

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 9

CX/PR 05/37/8
March 2005

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

Thirty-seventh Session

The Hague, The Netherlands, 18 - 23 April 2005

RISK ANALYSIS POLICIES USED BY THE COMMITTEE IN ESTABLISHING MRLS FOR PESTICIDES

Prepared by The Netherlands and Japan

Introduction

1. The Codex Alimentarius Commission, adopted at the Twenty-Sixth Session (30 June – 7 July 2003) the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius and the Definitions related to risk analysis.¹
2. The CAC requested that relevant Codex Committees develop or complete specific guidelines on risk analysis in their respective areas, for inclusion in the Procedural Manual, as recommended in the Action Plan. The Commission noted that these texts would be submitted to the Committee on General Principles in order to ensure coordination of work and consistency with the overarching Working Principles.
3. In the 35th Session of the Codex Committee on Pesticides Residues, it was pointed out that a clear CCPR policy framework was necessary to clarify the relation between risk assessment and risk management.²
4. The Committee agreed in its 36th Session that the chair, in cooperation with the delegation of Japan, should rewrite a paper on the risk analysis policies used by the Committee in establishing Maximum Residue Limits for Pesticides.³
5. Member States are requested to comment on the Proposed Draft Risk Analysis Principles applied by the Codex Committee on Pesticide Residues (Appendix 1).

¹ ALINORM 03/41, Appendix IV

² ALINORM 03/24A, 143

³ ALINORM 04/27/24, 176

APPENDIX 1

**PROPOSED DRAFT RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE
ON PESTICIDE RESIDUES****BACKGROUND⁴****Mandate of the CCPR**

1. The Terms of Reference of the Codex Committee on Pesticide Residues as contained in the Procedural Manual are as follows:

- to establish maximum limits for pesticide residues in specific food items or in groups of food;
- to establish maximum limits for pesticide residues in certain animal feeding stuffs moving in international trade where this is justified for reasons of protection of human health;
- to prepare priority lists of pesticides for evaluation by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR);
- to consider methods of sampling and analysis for the determination of pesticide residues in food and feed;
- to consider other matters in relation to the safety of food and feed containing pesticide residues; and,
- to establish maximum limits for environmental and industrial contaminants showing chemical or other similarity to pesticides, in specific food items or groups of food.

Definitions of Maximum Residue Limit

2. The definitions of Pesticides, Pesticide Residue and Good Agricultural Practice in the Use of Pesticides also appear in the Codex Alimentarius Procedural Manual. Codex maximum limit for pesticide residues is defined in the Procedural Manual as follows:

“Codex maximum limit for pesticide residues is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds. MRLs are based on Good Agricultural Practice (GAP) data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable.

Codex MRLs, which are primarily intended to apply in international trade, are derived from estimations made by the JMPR following:

- toxicological assessment of the pesticide and its residue, and
- review of residue data from supervised trials and supervised uses including those reflecting national good agricultural practice. Data from supervised trials conducted at the highest nationally recommended, authorized or registered uses are included in the review. In order to accommodate variations in national pest control requirements, Codex MRLs take into account the higher levels shown to arise such supervised trials, which are considered to represent effective pest control practices.

⁴ Most of the content of this Section has already been included in the Procedural Manual and therefore is included here for facilitating discussion only.

Consideration of the various dietary residue intake estimations and determinations both at the national and international level in comparison with the ADI⁵ should indicate that foods complying with Codex MRLs are safe for human consumption.”

Bodies involved

3. The Committee on General Principles has defined the responsibilities of the various bodies within the framework of Codex. The responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies (responsible for risk management) while the responsibility for risk assessment normally lies with the Joint FAO/WHO Expert Committees (responsible for risk assessment). Within the framework of pesticide residues, the risk management is undertaken by the CCPR, while the risk assessment is handled by JMPR.

SCOPE

1. This document addresses the respective applications of risk analysis principles by the Codex Committee on Pesticide Residues (CCPR) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and facilitates the uniform application of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius⁶.

