

# codex alimentarius commission E



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 9

CX/PR 09/41/7  
April 2009

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON PESTICIDE RESIDUES

#### Forty-first Session

Beijing, China, 20-25 April 2009

### REVISION OF RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES

Prepared by the Electronic Working Group led by Argentina

Governments and interested international organizations are invited to prepare their comments and be ready to consider it at the forthcoming 41<sup>st</sup> Session of the Codex Committee on Pesticide Residues.

#### BACKGROUND

At its 24<sup>th</sup> Session (April 2007), the Codex Committee on General Principles (ALINORM 07/30/33, paras 27-34) endorsed the Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues.

Some delegations then stressed the need to ensure consistency between the documents describing risk analysis policies throughout Codex, and noted that there were some discrepancies between the documents under consideration for pesticide residues and other risk analysis documents.

Other delegations expressed their concern that the principles were not consistent with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (see Chile's and Argentina's comments in the 2007 CCGP Session report).

It was also noted that the Draft Strategic Plan 2008-2013 for adoption by the 30<sup>th</sup> Session of the Commission included the review of the consistency of risk analysis principles elaborated by the relevant Codex Committees (Goal 2).

The Codex Committee on General Principles agreed "that following the adoption of the texts under consideration, all adopted risk analysis policies should be reviewed by the Committee especially as regards their consistency with the general *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*".

Other delegations expressed their concern (para. 32) with the practice of withdrawing MRLs when they were not supported by the industry although the compounds concerned were still used by member countries and no specific safety issues had been identified. They stated especially that it was likely to reduce the availability of pesticides that could be used by developing countries.

The Committee finally endorsed the document (para. 34) and agreed that this text and all other similar texts would be reviewed together once they had been adopted by the Commission.

At that Session, the Secretariat drew the attention of the Committee (para. 158) to the MRL Periodic Review Procedure, and recalled that since the present session had finalised the Draft Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues and the Criteria for Prioritization had been adopted by the Commission, there may be a need to reconsider the relevance of this text.

The Delegation of the Netherlands (para. 159), speaking as the former host country of the CCPR, recalled that the MRL Periodic Review Procedure had been adopted in 1997 and had provided very useful guidance to the CCPR in its systematic review of MRLs. The Delegation noted that the finalisation of new texts concerning risk analysis and prioritization justified its review in the framework of the CCPR. The Committee also agreed to recommend that the CCPR review the MRL Periodic Review Procedure in the light of more recent documents related to MRL setting process and consider the relevance of this procedure to be published in the Procedural Manual.

At the 30<sup>th</sup> Session of the Codex Alimentarius Commission (ALINORM 07/30/REP paras. 30-34), after some discussion, the Commission adopted the document on Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues as proposed, with the understanding that, in accordance with the Strategic Plan, this matter could be further considered when the Committee on General Principles reviewed all relevant texts on risk analysis policies applied by Codex Committees as a whole, in order to ensure consistency throughout Codex.

At its 40<sup>th</sup> Session, the Codex Committee on Pesticide Residues (CCPR) agreed to recommend the revision of the *Risk Analysis Principles applied by the Codex Committee on Pesticide Residues* to the Commission (Alinorm 08/31/24, paras. 129-134). It thus noted the decision made at its 39<sup>th</sup> Session on the basis of the recommendation of the 24<sup>th</sup> Session of the Codex Committee on General Principles, which had agreed to recommend, at its last session, the revision of the *MRL Periodic Review Procedure* in the light of more recent documents related to the MRL setting process and to consider whether this procedure should be published in the Procedural Manual. The Committee noted that all the relevant documents were contained in the working document CX/PR 08/40/7 and the question to be considered was whether the Procedure was still relevant for the work of the Committee and, if so, how it should be revised in light of the two newly adopted documents.

Consideration was also taken of the remarks of the Co-Chairperson, who drew the attention of the Committee to several overlaps and inconsistencies existing among these documents and proposed to establish an electronic working group led by Argentina, which would revise the *Risk Analysis Principles applied by the Codex Committee on Pesticide Residues* applied by the Codex Committee on Pesticide Residues and incorporate the *Criteria for the Prioritization Process of Compounds for Evaluation by JMPR* and the *MRL Periodic Review Procedure* and would also address the concerns of some delegations about the impact of the periodic review procedure on the revocation of MRLs when the pesticide was still used in some countries.

In accordance with paragraph 132, the Committee considered the scope of the revision. In this respect, the Delegation of Japan requested that the revision also address the newly introduced form for expressing concerns about draft MRLs. The Delegation of Argentina, referring to its written comments in CRD 11 and CRD 17, expressed concern on the current periodic review procedure in relation to the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* in that revocation of pesticide MRLs according to a pre-defined time frame rather than because of new scientific evidence was not a decision based on science.

After some discussion, the Committee agreed (para. 133) to request the approval of the Commission for new work on the revision of the *Risk Analysis Principles applied by the Codex Committee on Pesticide Residues*, which would incorporate the *Criteria for the Prioritization Process of Compounds for Evaluation by JMPR* and the *MRL Periodic Review Procedure* and take into account the above discussions, as well as the latest risk management policies developed by the CCPR.

The electronic working group led by Argentina was therefore entrusted with preparing a proposed revision for consideration by the 41<sup>st</sup> Session of the Committee, taking into account that the Codex Committee on General Principles was scheduled to review the consistency of risk analysis principles elaborated by the relevant Codex Committees by 2011.

Then, under Agenda Item 9 concerning the establishment of Codex priority list for pesticides, the United States proposed (para. 151) to modify current prioritization criteria with respect to compounds not leading to detectable residues. The Committee after some discussion decided to defer this discussion to the electronic working group led by Argentina which would be revising the *Risk Analysis Principles applied by the Codex Committee on Pesticide Residues*, which includes the prioritization criteria.

At its 31<sup>st</sup> Session, the Codex Alimentarius Commission approved the elaboration of new standards and related texts (ALINORM 08/31/REP, para. 92 Appendix X). With respect to the revision of the Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues, the creation of an electronic working group was approved following the recommendation arising from the Codex Committee on Pesticide Residues (ALINORM 08/31/24, paras. 129-134 and 151).

The members of electronic working group led by Argentina were Germany, Argentina, Brazil, Costa Rica, Chile, United States, France, Japan, Peru, Poland, Dominican Republic, Romania, Thailand, Uruguay, European Community, IFU (International Federation of Fruit Juice Producers), Crop Life International.

## **SUMMARY OF TASKS CONDUCTED**

As part of the work, an attempt has been made to integrate, in a single text, the Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues, the *Criteria for the Prioritization Process of Compounds for Evaluation by JMPR* and the *MRL Periodic Review Procedure*. Furthermore, the criteria in the Priority List have been modified to include compounds not leading to detectable residues, a proposal by the United States; and the Form for Guidance for Expressing concern on the Advancement of an MRL or Request for Clarification, as requested by Japan. In doing this, we deleted duplicate paragraphs.

In revising the three documents, it was noted that there were notes that provided substantial information on the criteria, procedures and data for submission and so should be an integral part of the text. For this reason, the notes were incorporated into the chair's paper.

The other proposed changes are intended to make this new text consistent with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*. For better understanding, some footnotes have been included indicating the articles of this text that have been considered in this task. The compiled document is attached as Annex.

Argentina and Chile's concerns over the removal of MRL re-evaluation only because of the passing of time and the deletion of MRL without scientific support have been considered in the document proposed by the chair. For this reason, the removal of the periodic re-evaluation has been proposed and all references to it have been deleted. Similarly, the paragraphs related to the procedure for MRL deletion without scientific support have been deleted from the text.

Given the type of changes in the compiled text proposed by the chair, it was not possible to use the track changes function in such a manner that it facilitated reading and understanding.

