codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 10 **CX/PR 10/42/12**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

42nd Session
Xian, China, 19 - 24 April 2010

REVISION OF THE 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 submit comments on the above document and should so in writing, preferably by an email **to**: Ms Duang Lifang, Institute for the Control of Agrochemicals, Ministry of Agriculture (ICAMA), P.R China, Fax: +86-10-59194252, email: ccpr@agri.gov.cn **with copy to:** Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 **by 15 March 2010.**

INTRODUCTION

In conformance with the express mandate received and as described under Background, we submit this Executive Summary on the work conducted to date.

BACKGROUND

At its 24th 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 30th 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 30th 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 40th 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 39th Session on the basis of the recommendation of the 24th Session of the Codex Committee on General Principles, which had agreed to recommend, at it 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 (EWG) led by Argentina was therefore entrusted with preparing a proposed revision for consideration by the 41st Session of the Committee.

In June/July 2.008 during its 31th session in Geneva Switzerland the Codex Alimentarius Commission finally approved the proposed revision.

During the rest of 2008 and beginning 2009 the electronic working group elaborated a new proposal for the *Risk Analysis Principles applied by the Codex Committee on Pesticide Residues*, incorporating the *Criteria for the Prioritization Process of Compounds for Evaluation by JMPR* and the *MRL Periodic Review Procedure* and taking into account the above mentioned discussions as well as the latest risk management policies developed by the CCPR.

At its 41th Session of the Codex Committee on Pesticide Residues (CCPR) in Beijing China, the Delegation of Argentina, speaking as the leading country of the Working Group, introduced the document and reported on progress to date and highlighted the pending issues for consideration by the Working Group, these included: the MRL Periodic Re-Evaluation Procedure; the deletion of MRLs without scientific grounds; the modification of the Criteria for the Prioritization with respect to compounds not leading to detectable residues; the consideration of other legitimate factors when establishing MRLs for pesticides; MRLs for fat-soluble pesticides and the establishment of acute reference dose (ArfD); and the consideration of a revised layout for the Risk Analysis Principles document which relates to a re-arrangement of the sections of the text but not to changes in the content of the document. The Delegation drew the attention of the Committee to the discrepancies between the English and Spanish versions and solicited their alignment in order to ensure consistency of both versions. (Alinorm 09/32/24 Para 178)

After the analysis the Committee agreed to retain the Periodic Re-Evaluation Procedure while acknowledging that there was a need to review data requirements and procedures for revocation of MRLs for pesticides. (ALINORM 09/32/24, Para. 183).

The Committee further agreed to re-convene the electronic Working Group led by Argentina, open to all Codex members and observers and working in English and Spanish, to revise the Risk Analysis Principles applied by the Committee on Pesticide Residues in light of the above discussion and comments submitted to the current Session and to address pending issues for circulation, comments and consideration at the 42nd Session of the Committee. (ALINORM 09/32/24, Para 184)

The Committee recalled that in 2011, the Committee on General Principles would review the consistency of risk analysis principles elaborated by relevant subsidiary bodies of the Commission, therefore, the revision should be done on the understanding that the document should be finalized by 2010 in order to present a revised Risk Analysis Principles to the CCGP in 2011. (ALINORM 09/32/24 Para 185)

The Delegation of France proposed that the four recommendations agreed should be considered for inclusion in the ongoing revision of the Risk Analysis Principles applied by the CCPR. (ALINORM 09/32/24 Para 221). So, these points were included in the proposal.

SUMMARY OF THE WORK PERFORMED

The Chair of the Electronic Working Group presents this document as a result of the work performed over the past two years. In order to reach a consensus on a project involving the reorganization of the Procedural Manual in the area of Risk Analysis performed by the CCPR.

Based on the express mandates received at the 40th and 41st CCPR meetings in Hangzhou and Beijing, China, in 2008 and 2009, and later approved at the CAC sessions in Geneva (ALINORM 08/31/24) and Rome (ALINORM 09/32/24), a work schedule with deadlines and objectives, which were met, was circulated to all members of the group.

The document was developed on the basis of:

- Current version of the Procedural Manual in the area of Risk Analysis; specially Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius and Risk Analysis Principles Applied by the CCPR.

- General Decisions of the Commission, in particular, those related to the Statement of Principle on the Role of Science in the Codex Decision-Making Process;

- MRL Periodic Review Procedure (CX/PR 08/40/7);

- Observations and proposals submitted by members of the Electronic Working Group.