ROLES OF CCPR AND JMPR IN RISK ANALYSIS

Interaction between CCPR and JMPR

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.

3. CCPR and JMPR recognize that an adequate communication between risk assessors and risk managers is a *conditio sine qua non* for successfully performing their risk analysis activities.

4. CCPR and JMPR should continue to develop procedures to enhance communication between the two committees.

5. CCPR and JMPR should ensure that their contributions to the risk analysis process are scientifically based, fully transparent, thoroughly documented and available in a timely manner to Member States⁷.

6. JMPR, in consultation with CCPR, should continue to explore developing minimum data requirements necessary for JMPR to perform risk assessments. These criteria should a.o. be used by CCPR 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.

Role of CCPR

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

8. CCPR shall base its risk management recommendations, such as MRLs, to the CAC on JMPR's risk assessments of the respective pesticides.

⁵ Note for this paper: currently not only ADIs but also ARfDs are used for comparison with dietary intake estimates.

⁶ ALINORM 03/26/6

⁷ 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

⁸ Reports of CCPR sessions are available from the Codex Alimentarius web site: www.codexalimentarius.net.

9. 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 more specific request to JMPR to provide the scientific guidance necessary for a risk management decision.
10. CCPR's risk management recommendations to the CAC shall be based on JMPR's [quantitative] risk assessments and other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade.
11. CCPR's risk management recommendations to the CAC shall take into account the relevant uncertainties and safety factors as described by JMPR.
12. 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.
13. CCPR shall base its recommendations on the 5(13) regional diets used to identify consumption patterns on a global scale when recommending MRLs in food. The 5(13) regional diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the consumption data provided by some member countries.
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 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 Medium-Term Plan of Work;
 - The Criteria for Inclusion of Compounds on the Priority List;
 - The Criteria for Selecting Food Commodities for which Codex MRLs or EMRLs should be Established;
 - The Criteria for Evaluation of New Chemicals;
 - The Criteria for Prioritising Chemicals for Periodic –Re-evaluation; and
 - A commitment to provide the necessary data for the evaluation in time.
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.

Role of JMPR

19. JMPR is primarily responsible for performing the risk assessments upon which CCPR and ultimately the CAC base their risk management decisions.⁹
20. JMPR should select scientific experts on the basis of their competence and independence, taking into account geographical representation where possible.
21. JMPR should strive to provide 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 ADIs and Acute Reference Doses where appropriate.
22. JMPR should provide CCPR with information on the applicability and any constraints of the risk assessment to the general population and to particular sub-populations and will as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g. children).
23. Recognizing that primary production in developing countries is largely through small and medium size enterprises, JMPR should strive to base its risk assessments on global data, including that from developing countries. These data may include monitoring data and exposure studies.
24. JMPR is responsible for evaluating exposure to pesticides. When evaluating intake of pesticides during its risk assessment, JMPR should take into account the 5 (13) regional diets used to identify consumption patterns on a global scale. The 5 (13) regional diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the consumption data as provided by some countries.
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.
26. JMPR should communicate to CCPR the basis for all assumptions used in its risk assessments.

⁹ JMPR reports and evaluation monographs are available from the FAO web site:
www.fao.org/ag/agp/agpp/Pesticid/Default.htm

ANNEX: LIST OF RISK MANAGEMENT POLICIES SO FAR USED BY CCPR

a. 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

b. CCPR has developed a policy document in relation to establishing a priority list of pesticides for evaluation or re-evaluation by JMPR¹⁰.