## **THE ADVANTAGES AND DRAWBACKS OF THE REMOVAL OF PERIODIC RE-EVALUATION AND MRL DELETION WITHOUT ANY SCIENTIFIC GROUNDS**

- It allows developing countries to continue using traditional chemicals that have not been challenged on scientific grounds for being harmful to consumer health.
- It reduces the costs arising from repeated toxicological and ecotoxicological studies.
- It prevents repetition of animal studies, in compliance with animal welfare and ethics guidelines.
- It would reduce conflicts in international trade owing to the lack of MRLs.

## **DRAWBACKS**

It may result in products not being revised that should be, because of a lack of interest, if the obligation of permanent updating is removed.

## **THE ADVANTAGES THE COMPILED TEXTS WOULD HAVE**

- Integration of documents facilitates understanding.
- It simplifies future updating of documents.

## **SUMMARY OF EWG COUNTRIES' COMMENTS**

The members of the working group made some practical corrections and suggestions on the compiled text, some of which were worked out by the chair. The general technical comments submitted are summarized below:

In the context of the EWG, **Argentina** supported the changes proposed in the chair's paper. However, they believe a deep re-structuring of the text is needed to provide more clarity. In particular, they state that given that this is a principles document, it should clearly distinguish the principles guiding risk analysis from the procedures and criteria applied by the CCPR and JMPR. They also propose to change the order of some parts of the text. They support the removal of the periodic re-evaluation and the deletion of MRLs without any scientific grounds.

**Australia** does not support the removal of the 15 year rule, particularly without further analysis by the CCPR. They believe that most countries have a chemical review process to re-determine the safety and efficacy based on new scientific data and that if given advance notice, countries can meet the requirements of the current re-evaluation system. In particular, they look forward to working to develop a mutually agreed revised Risk Analysis Principles paper.

**Brazil** believes the key element is the concern that MRLs are withdrawn only because of the passing of time, without scientific support; there could be implicit support; however, they do not express themselves in an exhaustive manner. They support the second part of the document. They propose the deletion of some sections to avoid overlapping and comment on fat-soluble pesticides.

In their preliminary comments, the European Community does not support the proposed changes. They note that some issues were developed that are outside the mandate of the Commission, even considering documents that were not included. They do not support the removal of the obligatory periodic re-evaluation providing their views, nor do they support setting Codex MRLs for pesticides that leave no residues.

They suggest the combination of the text in both sections of the Procedural Manual to avoid overlapping.

**Costa Rica** supports the Chair's proposal, in which they introduce minor changes, mainly in the wording. Regarding the original document, they comment on acute exposure and legitimate factors; they point out that CCPR should strive to identify pesticides that are used mainly in developing countries and have not been evaluated, with a concern over international trade. They made additional comments on which level (the higher or lower) should prevail in MRLs with limits recommended by JMPR and JECFA.

The **United States of America** do not support the changes to periodic re-evaluation and propose, as an alternative, broader participation by member countries in the provision of existing data and the registration status in their countries and participation in the working group on minor uses considering ways of finding and using all available information.

They believe the Risk Analysis Principles should provide both guidance and flexibility to prevent wrong decisions by the CCPR; the "principles" should not be used as absolute requirements.

Taking into consideration the current re-evaluation system, the two new documents and Argentina's concern over MRL withdrawals without scientific support, **Japan** proposes to retain the current periodic review procedure in a revised version of the risk analysis principles in a separate annex or document, where the revised text is clearly identified for consideration at the next session of the CCPR.

**Thailand** generally supports the document and the concept that Codex MRLs should not be deleted without scientific support only as a result of the passing of time. They believe deletion should be based on specific requests for certain MRLs. They believe re-evaluation should be based on human health, the significant change of use patterns and the significant change of scientific data relating to the pesticide.

Particular comments are included in the attached document.

#### **DOCUMENTS USED:**

Below are the Codex documents that the chair of the Electronic Working Group considered in undertaking this task, taking into account that Codex should ensure consistency in its decisions.

#### **31<sup>st</sup> Session of the Codex Alimentarius Commission. Geneva (Switzerland), 30 June-4 July 2008**

- ALINORM 08/31/REP.

#### **40<sup>th</sup> Session of the Codex Committee on Pesticide Residues. Hangzhou (China), 14-19 April 2008**

- CDR 9. Chile.
- CDR 11. Argentina.
- CDR 17. Argentina.

- CX/PR08/40/7. Discussion Paper on the Consideration of the MRLs Periodic Review Procedure (which includes the *Risk Analysis Principles applied by the Codex Committee on Pesticide Residues* and the *Criteria for the Prioritization Process of Compounds for Evaluation by JMPR*, which appear in the Procedural Manual, 17<sup>th</sup> Edition, and the *MRL Periodic Review Procedure*).
- CX/PR08/40/13. Achieving Globally Harmonized MRLs through Codex.
- ALINORM 08/31/24. 40<sup>th</sup> Session of the Codex Committee on Pesticide Residues. Hangzhou (China), 14-19 April 2008.

#### **30<sup>th</sup> Session of the Codex Alimentarius Commission. ROMA (ITALY), 2-7 JULY 2007.**

- ALINORM 07/30/REP.

#### **39<sup>th</sup> Session of the Codex Committee on Pesticide Residues , Beijing (CHINA), 7-12 MAY 2007.**

- CRD 16. United States.
- CRD 25. Establishment of Codex Priority List of Pesticides.
- CX/PR07/39/10. Discussion Paper about Enforcement of Codex MRLs.

#### **24<sup>th</sup> Session of the Codex Committee on General Principles. Paris (France), 2-6 April 2007.**

- CRD 6. Malaysia.
- ALINORM 08/30/33. 24<sup>th</sup> Session of the Codex Committee on General Principles.

#### **38<sup>th</sup> Session of the Codex Committee on Pesticide Residues. Fortaleza (Brazil), 3-8 April 2006**

- ALINORM 06/29/24. 38<sup>th</sup> Session of the CCPR – Appendix X. Form for Guidance for Expressing concern on the Advancement of an MRL or Request for Clarification.

#### **Procedural Manual, 17<sup>th</sup> Edition**

- Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius
- Risk Analysis Principles applied by the Codex Committee on Pesticide Residues
- Criteria for the Prioritization Process of Compounds for Evaluation by JMPR
- MRL Periodic Review Procedure
- Statements of Principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account
- Statements of Principle relating to the role of food safety risk assessment

#### **CONCLUSIONS**

We would like to start by pointing out that there are differences between the official versions in English and Spanish, which include not only translation issues but, as has been noted by WG members, differences in the contents of the texts as well. In view of this situation, guidance from the Secretariat is needed to harmonize the versions and to check the French version.

Overall, few countries have made comments on the layout of the compiled document. Argentina's comments on the structure the new text should have are not included in the attached revised text as, given the proposed re-ordering of the sections, we would have to reproduce their entire version. We therefore believe they should explain their proposal at the session.

It is clear from the comments received that more work is needed, that there is a substantive discussion on the issue of MRL periodic re-evaluation and on the deletion of MRLs for pesticides without any scientific grounds than needs to be addressed at the next CCPR session.

Similarly, the proposals to change the structure of the compiled document should be analyzed in depth for the revised version of these texts to provide more clarity on the Codex work and the principles guiding it.

Based on the results of this first stage, the group should continue its work as the complexity of the issues raised and comments made by Members show that the terms of reference have not been finalised.

**ANNEX I****RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES****SCOPE:**

- 1- 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. This document should be read in conjunction with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

*Costa Rica: wording and verb tense discrepancies in the Spanish version of this paragraph.*

**ROLES OF CCPR AND JMPR IN RISK ANALYSIS****INTERACTION BETWEEN CCPR AND JMPR INTERACTION**

- 2- In addressing pesticide residue issues in Codex, providing advice on risk management is the responsibility of the Codex Alimentarius Commission (CAC) and CCPR while conducting risk assessment is the responsibility of JMPR.