In 2009, the Electronic Working Group continued working on the basis of the document presented at the 41st Session of the Codex Committee on Pesticide Residues (CCPR) in Beijing, China.

In that year, and in response to comments and opinions expressed by the members, contents were added and modified, the Main Document was reorganised, the Form to Express Concerns was relocated and placed in a separate item, a summary of the process was added, timeframes and the work methodology of the Electronic Working Group on Priorities for Evaluation and Re-evaluation, and mainly some stages of the Re-Evaluation process were modified, respecting that CXLs must be included in the process every 15 years, all in accordance with, and specifically this last issue, under the express mandate received at the 41st meeting in Beijing, China (ALINORM 09/32/13) and the clearly established "Statements of Principles" particularly, the science base of Risk Analysis.

The members of the Electronic Working Group were repeatedly invited to express their views throughout the year, which they did, especially after the two new summaries submitted by the Chair at the end of June and September 2009, the latter, specifically, to reach a consensus.

After determining the issues regarding which there was consensus, the last version of the document was developed adopting the opinion of the majority of the members, highlighting the points where exists disagreements indicating the proposals that share with the Chair document but with other alternatives or dissent.

Formal aspects of the document such as titles, order and minor drafting issues were modified pursuant to the opinion of the majority of the members; disagreements were not included.

Comments received on issues not contained in the mandates were placed in a separate item for future consideration but not included in the final document as there was insufficient time to reach a consensus.

We have tried to make the Main Document simple and easy to read, including only the proposed final text.

SCHEDULE

In response to the request from the Secretariat to develop a proposal by February 2010, the following schedule was established:

a) New summary / position of the Chair Deadline: end of June

b) Comments from the countries to reach Deadline: beginning of August

a preliminary agreement

c) Summary and preliminary conclusions from the Chair Deadline: end of September

d) Second Round of comments from the countries Deadline: end of November

and search for an agreement

e) Summary and final conclusions from the Chair Deadline: end of February

It should be noted that in order to present a comprehensive proposal, all comments, including those received after the deadlines established in the work schedule, were given due consideration.

This document and pertinent comments will be submitted for review and discussion at the next CCPR meeting in Xian, China.

WORK PLAN AND TECHNICAL JUSTIFICATION

In the different phases of the work and pursuant to the indications from the Secretariat and the observations submitted by the Countries and International Organizations that participated in the EWG, we sought to:

- Integrate in a single text the documents on Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues, Criteria for the Prioritisation Process of Compounds for Evaluation by JMPR and MRL Periodic Review Procedure, including, as an introduction, a summary of the process;

- Elaborate an index with the purpose of classify the issues and aid the searching process.

- Reorganise the criteria applicable to the Priority List establishing specific timeframes to provide information to the pertinent Working Groups and including the chemicals not leading to detectable residues in a category with a lower priority;

- Create a separate item to express concerns regarding MRLs and the “ad hoc” form;

- Eliminate the paragraphs that were duplicated;

- Reorganise and include in the text the “notes” that contributed substantial information;

- Reformulate the issues in the text regarding which an adequate consensus was reached;

- Redefine and reformulate the re-evaluation procedure respecting the periodicity and trying, when re-evaluations of compounds by JMPR are required, to restrict the re-evaluation to the issues challenged on the basis of public health concern or new scientific data not reviewed at the time of the previous evaluation/re-evaluation.

- Mainly taking into account for the Re-evaluations:

  a) The WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION IN THE FRAMEWORK OF THE CODEX ALIMENTARIUS, items 4-9-10-20-34-35 and 36 of the Procedural Manual (17th Edition);

  b) The STATEMENT OF PRINCIPLE CONCERNING THE ROLE OF SCIENCE IN THE CODEX DECISION-MAKING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT – item 1, and Criteria to take into account other factors included in the 2nd Statement of Principles, items 1 and 3 of the Procedural Manual (17th Edition);

  c) The STATEMENT OF PRINCIPLE RELATING TO THE ROLE OF FOOD SAFETY RISK ASSESSMENT, item 2 – Procedural Manual (17th Edition); and

d) The needs of developing countries.

ADVANTAGES OF THIS PROPOSAL:

- Permits developing countries to continue using traditional products which have not been challenged on scientific grounds for causing public health concerns;
- Reduces food production costs at a crucial time for the world by allowing continued use of lower cost products that have not been challenged on scientific grounds for causing health concerns;
- Reduces the cost of repeating toxicological and eco-toxicological studies;
- Eliminates repeated testing in animals, in conformance to the Guidelines on Animal Welfare and Ethics;
- Reduces problems in international trade due to the lack of MRLs.