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

- be available for use as a commercial product; and
- not have been already accepted for consideration.

d. To meet the criteria for inclusion in the priority list, the use of the pesticide 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.

e. When prioritising new chemicals for evaluation by the JMPR, the Committee shall consider the following criteria:

- if the chemical has a reduced acute and/or chronic toxicity to humans compared with other chemicals in its classification;
- the data nominated;
- the date that data will be submitted; and
- where possible, allocating new chemicals to be evaluated on a 50:50 basis with periodic re-evaluation chemicals to be evaluated.

f. When prioritising chemicals for periodic re-evaluation by the JMPR, the Committee shall consider the following criteria:

- chemicals that have been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits;
- the year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation – not yet scheduled;
- the date that data will be submitted;
- if the intake and/or toxicity profile indicate a high level of public health concern;
- whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;
- if there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently; and

¹⁰ Proposed Revised Criteria for Prioritization Process; ALINORM 03/24A, Appendix IX

- allocating periodic re-evaluation chemicals to be evaluated on a 50:50 basis with new chemicals to be evaluated.

g. Once the JMPR has reviewed a chemical, three scenarios may occur:

- the data confirm the existing Codex MRL, it remains in place, or
- a new MRL is recommended or an amendment of an existing MRL. The new or amended proposal enters step 3 of the Codex procedure. The existing MRL remains in place for no more than four years or
- insufficient data have been submitted to confirm or amend an existing Codex MRL. The Codex MRL is recommended for withdrawal. However, the manufacturer may provide a commitment to the JMPR and CCPR to provide the necessary data for review within four years. The existing Codex MRL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted.

MRLs for Commodities of Animal Origin

h. 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.

i. If no adequate studies are available, no MRLs will be established for commodities of animal origin.

j. 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.

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

k. 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 under discussion at the moment.

MRLs for spices

l. 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

m. [Under discussion at the moment]

Establishment of MRLs

n. 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)¹¹. The JMPR is recommending MRLs establishing Supervised Trial Median Residues (STMRs) for new and periodic review 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.

¹¹ Programme of Food Safety and Food Aid; WHO/FSF/FOS/97.7

- o. When for a given pesticide the ADI is not exceeded in any of the five regional diets, the MRLs of that pesticide can be advanced to step 8 for adoption by the Commission, even when objected by a Government. The latter flags a situation of non-acceptance of MRLs by a given Government which ultimately may be also of relevance in view of the WTO SPS-Agreement. However, 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 (and CXLs) are withdrawn until the remaining MRLs and CXLs give no longer rise to intake concerns. This procedure should be reviewed at regular interval.
- p. 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.
- q. When for a given pesticide the ARfD is not exceeded for a given commodity, the MRLs of that pesticide can be advanced to step 8 for adoption by the Commission, even when objected by a Government. The latter flags a situation of non-acceptance of MRLs by a given Government which ultimately may be also of relevance in view of the WTO SPS-Agreement. However, 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.
- r. If further refinement is not possible then MRLs (and CXLs) are withdrawn. More sophisticated methodologies like probabilistic approaches are under investigation at the moment.
- s. 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.

Establishment of EMRLs

- t. 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.
- u. 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.
- v. 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 data¹².
- w. 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.

CCPR considers 0,5% as an acceptable violation rate when considering the EMRL proposals of JMPR.

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

¹² 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

x. 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.

Periodic Review Procedure

y. The Committee agreed on the Periodic Review Procedure, which was endorsed by the CAC and attached to the list of MRLs prepared for each session of the CCPR. Those Codex MRLs confirmed by JMPR under the Periodic Review shall be distributed to member countries and interested organizations for comments.

DELETING Codex MRLs

z. Every year new compounds are introduced. These compounds are often new pesticides which are safer than existing ones. Old compounds are then no longer supported/produced by industry and existing Codex MRLs (CXLs) can be deleted.

aa. If information is delivered between two sessions of CCPR, that a certain compound is no longer supported, this information will be shared during the first coming session ($t=0$). The proposal will be to delete the existing CXLs at the following session ($t=0+1$ year).

bb. It may happen that compounds are no longer supported in Codex, but are supported in some selected countries. If there is no international trade in commodities where the active compounds may have been used, CCPR will not establish MRLs.

MRLs AND METHODS OF ANALYSIS

cc. 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.

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