*Costa Rica: wording discrepancy in the Spanish version of this paragraph.*

- 3- CCPR and JMPR recognize that an adequate communication between risk assessors and risk managers is an essential requirement for successfully performing their risk analysis activities.
- 4- CCPR and JMPR should continue to develop procedures to enhance communication between the two bodies.

*Costa Rica: CCPR and JMPR should ~~continue to~~ develop procedures to enhance communication between the two bodies.*

- 5- CCPR and JMPR should ensure that their respective contributions to the risk analysis process result in outputs that are scientifically based, fully transparent, thoroughly documented and available in a timely manner to members<sup>1</sup>.

*Costa Rica: wording discrepancy in the Spanish version of this paragraph.*

- 6- JMPR, in consultation with CCPR, should continue to explore developing minimum data requirements necessary for JMPR to perform risk assessments.

*Costa Rica: JMPR, in consultation with CCPR, should ~~continue to explore developing~~ develop minimum data requirements necessary for JMPR to perform risk assessments.*

- 7- These requirements should be used by CCPR as a fundamental criterion as described in the Annex in preparing its Priority List for JMPR. The JMPR Secretariat should consider whether these minimum data requirements have been met when preparing the provisional agenda for meetings of JMPR.

*Costa Rica: Verb tense discrepancy in the Spanish version of this document.*

**ROLE OF CCPR**

- 8- CCPR is primarily responsible for recommending risk management proposals for adoption by the CAC.

*USA: CCPR is primarily responsible for recommending risk management proposals, such as MRLs, for adoption by the CAC.*

- 9- CCPR shall base its risk management recommendations, such as MRLs, to the CAC following JMPR's risk assessments 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.

---

<sup>1</sup> Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed, FAO Plant Production and Protection Paper, 170, 2002, ISBN 92-5 – 104759-6

**USA:** CCPR shall base its risk management recommendations to the CAC following JMPR's risk assessments 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.

10- 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.

**Costa Rica:** In cases where JMPR has performed a risk assessment and CCPR or the CAC determines that additional scientific ~~guidance~~ advice is necessary, CCPR or CAC may make a specific request to JMPR to provide further scientific guidance necessary for a risk management decision. (Wording discrepancy for the term "further" in the Spanish version)

11- CCPR's risk management recommendations to the CAC shall take into account the relevant uncertainties as described by JMPR

12- CCPR shall consider maximum residue limits (MRLs) only for those pesticides for which JMPR has completed a full safety evaluation.

**Costa Rica:** CCPR shall consider maximum residue limits (MRLs) only for those pesticides for which JMPR has completed a full ~~safety~~ toxicity evaluation.

**USA:** CCPR shall consider maximum residue limits (MRLs) only for those pesticides for which JMPR has completed an appropriate safety evaluation.

13- CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns on a global scale when recommending MRLs in food. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by members.

**Costa Rica:** CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns on a global scale when recommending MRLs in food. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by members. (are the worst consumption scenarios considered?)

**USA:** CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns on a global scale when recommending MRLs in food. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by members and compiled by GEMS/Food.

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

**Costa Rica:** When establishing its standards, CCPR shall clearly state when it applies any considerations based on other legitimate factors (consideration should be given to what these legitimate factors would be) in addition to JMPR's risk assessment and recommended maximum residue levels and specify its reasons for doing so.

15- CCPR shall consider the following when preparing its priority list of compounds for JMPR evaluation:

- CCPR's Terms of Reference;
- JMPR's Terms of Reference;
- The Codex Alimentarius Commission's Strategic Plan;
- The Criteria for the Establishment of Work Priorities;
- The Criteria for Inclusion of Compounds on the Priority List;
- The Criteria for Selecting Food Commodities for which Codex MRLs or Extraneous Maximum Residue Limits (EMRLs) should be Established;
- The Criteria for Evaluation of New Chemicals;
- The Criteria for Prioritization Process of Compounds for Evaluation by JMPR;

- A commitment to provide the necessary data for the evaluation in time.

*USA: In cases where a legitimate rationale exists to add a compound to the priority list, these criteria shall not be used as a definitive reason to exclude a compound from the list.*

- 16- When referring substances to JMPR, the CCPR shall provide background information and clearly specify the reasons for the request when chemicals are nominated for evaluation.
- 17- When referring substances to JMPR, the CCPR may also refer a range of risk management options, with a view toward obtaining JMPR's guidance on the attendant risks and the likely risk reductions associated with each option.
- 18- CCPR shall request JMPR to review any methods and guidelines being considered by CCPR for assessing maximum limits for pesticides.

*Costa Rica: "CCPR shall strive to identify pesticides used mainly in developing countries that are of great importance to agricultural production and are very relevant in public health and international food trade, and which have not been evaluated."*

### **ROLE OF JMPR**

- 19- 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 Directors General of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on pesticide residues.
- 20- 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.
- 21- JMPR is primarily responsible for performing the risk assessments upon which CCPR and ultimately the CAC base their risk management decisions. JMPR also proposes MRLs based on Good Agricultural Practices (GAPs)/ registered uses or in specific cases, such as EMRLs, based on monitoring data.

*Costa Rica: JMPR is primarily responsible for performing the risk assessments upon which CCPR and ultimately the CAC base their risk management decisions. JMPR also ~~proposes~~ recommends MRLs based on Good Agricultural Practices (GAPs)/ registered uses or in specific cases, such as EMRLs, based on monitoring data.*

*USA: JMPR is primarily responsible for performing the risk assessments and proposing MRLS upon which CCPR and ultimately the CAC base their risk management decisions. JMPR also proposes MRLs based on Good Agricultural Practices (GAPs)/ registered uses or in specific cases, such as EMRLs, based on monitoring data.*

- 22- JMPR provides CCPR with science-based risk assessments that include the four components of risk assessment as defined by CAC<sup>2</sup>, namely hazard identification, hazard characterization, exposure assessment and risk characterization, 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.

*Costa Rica: JMPR provides CCPR with science-based risk assessments that include the four components of risk assessment as defined by CAC, namely hazard identification, hazard characterization, exposure assessment and risk characterization, and ~~safety~~ toxicity 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. (Verb tense discrepancy for "should continue" in the Spanish version of this paragraph)*

**CHAIR NOTE:** *the added text was taken from the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, Risk Assessment, para. 19, Procedural Manual, seventeenth edition.*

---

<sup>2</sup> Text taken from the "Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius", (paragraph 19, Risk Analysis, Procedural Manual 17<sup>th</sup> Edition)



23- 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 subpopulations and will as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g. children).

*Costa Rica: Wording discrepancy in the Spanish version of the paragraph.*

*USA: JMPR should identify and communicate to CCPR in its assessments any information on the applicability and any constraints of the risk assessment in regard to the general population and to particular subpopulations and should, as far as possible, identify potential risks to populations of potentially enhanced vulnerability (e.g. children).*

24- JMPR is responsible for evaluating exposure to pesticides. 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 may be used. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the available high percentile consumption data as provided by members.

*Costa Rica: JMPR is responsible for evaluating exposure to pesticides. JMPR should 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 may be used. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the available high percentile consumption data (this is unclear, clarification should be provided) as provided by members. (Wording discrepancy in the Spanish version of the paragraph).*

*USA: JMPR is responsible for evaluating exposure to pesticides. 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 may be used. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the available high percentile consumption data as provided by members and compiled by GEMS/Food.*

25- JMPR should communicate to CCPR the magnitude and source of uncertainties in its risk assessments. When communicating this information, JMPR should provide CCPR a description of the methodology and procedures by which JMPR estimated any uncertainty in its risk assessment.

