Decisions of the Commission**, included in the Procedural Manual, which incorporated the *Statements of Principles Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors Are Taken into Account*, Decision adopted at the 21st session of the Codex Alimentarius Commission of 1995; *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle*, Decision adopted at the 24th session of the Codex Alimentarius Commission of 2001 and; *Statements of Principle Relating to the Role of Food Safety Risk Assessment*, Decision adopted at the 22nd session of the Codex Alimentarius Commission of 1997”.

CANADA

The document gathers information from the several guidelines or related texts used by JMPR and CCPR, such as the FAO Manual on Data Submission and Evaluation of Pesticide Residues Data for the Estimation of Maximum Residue Levels in Food and Feed, the WHO Guidelines for Predicting Dietary Intake of Pesticide Residues, the agreed CCPR policy on EMRL setting, and the periodic review procedure into a single framework.

Canada continues to support the development of risk analysis principles for use by member governments. Canada suggests defining what is meant by minimum data requirements necessary for JMPR to perform risk assessments (in this context).

It should be noted that the paper (CL 2005/41-PR, Item 8) unambiguously indicates that when establishing its standards, that the CCPR will clearly state when it applies any non-science-based considerations, in addition to JMPR's risk assessment and specify its reasons for doing so. Canada continues to advocate, that CCPR adhere to the use of science to support its recommendations to the CAC.

THE FAO/WHO JOINT SECRETARIAT TO THE JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES (JMPR)

Our comments are based on an assessment of the draft by the JMPR 2006 (see Annex) and further discussions between both Secretariats.

We understand that this document is fairly advanced but the following comments and suggested minor changes in wording are aimed to increase the clarity of the document and to improve its understanding outside of CCPR.

General remarks

It should be noted that the Joint FAO/WHO Meeting on Pesticide Residues which consists of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group is an **independent scientific expert body** convened by both Director Generals of FAO and WHO. The available resources are provided by regular budget and extra-budgetary funds from both organizations; expert selection, working procedures, other applicable rules are defined by FAO and WHO and the JMPR itself.

It is recognized that the Codex Alimentarius Commission is the main "customer" to JMPR and requests for the evaluation of pesticide residues which are received from CCPR are the main part of the expert body's work. This close relation needs to be described properly and therefore the draft principle are a step welcomed by FAO and WHO; however, the independence of JMPR in its scientific work shall be secured by the document.

FAO and WHO also provide scientific advice on other food safety matters (additives, residues of veterinary drugs, microbiological risks, biotechnology, nutrition) via other expert bodies. Both organizations emphasize and welcome any steps by Codex to harmonize where possible the rules and procedures applied to these different areas i.e. developing risk analysis principles which allow interested parties to understand how the general Codex principles on risk analysis are implemented by the technical Codex committees.

Specific comments and proposals for changes (in red):

Para 1: Stress upfront the complementary roles of JMPR and CCPR:

"This document addresses the respective applications of risk analysis principles by the Codex

Committee on Pesticide Residues (CCPR) **as the risk management body** and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) **as the risk assessment body**, and facilitates the uniform application of the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*."

Para 4: JMPR is not a standing committee; communication and continuous dialogue are also task of the Joint Secretariat.

"CCPR and JMPR should continue to develop procedures to enhance communication between the both **bodies**."

Para 5: The different tasks of risk managers and risk assessors are mixed and not clearly separated.

"CCPR and JMPR should ensure that their **respective** contributions to the risk analysis process **result in outputs from the joint risk analysis process that are** scientifically based, fully transparent, thoroughly documented and available in a timely manner to Member States."

Para 6: This paragraph is too vague and does not provide enough guidance to JMPR and the Joint Secretariat what to do. It is not clear what 'minimum data requirements' refer to, to preliminary work and assessment of availability of data before priorities can be set, or to minimum data that allow an evaluation.

