

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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Agenda Item 8

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

Fortieth Session

Hangzhou, China, 14 - 19 April 2008

DISCUSSION PAPER ON THE CONSIDERATION OF THE MRLS PERIODIC REVIEW PROCEDURE

Prepared by the Codex Secretariat

BACKGROUND

The 24th Session of the Codex Committee on General Principles had considered the Structure and Presentation of the the Procedural Manual (for details of consideration see ALINORM 07/30/33, paras 156-165). While considering it, the Secretariat drew the attention of the Committee to the MRL Periodic Review Procedure, and recalled that since the the Draft Risk Analysis Principles Applied by the Committee on Pesticide Residues had been reviewed by the Committee (CCGP) 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, 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, and noted that the finalisation of new texts concerning risk analysis and prioritization justified its review in the framework of the CCPR. The Committee 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 39th Session of the Codex Committee on Pesticide Residues the Secretariat drew the attention of the Committee to the above recommendation of the 24th Session of the Codex Committee on General Principles that the MRLs Periodic Review Procedure should be reviewed in the light of more recent documents related to the MRL setting process and consider whether this procedure should be published in the Procedural Manual. The Committee noted that this matter should be discussed in more detail on the basis of a paper to be prepared for consideration at the next session of the Committee (ALINORM 07/30/24, para. 11).

The MRL Periodic Review Procedure was finalized by the 28th Session of the Codex Committee on Pesticide Residues in 1996 (see ALINORM 97/24 Appendix III) and submitted to the 22nd Session of the Commission in 1997 for endorsement.

Since 1998, the MRLs Periodic Review Procedure was always attached to the document presenting the List of MRL at various Steps of the Procedure prepared for each session of the CCPR.

The MRL Periodic Review Procedure is referenced in Annex: *List of Risk Management Policies Used by the CCPR* to the Risk Analysis Principles Applied by the Committee on Pesticide Residues adopted by the 30th Session of the Commission and included in the 17th Edition of the Procedural Manual.

RECOMMENDATION

The Committee is invited to review the MRLs Periodic Review Procedure in the light of adoption of more recent texts describing the procedures for MRL setting and consider whether this procedure should be published in the Procedural Manual.

For easier reference the MRL Periodic Review Procedure is attached as Appendix I, the Risk Analysis Principles Applied by the Committee on Pesticide Residues as Appendix II and Criteria for Prioritization of Compounds for Evaluation by JMPR as Appendix III.

APPENDIX I**MRL PERIODIC REVIEW PROCEDURE**

The periodic Review Procedure consists of two distinct phases as described below:

PHASE I**IDENTIFY PERIODIC REVIEW CHEMICALS AND SOLICIT DATA COMMITMENTS**

(Year 1, CCPR Meeting)

1. Identify Candidate Chemicals for Re-evaluation

On an annual basis the CCPR (Working Group on Priorities) lists chemicals meeting the following criteria:

- pesticide chemicals for which MRLs were first estimated more than 10 years ago; or
- pesticide chemicals for which a periodic review was conducted more than 10 years ago.

Tentative lists for several years may be prepared when feasible.

2. Notify Data Owners or Other Parties of Candidate List

Governments and international organizations represented at the annual CCPR Meeting expeditiously notify current data owners (or other interested parties) of the candidate list for periodic reviews, and when available, tentative lists for the following years. A copy of the most recent procedure for periodic review is also included.

3. Invite Commitment to Support Continued (or New) Codex Maximum Residue Limits (CXLs)

With their notification to data owners (or other interested parties) on the candidacy of chemicals for periodic review, governments and international organizations inquire of these parties their willingness to provide data for that review and as well as to advise them of the implications if they choose not to.

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 support CXLs.
- b. A brief summary of all current Good Agricultural Practice (GAP) which they are willing to provide and which is pertinent to residue data they are willing to provide (e.g. commodities and countries for which 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 make complete data package submissions 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.

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 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.