*Costa Rica: (Verb tense discrepancy in the Spanish version of the paragraph).*

26- JMPR should communicate to CCPR the basis for all assumptions used in its risk assessments.

*Costa Rica: (Verb tense discrepancy in the Spanish version of the paragraph).*

## **ANNEX: LIST OF RISK MANAGEMENT POLICIES USED BY CCPR**

*EC: The EC supports to combine the text in both sections of the Procedural Manual and to avoid overlapping.*

1. This part of the document addresses the risk management policy that is used by the Codex Committee on Pesticides Residues (CCPR) when discussing the risk assessments, the exposure to pesticides and the proposals for MRLs which are the outcomes of the Joint FAO/WHO Meeting on Pesticides Residues (JMPR).

## **ESTABLISHMENT OF MRLs/EMRLs**

### **Procedure for Proposing Pesticides for Codex Priority Lists**

2. CCPR has developed a policy document in relation to establishing a priority list of pesticides for evaluation or re-evaluation by JMPR, which appears below.

## CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR<sup>3</sup>

### 1. GENERAL CRITERIA

#### 1.1 The Criteria for Inclusion of Compounds on the Priority List

Before a pesticide can be considered for the Priority List, it:

**Costa Rica:** (*Wording discrepancy in the Spanish version of the paragraph*).

- i) must be registered for use in a member country;

**USA:** *must be registered for use in a member country or be expected to be registered in a member country by the time the MRLs are proposed to the CCPR*

**Brazil:** *1.1 Criteria for inclusion of compounds in the priority List:*

*A new criterion has been created (a): “must be registered for use in a member country”. Brazil is concerned over the inclusion of this criterion as it is inconsistent with the new work approved by the CCPR, which will be developed by a working group led by the US, i.e. to describe a pilot process to establish globally harmonized MRLs for new compounds.*

- ii) must be available for use as a commercial product;

**USA:** *b) must be available for use as a commercial product or be expected to be registered for use as a commercial product in a member country by the time the MRLs are proposed to the CCPR;*

- iii) must not have been already accepted for consideration;

**Costa Rica:** *must not have been already accepted for ~~consideration~~ evaluation;*

**USA:** *must not have been already accepted for consideration*

- iv) must give rise to residues in or on a food or feed commodity moving in international trade, the presence of which is (or may be) a matter of public health concern and thus create (or have the potential to create) problems in international trade; or may give rise to residues that are not detectable for which it is deemed appropriate to establish Codex standards which demonstrate that no residues are expected (to avoid the potential for creating problems in international trade as the result of the lack of a standard)

**EC:** *The EC does not support setting Codex MRLs for pesticides that leave no residues. The EC considers that pesticides that may give rise to residues that are not detectable with routine methods of analysis might be included in the priority list. However, the conditions to include them should be defined.*

**Costa Rica:** *Wording discrepancy in the Spanish version of the paragraph.*

**USA:** *must, in general, give rise to residues in or on a food or feed commodity moving in international trade, the presence of which is (or may be) a matter of public health concern and thus creates (or has the potential to create) problems in international trade; however, a pesticide can also be considered if it may give rise to residues that are not detectable (if it is deemed appropriate to establish Codex standards which demonstrate that no residues are expected to avoid the potential for creating problems in international trade as the result of the lack of a standard).*

**CHAIR NOTE:** *this text has been added based on a US proposal. CRD 25 (Beijing, China 2007).*

#### 1.2 Criteria for Selecting Food Commodities for which Codex MRLs or EMRLs Should Be Established

The commodity for which the establishment of a Codex MRL or EMRL is sought should be such that it may form a component in international trade. A higher priority will be given to commodities that represent a significant proportion of the diet.

---

<sup>3</sup> Text taken from the “Criteria for the Establishment of Work Priorities”, (paragraph 19, Risk Analysis, Procedural Manual 17<sup>th</sup> Edition)

**Brazil:** 1.2. Criteria for Selecting Food Commodities for which Codex MRLs or EMRLs Should Be Established

Brazil suggests deleting this section because it is already covered in other parts of the proposal.

(**CHAIR NOTE:** we propose to include this note as part of the body of the document) Before proposing a pesticide/commodity for prioritization, it is recommended that governments check if the pesticide is already in the Codex system. Pesticide/commodity combinations that are already included in the Codex system or under consideration are found in a working document prepared for and used as a basis of discussion at each Session of the Codex Committee on Pesticide Residues. Consult the document of the latest session to see whether or not a given pesticide has already been considered.

## 2 CRITERIA FOR PRIORITISATION

### 2.1. New Chemicals

When prioritizing new chemicals for evaluation by the JMPR, the Committee will consider the following criteria:

- 1) If the chemical has a reduced acute and/or chronic toxicity risk to humans compared with other chemicals in its classification (insecticide, fungicide, herbicide);
- 2) The date when the chemical was nominated for evaluation;
- 3) Commitment by the sponsor of the compound to provide supporting data for review with a firm date for data submission;
- 4) The availability of regional/national reviews and risk assessments, and coordination with other regional/national lists; and
- 5) Allocating priorities to new chemicals, so that at least 50% of evaluations are for new chemicals, if possible.

**Brazil:** 2.1. New Chemicals:

We have noted that two new criteria have been included (c and d). The inclusion of these criteria does not seem to change the current scenario.

**Costa Rica:**

a) If the chemical has a reduced acute and/or chronic toxicity risk to humans compared with other chemicals in its classification (insecticide, fungicide, herbicide); (Wording discrepancy in the Spanish version of the this sentence)

b) The date when the chemical was nominated for evaluation;

c) Commitment by the sponsor of the compound to provide supporting data for ~~review~~ analysis with a firm date for data submission;

d) The availability of regional/national ~~reviews~~ analyses and risk assessments, and coordination with other regional/national lists; and

e) Allocating priorities to new chemicals, so that at least 50% of evaluations are for new chemicals, if possible. (Wording discrepancy in the Spanish version of the this sentence)

**Note:** In order to satisfy the criterion that the proposed new chemical is a “safer” or “reduced risk” replacement chemical, the nominating country is required to provide:

**Costa Rica:** Wording discrepancy in the Spanish version of the above paragraph.

- i) the name(s) of the chemicals for which the proposed chemical is likely to be an alternative;
- ii) a comparison of the acute and chronic toxicities of the proposed chemical with other chemicals in its classification (insecticide, fungicide, herbicide);
- iii) a summary of acute and chronic dietary exposure calculations encompassing the range of diets considered by CCPR; and
- iv) other relevant information to support classification of the proposed chemical as a safer alternative chemical.

## 2.2 Re-evaluation

**CHAIR NOTE:** *The re-evaluation is deleted with the mere passing of time without scientific support; thus, the word “periodic” has been deleted in all paragraphs containing the phrase “periodic re-evaluations”. The withdrawals arising from the lack of chemical support have also been deleted.*

**EC:** 2.2

*This text refers to new chemicals and should be under 2.1 instead of in a new point.*

*Point 6.2 (page 151 of the 17<sup>th</sup> ed. of the manual of Procedure) should be included in the text as explained above.*

**Australia** notes that the 15 year rule has been removed. Australia believes that most countries with chemical registration schemes have a chemical review process (with designated period 10 - 20 years) which considers new scientific data to re-determine the safety, efficacy etc. of the particular chemical.

When prioritizing chemicals for re-evaluation by the JMPR, the Committee will consider the following criteria:

- 1). If the intake and/or toxicity profile indicate some level of public health concern;

**Costa Rica:** *If the intake and/or toxicity profile indicate, through scientific and/or technical data, some level of public health concern;*

- 2) (Deleted)
- 3). The year the chemical is listed in the list for Candidate Chemicals for Re-evaluation – Not Yet Scheduled;
- 4). The date that data will be submitted;
- 5). Whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;
- 6). If there is a closely related chemical that is a candidate for reevaluation that can be evaluated concurrently;
- 7). The availability of labels arising from recent national re-evaluations.
- 8). The availability of a classification of the chemical arising from recent re-evaluations.