Para 8: We suggest to merge Para 8 and Para 10 which overlap:

"CCPR shall base its risk management recommendations, such as MRLs, to the CAC **following** JMPR's risk assessment of the respective pesticides, **and considering, where appropriate, other legitimate factors such as relevant to the health protection of consumers and for the promotion of fair practices in food trade.**

Para 9: One small editorial change improves possibly reading.

"In cases where JMPR has performed a risk assessment and CCPR or the CAC determines that additional scientific guidance is necessary, CCPR or CAC may make a specific request to JMPR to provide further scientific guidance necessary for a risk management decision."

Para 10: Join with 8.

Para 11: Safety factors as applied by JMPR are an inherent part of the risk assessment. We do not think that they as such are up for discussion at CCPR.

"CCPR's risk management recommendations to the CAC shall take into account the relevant uncertainties and safety factors as described by JMPR."

Para 12: There is no accepted definition for "quantitative risk assessment", people have quite different ideas about it. We suggest a more general statement

"CCPR shall consider maximum residue levels (MRLs) only for those pesticides for which JMPR has completed a full safety evaluation including a quantitative risk assessment."

Para 13: See comment under para 24.

Para 14: Suggestion for clarification (not all people consider MRL to be an element of risk assessment).

14. When establishing its standards, CCPR shall clearly state when it applies any non-science-based considerations in addition to JMPR's risk assessment and recommended maximum residue levels and specify its reasons for doing so.

Role of JMPR

New para 18a: FAO and WHO suggest to clearly state at the beginning what JMPR's role is within the FAO/WHO/Codex framework.

"The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) consists of the *FAO Panel of Experts on Pesticide Residues in Food and the Environment* and the *WHO Core Assessment Group*. It is an independent scientific expert body convened by both Director Generals of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on pesticide residues.

This guidance document applies to the work of JMPR in the context of Codex and in particular as it relates to advice requests from CCPR."

Para 20: Selection of experts is done by both parent organizations.

"FAO and WHO should select scientific experts on the basis of their competence and independence, taking into account geographical representation and gender where possible."

Para 21: The wording needs to be stronger, because this is JMPR's task.

"JMPR provides CCPR with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCPR's risk-management discussions. JMPR should continue to use its risk assessment process for establishing Acceptable Daily Intakes (ADIs) and Acute Reference Doses (ARfDs) where appropriate."

Para 22: The risk assessments prepared by JMPR consider already applicability, constraints, sub-populations: Such aspects are integral part of the experts' work. Therefore the wording should be clarified:

"JMPR should identify and communicate to CCPR in its assessments any information on the applicability and any constraints of the risk assessment to the general population and to particular sub-populations with potentially enhanced vulnerability (e.g. children)."

Para 23: The term "risk assessment" is used ambiguously. This paragraph should come after the revised para 24.

"Recognizing that primary production in developing countries is largely through small and medium size enterprises, JMPR should strive to base its **exposure assessment and hence the dietary risk** assessments on global data, including that from developing countries. **In addition to GEMS/Food data**, monitoring data and exposure studies shall be used."

Para 24 and Para 13: Both paragraphs allocate the same tasks to JMPR and CCPR - it is unclear and does not follow functional separation of risk assessment (which includes exposure assessment) and risk management. Please consider!

Annex [JMPR Report 2005, page 35]

2.17 Risk analysis principles

At the request of the Joint Secretariat, the Meeting provided comments on the *Proposed Draft Risk Analysis Principles applied by the Codex Committee on Pesticide Residues* (ALINORM 05/28/24, Appendix XIII). The current draft was considered to be a concise and accurate description of the tasks assigned to JMPR.

The Meeting stressed that JMPR's contribution to risk analysis is based solely on science whereas the consideration of other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade is the responsibility of CCPR.

The Meeting also noted that it will continue to propose MRLs for plant and animal commodities based on the available data related to registered uses that reflect national GAPS. The decision whether an adopted CXL for a commodity shall be revoked although sufficient data are available to recommend a MRL, is the responsibility of CCPR, not JMPR.