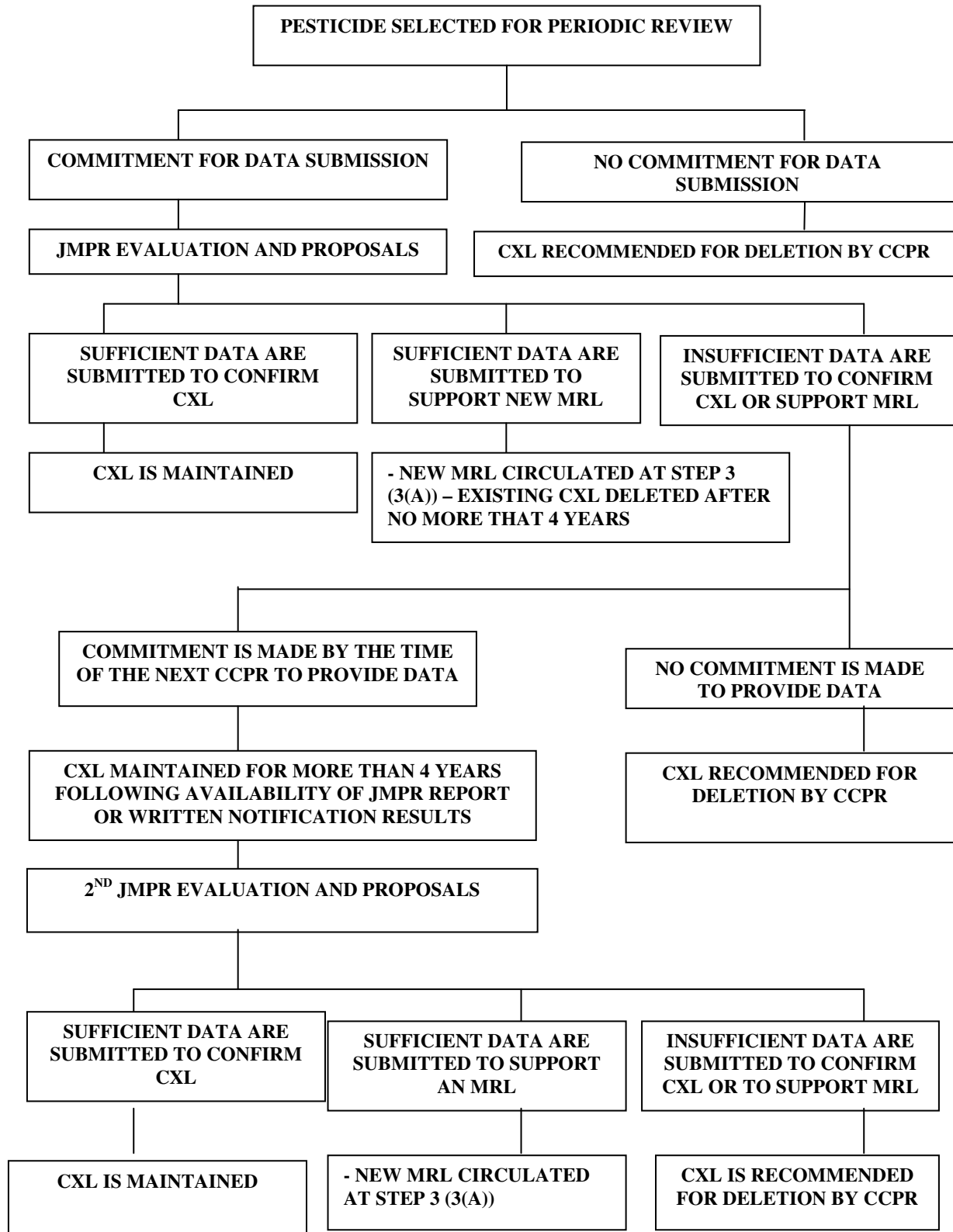
PHASE II

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 such as withdrawal of CXLs.
2. **Response to Data Commitments**
 - a. If there is no commitment – to provide and identify or develop data to support current CXLs, the CXL(s) will be recommended by the CCPR for withdrawal by the next session of the Codex Alimentarius Commission.
 - b. If a commitment is made – to provide and identify or develop data to support current CXLs, the MRL(s) are scheduled for JMPR review. The JMPR review will result in one of the following scenarios:
 - Sufficient data are submitted to confirm the CXL and it remains in place.
 - Sufficient data are submitted 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 support a new MRL or to confirm the existing CXL, data submitters are so advised by written notification from the FAO Joint Secretary and/or by issuance of the JMPR Report. On being advised of the data inadequacy, data submitters may be 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 within 4 years. The CXL is maintained for no more than 4 years following advice of data inadequacy (by direct notification or by issuance of the JMPR Report). The 4 year period may be extended by the CCPR only to the extent necessary for the JMPR to schedule and complete review of the available new data. The new data are scheduled for the second JMPR review and the first part of the PHASE II 2b procedure is repeated:
 - Sufficient data are submitted to confirm the CXL and it remains in place.
 - Sufficient data are submitted to support a new proposed MRL, it enters the process at Step 3. The CXL is automatically deleted no more than the 4 years after the new proposal enters the process.
 - Insufficient data are submitted to confirm the CXL or support a proposed MRL the CCPR recommends deletion of the CXL.
 - c. If the committed data are not submitted, or if the data submitted for the initial periodic review are insufficient and no commitment is made by the next CCPR Meeting to generate new data, the CCPR recommends deletion of the CXL.

SUMMARY OF PERIODIC REVIEW PROCEDURE FOR CODEX MRLS



APPENDIX II

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.

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 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.

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 members¹.

6. JMPR, in consultation with CCPR, should continue to explore developing 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.

ROLE OF CCPR

8. CCPR is primarily responsible for recommending risk management proposals 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.

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.

¹ 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

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.
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.
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.
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.
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. 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.

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

ANNEX: LIST OF RISK MANAGEMENT POLICIES USED BY CCPR

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 JMPR².
3. 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.
4. 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.
5. When prioritising 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;

² Criteria for Prioritization Process of Compounds for Evaluation by JMPR, Procedural Manual

4. The availability of regional/national reviews and risk assessments, and coordination with other regional/national lists; and
6. Allocating priorities to new chemicals, so that at least 50% of evaluations are for new chemicals, if possible.
6. When prioritising chemicals for periodic 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;
 2. Chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits for 15 years;
 3. The year the chemical is listed in the list for Candidate Chemicals for Periodic 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 periodic re-evaluation that can be evaluated concurrently; and
 7. The availability of current labels arising from recent national re-evaluations.