**CHAIR NOTE:** *This text has been taken from the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, Establishment of MRLs/EMRLs, Procedure for Proposing Pesticides for Codex Priority Lists, paragraph 6.7 Procedural Manual, 17<sup>th</sup> edition (this applies to the Spanish version, where 6.7 is different from bullet 7) above).*

**EC:** *It appears that there is a discrepancy between the English and Spanish versions of the Procedural Manual. The text corresponding to point 6.7 in the EN version of the 17<sup>th</sup> ed. of the Procedural Manual is the text in letter f). The proposed text does not appear in the EN version of the Procedural Manual. Further clarification is needed by the Codex Secretariat.*

**Brazil:** 2.3. Re-evaluation:

*This item appears under paragraph 6 in the original document and a new criterion has been introduced (f). The relevance of this criterion is unclear to Brazil. We therefore request clarification on its relevance.*

## 2.3 Evaluations

When prioritizing proposed toxicological or residue evaluations by the JMPR the Committee will consider the following criteria:

- 1) The date the request was received;
- 2) Commitment by the sponsor to provide the required data for review with a firm date of submission;

**Costa Rica:** *Commitment by the sponsor to provide the required data for ~~review~~ analysis with a firm date of submission;*

- 3) Whether the data is submitted under the 4-year rule for evaluations; and

- 4) The nature of the data to be submitted, and the reason for its submission; for example, a request from CCPR.

*USA: The above 4 criteria should be included elsewhere...the first two are already included above under "2.1. New Chemicals".*

**CHAIR NOTE:** *we propose to include this note as part of the body of the document.*

Where a pesticide has already been evaluated by the JMPR and MRLs, EMRLs or GLs have been established, new evaluations may be initiated if one or more of the following situations arise:

- i) New toxicological data becomes available to indicate a significant change in the ADI or ARfD.
- ii) The JMPR may note a data deficiency in a Re-evaluation or New Chemical evaluation. In response, national governments or other interested parties may pledge to supply the information to the appropriate Joint Secretary of the JMPR with a copy for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data should be submitted subsequently to the appropriate Joint Secretary of the JMPR.
- iii) Where new scientific data becomes available to support a change in MRLs, the CCPR may place a chemical under the four-year rule, in which case the government or industry should indicate support for the specific MRLs to the FAO Joint Secretary of the JMPR. Following scheduling in the JMPR tentative schedule, any data in support of maintenance of the MRL(s) would be submitted to the FAO Joint Secretary of the JMPR.
- iv) A government member may seek to expand the use of an existing Codex chemical: that is, obtain MRLs for one or more new commodities where some MRLs already exist for other commodities. Such requests should be directed to the FAO Joint Secretary of the JMPR and submitted for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.
- v) A government member may seek to review a MRL due to a change in GAP. For example a new GAP may necessitate a larger MRL. For example a new GAP may necessitate a larger MRL. In this case the request should be made to the FAO Joint Secretary with a copy for consideration by the Committee. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.
- vi) The CCPR may request a clarification or reconsideration of a recommendation from the JMPR. In such cases the relevant Joint Secretary will schedule the request for the next JMPR.
- vii) A serious public health concern may emerge in relation to a particular pesticide for which MRLs exist. In such cases government members should notify the WHO Joint Secretary of the JMPR promptly and provide appropriate data to the WHO Joint Secretary

**CHAIR NOTE:** *we propose to include this note as part of the body of the document*

#### **EC: 2.4 Evaluations**

**New para. 29:** *the EC will provide comments on this paragraph at a later stage.*

#### **Costa Rica:**

- a) *If new toxicological data becomes available to indicate a significant change in the ADI or ARfD.*
- b) *If the JMPR ~~may~~ notes a data deficiency in a Re-evaluation or New Chemical evaluation. In response, national governments or other interested parties may pledge to supply the information to the appropriate Joint Secretary of the JMPR with a copy for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data should be submitted subsequently to the appropriate Joint Secretary of the JMPR.*
- c) *Where new scientific data becomes available to support a change in MRLs, the CCPR may place a chemical under the four-year rule, in which case the government or industry should indicate support for the specific MRLs to the FAO Joint Secretary of the JMPR. Following scheduling in the JMPR tentative schedule, any data in support of maintenance of the MRL(s) would be submitted to the FAO Joint Secretary of the JMPR.*

d) Where a government member ~~may~~ seeks to expand the use of an existing Codex chemical: that is, obtain MRLs for one or more new commodities where some MRLs already exist for other commodities. Such requests should be directed to the FAO Joint Secretary of the JMPR and submitted for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.

e) Where a government member ~~may~~ seeks to review a MRL due to a change in GAP. For example a new GAP may necessitate a larger MRL. For example a new GAP may necessitate a larger MRL. In this case the request should be made to the FAO Joint Secretary with a copy for consideration by the Committee. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.

f) Where the CCPR ~~may~~ requests a clarification or reconsideration of a recommendation from the JMPR. In such cases the relevant Joint Secretary will schedule the request for the next JMPR.

**CHAIR NOTE:** paragraphs 3, 4, 5, 6 (except 6.7) and 7 from the “Procedure for Proposing Pesticides for Codex Priority Lists” (Procedural Manual, 17<sup>th</sup> Edition, page 150 to 152, Spanish version) have been deleted as they are practically the same as those contained in the “Criteria for the Prioritization Process of Compounds for Evaluation by JMPR”. (Procedural Manual, 17<sup>th</sup> Edition, page 78, Spanish version). Par. 6.7 has been moved to “2.2 Re-evaluation”, as previously stated.

### **MRLs for Commodities of Animal Origin**

3. No farm animal metabolism studies are required whenever a pesticide is applied directly to livestock, to animal premises or housing, or when significant residues remain in crops or commodities used in animal feed, in forage crops, or in plant parts that could be used in animal feeds. The results of farm animal feeding studies and residues in animal feed serve also as a primary source of information for estimating maximum residue levels in animal products.

*EC: New para 30: there is a discrepancy between the English and Spanish versions of the Procedural Manual. This should be further clarified by the Codex Secretariat*

4. If no adequate studies are available, no MRLs will be established for commodities of animal origin. MRLs for feeds (and the primary crops) should not be established in the absence of animal transfer data. MRLs for feeds (and the primary crops) should not be established in the absence of animal transfer data. Where the exposure of livestock to pesticides through feeds leads to residues at the limit of quantitation, MRLs at the LOQ must be established for animal commodities. MRLs should be established for all mammalian species where pesticides on feeds are concerned and for specific species (e.g cattle, sheep) where direct treatments of pesticides are concerned.

*Costa Rica: 31. If no adequate studies are available, no MRLs ~~will~~ can be established for commodities of animal origin. MRLs for feeds (and the primary crops) should not be established in the absence of animal transfer data. MRLs for feeds (and the primary crops) should not be established in the absence of animal transfer data. Where the exposure of livestock to pesticides through feeds leads to residues at the limit of quantitation, MRLs at the LOQ must be established for animal commodities. MRLs should be established for all mammalian species where pesticides on feeds are concerned and for specific species (e.g cattle, sheep) where direct treatments of pesticides are concerned.*

*EC: New para. 31: second sentence (in EN version) is repeated. Further clarifications are required on the deletion of a sentence in original para. 9 (page 152) (EN version). This paragraph also includes the text of new para. 32 (EN version).*

5. Where the recommended maximum residue limits for animal commodities resulting from direct treatment of the animal, regardless of whether they are recommended by JMPR or JECFA, and from residues in animal feed do not agree, the higher recommendation will prevail.

*Costa Rica: (Why?) Costa Rica believes that the decision taken has no technical or scientific grounds and so it is appropriate to conduct an evaluation to determine which MRL should prevail.*

### MRLs for Processed or Ready-to-eat Foods or Feeds

6. CCPR agreed not to establish MRLs for processed foods and feeds unless separate higher MRLs are necessary for specific processed commodities. However, this policy is now under review.

*USA: CCPR agreed that MRLs for processed foods and feeds will not be established unless separate higher MRLs are necessary for specific processed commodities. A paper is currently being developed to provide the details on this policy.*

### MRLs for spices

7. CCPR agreed that MRLs for spices can be established on the basis of monitoring data in accordance with the guidelines established by JMPR.

### MRLs for fat-soluble pesticides

8. If a pesticide is determined as “fat soluble” after consideration of the following factors, it is indicated with the text “The residues are fat soluble” in the residue definition:

- When available, it is the partitioning of the residue (as defined) in muscle versus fat in the metabolism studies and livestock feeding studies that determines the designation of a residue as being “fat soluble”;
- In the absence of useful information on the distribution of residues in muscle and fat, residues with  $\log Pow > 3$  are likely to be “fat soluble”.

*Costa Rica: In particular, Costa Rica believes this section is more confusing to Codex members since, as it is, it should also take into account livestock breeds, feeding, amount of milk, the lactation stage the animals are at.*

9. For fat soluble pesticides, two MRLs are recommended if data permit: one for whole milk and one for milk fat. For enforcement purposes, a comparison can be made either of the residue in milk fat with the MRL for milk fat or of the residue in whole milk with the MRL for milk.

*Costa Rica: In this regard, consideration should be given to the provisions of CX/PR 08/40/6 and CX/ PR 08/40/11, and paragraphs 124, 125, 161 and 162 of the Report of the 40th session of the CCPR ( ALINORM 08/31/24 ) as the problem arises with the separation of fat for analysis.*

### Establishment of MRLs

10. The CCPR is entrusted with the elaboration of Maximum Residue Limits (MRLs) of pesticide residues in food and feed. The JMPR is using the WHO Guidelines for predicting dietary intake of pesticides residues (revised) (1997)<sup>4</sup>. The JMPR is recommending MRLs establishing Supervised Trial Median Residues (STMRs) for new and re-evaluation compounds for dietary intake purposes. In cases the intake exceeds the Acceptable Daily Intake (ADI) in one or more of the regional diets, the JMPR, when recommending MRLs, flags this situation indicating the type of data which may be useful to further refine the dietary intake estimate.

*Costa Rica: The CCPR is entrusted with the ~~elaboration~~ establishment of Maximum Residue Limits (MRLs) of pesticide residues in food and feed. The JMPR is using the WHO Guidelines for predicting dietary intake of pesticides residues (revised) (1997). The JMPR is recommending MRLs establishing Supervised Trial Median Residues (STMRs) for new and re-evaluation compounds for dietary intake purposes. In cases the intake exceeds the Acceptable Daily Intake (ADI) in one or more of the regional diets, the JMPR, when recommending MRLs, flags this situation indicating the type of data which may be useful to further refine the dietary intake estimate. (Wording discrepancy in the SP version of this paragraph).*

11. When the ADI is exceeded in one or more regional diets, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level. If further refinement is not possible then MRLs are withdrawn until the remaining MRLs give no longer rise to intake concerns. This procedure should be reviewed at regular interval.

*EC: Text of New para. 40 is identical to first sentence of new para. 38.*

<sup>4</sup> Programme of Food Safety and Food Aid, World Health Organization, WHO/FSF/FOS/97.7.

*Costa Rica: Wording discrepancy in SP version of this paragraph.*

12. The JMPR is currently routinely establishing acute reference doses (ARfDs), where appropriate, and indicates cases where an ARfD is not necessary. The 1999 JMPR for the first time calculated the short-term dietary intake estimates following an approach using the International and National Estimates of Short-term Intake (IESTI, NESTI). The procedure allows for estimating the short-term risk for relevant subgroups of the population, like children. The JMPR flags cases when the IESTI for a given commodity exceeds the acute RfD.

*USA: 39 The JMPR is currently routinely establishing acute reference doses (ARfDs), where appropriate, and indicates cases where an ARfD is not necessary. The 1999 JMPR for the first time calculated the short-term dietary intake estimates following an approach using the International and National Estimates of Short-term Intake (IESTI, NESTI). The procedure allows for estimating the short-term risk for relevant subgroups of the population, like children. The JMPR flags cases when the IESTI for a given commodity exceeds the acute RfD.*

*During each residue evaluation where the ARfD is exceeded using the highest residue values, the JMPR examines available information on alternative GAPs and associated residue trials where the ARfD is not exceeded and recommends an MRL associated with this alternative GAP. If acceptable alternative GAP is not available the JMPR report should describe the particular situation that gives rise to the intake concern in order to aid potential data submitters. This procedure has been referred to as the “prospective alternative GAP analysis”.*

*Under this procedure having analyzed the situation interested parties should be able to supply both labels and field trial data that support an alternative GAP within the 3 year period that will have elapsed until the pesticide/commodity combination is returned 3 times to Step 6 and is referred to the JMPR for alternative GAP analysis under the “retrospective” procedure. If no data are supplied the CCPR should proceed to withdraw the draft MRL.*

13. When the ARfD is exceeded for a given commodity, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level.

*USA: 40 When the ARfD is exceeded for a given commodity, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level*

14. When a Draft MRL has been returned to Step 6 three times, the CCPR should ask JMPR to examine residue data from other appropriate GAPs and to recommend MRLs which cause no dietary intake concerns if possible.

*Costa Rica: provided the expressed concerns have technical and scientific grounds.*

*USA: 41 Under the “retrospective” procedure, when a Draft MRL has been returned to Step 6 three times, the CCPR should ask JMPR to examine residue data from other appropriate GAPs and to recommend MRLs which cause no dietary intake concerns if possible.*

15. If further refinement is not possible then MRLs are withdrawn. More sophisticated methodologies such as probabilistic approaches are under investigation at the moment.

16 The estimate of the short-term dietary intake requires substantial food consumption data that currently are only sparsely available. Governments are urged to generate relevant consumption data and to submit these data to the WHO.

#### **Utilization of Steps 5/8 for elaboration of MRLs**

17. *Preconditions for utilization of Step 5/8 Procedure*

- New MRL circulated at Step 3
- JMPR report available electronically by early February
- No intake concerns identified by JMPR

18. *Steps 5/8 Procedures (Recommendation to omit Steps 6 and 7 and adopt the MRL at Step 8)*

- If the preconditions listed above are met.



- If a delegation has a concern with advancing a given MRL, a concern form should be completed detailing the concern along with a description of the data that will be submitted to substantiate the concern preferably as comments at Step 3, or at the latest, one month after the CCPR session.

**Costa Rica:** *Wording discrepancy in SP version of this paragraph.*

- If the JMPR Secretariat or the CCPR can address that concern at the upcoming CCPR session, and the JMPR position remains unchanged, the CCPR will decide if the MRL will be advanced to Step 5/8.
- If the concern cannot be addressed at the meeting, the MRL will be advanced to Step 5 at the CCPR session and the concern will be addressed by the JMPR as soon as possible but the rest of the MRLs should be advanced to Step 5/8.
- The result of the consideration of the concern by the JMPR will be considered at the next CCPR session. If the JMPR position remains unchanged, the CCPR will decide if the MRL will be advanced to Step 8.

### **Establishment of EMRLs**

19. The Extraneous Maximum Residue Limit (EMRL) refers to a pesticide residue or a contaminant arising from environmental sources (including former agricultural uses) other than the use of the pesticide or contaminant substance directly or indirectly on the commodity. It is the maximum concentration of a pesticide residue that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food, agricultural commodity or animal feed.