7. 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 at 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 or countries 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

8. 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.
9. 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. 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.
10. 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

11. CCPR agreed not to establish MRLs for processed foods and feeds unless separate higher MRLs are necessary for specific processed commodities.

MRLs for spices

12. 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

13. 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 $\log P_{ow} > 3$ are likely to be “fat soluble”
14. 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.

Establishment of MRLs

15. 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)³. 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.
16. 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.
17. 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.
18. 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.
19. 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.
20. If further refinement is not possible then MRLs are withdrawn. More sophisticated methodologies such as probabilistic approaches are under investigation at the moment.
21. 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*22. Preconditions for utilization of Step 5/8 Procedure*

- New MRL circulated at Step 3

3

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

- JMPR report available electronically by early February
 - No intake concerns identified by JMPR
23. *Steps 5/8 Procedure (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.
- 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

24. 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.
25. 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.
26. 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 data⁴.
27. 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.
28. Because residues gradually decrease, CCPR evaluates every 5 years, if possible, the existing EMRLs, based on the reassessments of the JMPR.
29. 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

30. 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 members and interested organizations for comments.

⁴ 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

Deleting Codex MRLs

31. 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 can be deleted.
32. 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 MRLs at the following session (t=0+1 year).
33. 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

34. 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.
35. If no methods of analysis are available for enforcing MRLs for a specific compound, no MRLs will be established by CCPR.

APPENDIX III

CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR

1. GENERAL CRITERIA

1.1 Criteria for Inclusion of Compounds on the Priority List

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

- i must be registered for use in a member country;
- ii must be available for use as a commercial product;
- iii must not have been already accepted for consideration; and
- 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.

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.

Note: 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;
5. 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.

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:*

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 Periodic Re-Evaluation

When prioritizing chemicals for periodic 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;
2. Chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits for 15 years;
3. The year the chemical is listed in the list for Candidate Chemicals for Periodic 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 periodic re-evaluation that can be evaluated concurrently; and
7. The availability of current labels arising from recent national re-evaluations.

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;
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.

Note: *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 Periodic 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 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. 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.*