20. Chemicals for which EMRLs are most likely to be needed are persistent in the environment for a relatively long period after uses have been discontinued and are expected to occur in foods or feeds at levels of sufficient concern to warrant monitoring.

21. All relevant and geographically representative monitoring data (including nil-residue results) are required to make reasonable estimates to cover international trade. JMPR has developed a standard format for reporting pesticide residues monitoring data<sup>5</sup>.

22. The JMPR compares data distribution in terms of the likely percentages of violations that might occur if a given EMRL is proposed to the CCPR.

23. Because residues gradually decrease, CCPR evaluates every 5 years, if possible, the existing EMRLs, based on the reassessments of the JMPR.

24. The CCPR generally agreed at the 30th Session on the potential elements for inclusion in a set of criteria for estimation of EMRLs while it also agreed not to initiate a full exercise of criteria elaboration.

### **MRL [RE-EVALUATION] PROCEDURE**

**CHAIR NOTE:** *taken from CX/08/40/7-CCPR Hangzhou (China), Appendix I – p. 3, originally completed by the 28<sup>th</sup> session of the CCPR in 1996, ALINORM 97/24, Appendix I. Changes have been made in connection with the deletion of re-evaluation with the mere passing of time.*

**EC:** *The new proposed paragraph 52 is unclear and further clarification would be appreciated. Should it be placed here or under the next heading?*

**Thailand:** *The criteria proposed in paras 52 and 55 on animal health and environment may not be correct. These 2 criteria are for national register of pesticide and not for Codex MRL setting. The criteria for re-evaluation should be on human health, the significant change of use patterns and the significant change of scientific data relating to the pesticide.*

[On the proposal of the CCPR or JMPR, when new scientific data becomes available to indicate that a plant protection product may compromise human health, animal health or the environment and to justify a re-evaluation, the MRL list of this product will be included for review by the JMPR at the next CCPR session in order to agree on its re-evaluation.]

---

<sup>5</sup> Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant Protection and Protection Paper, 170, 2002, ISBN 92-5-104759-6. Available only in English.

The re-evaluation procedure consists of two distinct phases as described below:

## PHASE I

### IDENTIFY [RE-EVALUATION] CHEMICALS (Year 1, CCPR Meeting)

#### 1- Identify Candidate Chemicals for Re-evaluation

On an annual basis, the CCPR (Working Group on Priorities) lists the chemicals [that have been challenged with scientific support and that meet the necessary criteria or re-evaluation].

Tentative lists for several years may be prepared [when necessary].

#### 2- Notify Owners of Data [Scientifically Challenging] a Plant Protection Product or Other Interested Parties of Candidate List for Re-evaluation

Governments and international organizations represented at the annual CCPR Meeting expeditiously notify current data owners (or other interested parties) of the candidate list for re-evaluation, and when available, tentative lists for the following years.

[3]- With their notification to data owners (or other interested parties) on the candidacy of chemicals for [re-evaluation], governments and international organizations inquire of these parties their willingness to provide data for that review [and inform about the consequences of not supplying such data].

The invitation for a commitment will request a written response within six months to be provided to:

Chairman, CCPR

Chairman, Priorities Working Group

JMPR Secretariats

The requester (government or international organization representative) (Names, titles and addresses will be provided).

The invitation will request that the following information be provided in the response:

- a- A list of all commodities for which interested parties are willing to [challenge] CXLs.
- b- A brief summary of all current Good Agricultural Practice (GAP) which is pertinent to residue data they are willing to provide (e.g. commodities and countries for with detailed GAP summaries and representative labels can be provided).
- c- A list of all chemistry (residue, metabolism, animal transfer, processing, analytical sample storage stability, analytical methods etc.) and toxicology studies and other data that they are willing to provide (regardless of whether previously provided) and the data they commit to submit to the JMPR.

Comments on the status of registrations for the chemicals at the national level are encouraged. Data for which a submission is committed should be identified in the response by study or report title and number, author, date.

*Costa Rica: A list of all chemistry (residue, metabolism, animal transfer, processing, analytical sample storage stability, analytical methods etc.) and toxicology studies and other data that they are willing to provide (regardless of whether previously provided) and the data they commit to submit to the JMPR, which will complement existing studies.*

*Member Countries' comments on the status of registrations for the chemicals at the national level are encouraged. Data for which a submission is committed should be identified in the response by study or report title and number, author, date.*

#### 4- Repeat the Notification and Invitation

By means of a Codex Circular Letter to accompany the report of the Meeting, the Secretariat will repeat the notification and request. On receipt of the request by the Circular Letter, governments and international organizations will immediately repeat their notification and invitation to identified interested parties who may or may not have been represented at the CCPR (they would not have received the report of the Meeting and the accompanying Circular Letter). Interested parties need only respond to one of the request, but should copy addresses listed in item 3 above.

**PHASE II****STATUS REPORT ON DATA COMMITMENTS AND CCPR FOLLOW-UP**

(Year 2, CCPR Meeting)

1- **Status Report on Data Commitments** - The Priorities Working Group will provide a report and room document to the CCPR on the status of commitments received to provide data for each compound identified in year 1. This information will be used to schedule JMPR reviews [or to make other recommendations, e.g. withdrawal of CXL's].

**2- Response to Data Commitments**

[a] If a commitment is made – to provide and identify or develop data to change current CXLs challenged with scientific support, the MRL(s) are scheduled for JMPR review. The JMPR review will result in one of the following scenarios:]

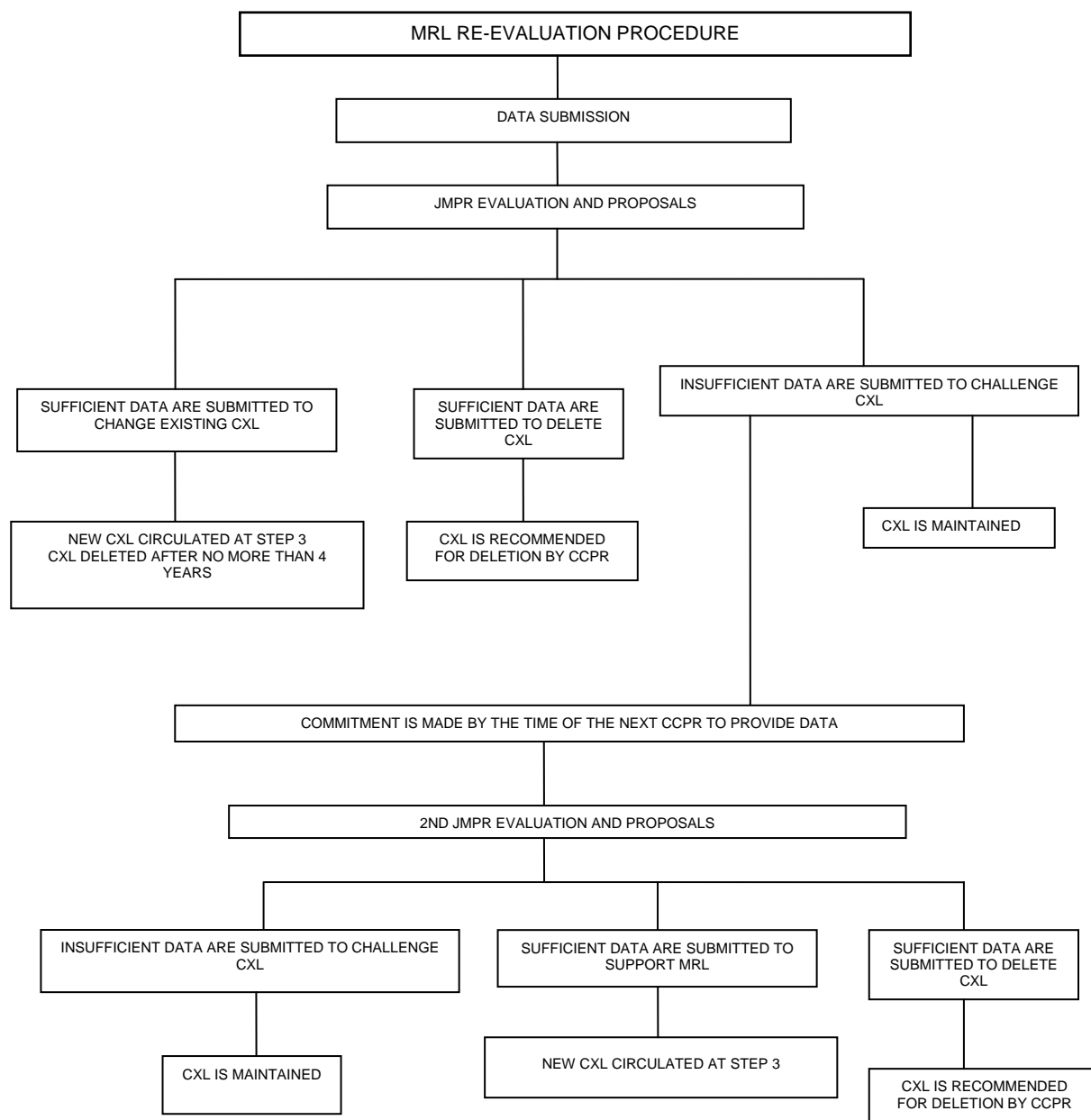
- Insufficient data are submitted to [challenge] the CXL and it remains in place.
- Sufficient data are submitted to [challenge the existing CXL] and to support a new proposed MRL, it enters the process at Step 3 and the existing CXL is deleted automatically after no more than 4 years.
- Insufficient data have been submitted to [challenge] the existing CXL: data submitters are so advised by written notification from the FAO Joint Secretary and/or by issuance of the JMPR Report.
- [It is a re-evaluation justified by scientifically supported challenges concerning human health, animal health or the environment, which the JMPR deems sufficient to delete existing the CXL, the CCPR recommends deletion of the CXL].

[b] On being advised of the data inadequacy, data submitters may, by the next CCPR Meeting, provide to the FAO and the CCPR Secretaries a written commitment to generate and submit a complete dossier of required data for review. The CXL is maintained following advice of data inadequacy (by direct notification or by issuance of the JMPR Report). The new data provided will be included in the second JMPR review, and the first part of PHASE II 2a procedure is repeated:

25. [Codex MRLs by JMPR in the framework of re-evaluations will be distributed to interested governments and organizations for comment].

## SUMMARY OF PERIODIC REVIEW PROCEDURE FOR CODEX MRLS

**CHAIR NOTE:** a new flow chart is proposed for this section.



## CODEX MRL DELETION

**CHAIR NOTE:** The working group Chair believes that in order to complete the regulatory treatment of this issue, the reasons why Codex Limits could be deleted need to be identified. We therefore suggest the following:

26. The Codex MRL deletion is stipulated in the following scenarios:

- a) New scientific data indicating that active compound use may compromise human health, animal health or the environment

**Costa Rica:** a) Where new scientific data, following a risk analysis, indicate that active compound use may compromise human health, animal health or the environment

- b) It is no longer produced and there is no remaining stock

**Costa Rica:** b) The active compound is no longer produced and there is no remaining stock

- c) The active compound is produced but is not used in food

- d) There is no international trade of commodities in which the active compound may have been used

**Thailand:** We generally support the new paras 55-57 to replace the previous paras 31-32, however para 55 need to be amended in connection with the review of MRL re-evaluation procedure.

**Japan:** Para. 55 c)

To be precise, an active compound is not used “in food” but “in producing food and feed commodities”. Therefore, we proposed to amend the text as follows:

c) The active compound is manufactured but is not used in producing food and feed commodities.

**EC:** The EC might support the proposed new para 55. However paragraphs 31 and 32 of the Procedural Manual (page 138) should be included in this section. Then, the new para 56 should be amended accordingly

27. When a compound meets b, c or d above, its MRL list will be included in the next CCPR session in order to agree on the deletion or maintenance. The MRL deletion will be valid a year after the CCPR accepts it.

**Japan:** Para. 56

When CCPR agrees on the deletion of existing MRL(s), such agreement will be forwarded to the CAC for adoption. Only the CAC has the right and authority to revoke any its previously adopted standards including MRLs. Decisions of the CAC whether adoption or revocation will take effects immediately after the close of the session of the CAC where such decisions were made. The current wording is not in compliance with the Codex procedure.

**Costa Rica:** When a compound meets b, c or d above, Member Countries will be informed and its MRL list will be included in the next CCPR session in order to agree on the deletion or maintenance. The MRL deletion will be valid a year after the CCPR accepts it.

28. Some compounds may no longer be [supported] in Codex, but they may in given countries. If there is no international trade of commodities where active compounds may have been used, the CCPR will not set an MRL.

## **MRLs AND METHODS OF ANALYSIS**

29. JMPR needs data and information for their evaluations. Among these are methods of analysis. Methods should include specialized methods used in supervised trials and enforcement methods.

**Costa Rica:** JMPR needs data and information for their evaluations. Among these are methods of analysis. Methods should include specialized methods used in supervised trials and MRL enforcement methods.

**EC:** New paras 58 and 59: texts proposed are very similar to those of paras 34 and 35 of the original document. CE would prefer to keep the original text as it is.

30. If no methods of analysis are available for enforcing MRLs for a specific compound, no MRLs will be established by CCPR.

**Costa Rica:** Wording discrepancy in the SP version of the paragraph.

Where *debería* is replaced with *debe* (Spanish for “should”), the rationale is that the text should be mandatory; there should be no room for taking actions subjectively or for not taking them

**FORM FOR EXPRESSING CONCERNS WITH ADVANCEMENT OF AN MRL/OR REQUEST FOR CLARIFICATION OF CONCERNS**

**CHAIR NOTE:** *This form is included upon the request of Japan (Alinorm 08/31/24, par. 132)*

<b>Submitted by:</b>			
<b>Date:</b>			
<b>Pesticide/ Pesticide Code Number</b>	<b>Commodity/ Commodity Code Number</b>	<b>MRL (mg/kg)</b>	<b>Present Step</b>
<b><i>Is this a Request for Clarification?</i></b>			
<b><i>Is this a Concern?</i></b>			
<b><i>Is this a Continuing Concern?</i></b>			
<b><i>Concern</i></b> (Specific statement of reason for concern to the advancement of the proposed MRL).			
<b><i>Request for Clarification</i></b> (Specific statement of clarification requested).			
<b><i>Do you wish this Concern to be Noted in the CCPR Report?</i></b>			
<b><i>Data/Information</i></b> (Description of each separate piece of data/information which is attached or will be provided to the appropriate JMPR secretary within one month of the CCPR meeting.)			

**Japan: Concern form**

*The draft proposal includes the “concern form” only. However, to facilitate clear understanding of principle for using the concern form, we think that the proposal should include the relevant parts of the report of 38<sup>th</sup> CCPR session (paras 42, 25 and 46 of ALINORM 06/29/24) for inclusion in the Procedural Manual (e.g. “Procedure for Submitting Concern Form Against Proposed/Draft MRL Settled by CCPR”, etc.). See the attachment*

**USA, second round of comments:** *(We suggest in the form below that “continuing concern” be defined—but we couldn’t seem to type on the form—the definition would be, “A concern based on policy differences with the JMPR where there is no expectation that the JMPR will concur; but the submitter would like to register the concern. These are cases where the CCPR may wish to consider other methods for addressing the concern.”*