With regard to the restructuring, the proposal:

- Unifies criteria and facilitates understanding;
- Updates the norms in accordance with the most recent Codex documents;
- Simplifies future updates of the criteria.

SUMMARY OF COMMENTS FROM THE MEMBERS OF THE EWG

The members that: submitted observations to the working document, are listed below in alphabetical order:

Countries and regions: Argentina, Australia, Brazil, Costa Rica, United States of America, Japan, Thailand, European Union.

Organizations: World Health Organisation, CropLife and ALINA

Argentina: Expressed agreement with the document submitted by the Chair, in particular, with regard to retaining the MRLs unless there is a science-based reason to withdrawal; submitted a separate document proposing a new restructuring of the re-evaluation procedure; stated that reevaluations should only be performed on challenged aspects related to a risk to public health and/or scientific breakthrough not covered in previous evaluations

Australia: Stated that it is fundamental that MRLs not be withdrawn unless there are science-based reasons; requested a simplification of the documents; suggested establishing deadlines or specific dates to request prioritization of compounds for re-evaluation; submitted a summary of the evaluation/re-evaluation procedure; expressed an opinion with regard to compounds not leading to detectable residues; proposed restructuring the document in general and contributed several minor modifications.

Brazil: Expressed that the key point is that MRLs are withdrawn based on a pre-defined timeframe rather than on new scientific evidence; supported the second part of the reviewed document; expressed an opinion with regard to improving the drafting; suggested eliminating some items which seemed to be duplicated; submitted comments on fat-soluble pesticides and requested that economic aspects be considered when replacing older compounds with new, lower-risk pesticides.

European Economic Community: Accepted, if requested by developing countries, that compounds not be re-evaluated if they are no longer supported if these compounds do not give rise to health concerns based on current scientific data and no pesticides or methods with reduced toxicity and similar effectiveness and efficacy are available. Stated that no MRLs should be established for compounds not leading to detectable residues unless problems in international trade are foreseen, in which case new criteria should be established to determine their position in the priority list; submitted comments on fat-

soluble pesticides and ready-to-eat foods; proposed deleting items that are unnecessary for the process and suggested granting an additional one-year period for CODEX MRLs established on the basis of uses in the EU if the compounds are no longer authorised in the EU provided a commitment has been submitted to carry out the studies.

Costa Rica: Supported, in general, the document submitted by the Chair and stated that withdrawal or modification of MRLs should be based on technical and/or scientific grounds; suggested modifications to the wording and in the translations; noted legitimate factors in relation to the original document on acute exposure; stated that the CCPR should make an effort to identify pesticides mainly used in developing countries, particularly those that could affect international trade, and presented a position with regard to fat-soluble pesticide residues in milk.

United States of America: Suggested that the Risk Analysis Principles should serve as a guideline and be more flexible, or less rigid, to avoid erroneous decisions by the CCPR; stated, with regard to the periodic re-evaluation, that compounds which are supported by the industry should be re-evaluated and a procedure should be established allowing JMPR or CCPR to decide the course of action in response to concerns regarding a particular MRL for a compound that is not supported by the industry, specially the type of information that should be submitted to express concern or support a product; noted that CCPR members could test whether the compounds are commercially used with the corresponding labels and uses.

Requested that compounds not leading to detectable residues be included in the Priority List (with a lower priority) and, with regard to the requirements for including pesticides in the Priority List, requested that a product which has not yet been registered or that is not commercially used but that will be at the time of the evaluation by the JMPR be included in the Priority List. Propose alternatives in the re-evaluation process.

Japan: Proposed maintaining the current periodic review procedure in a separate document or as an annex to the revised version of the risk analysis principles; suggested changes in the titles of the document;

Requested including the form to express concern in a special section; stated, with regard to the withdrawal of MRLs, that the criterion to withdraw an MRL when the compound is not supported or manufactured should be maintained, and agreed with the concept of requiring members to submit labels with current uses to maintain the MRLs.

Thailand: Supported not withdrawing MRLs simply because no scientific data is submitted for the periodic review; considered that the existence of labels and Good Agricultural Practices is sufficient to maintain the MRLs and, if not available, the MRLs may be candidates for withdrawal; stated that the information which should be submitted to support a CXL must be defined on a case-by-case basis; noted that re-evaluations should be centred on human health, significant changes in use patterns and significantly different scientific data regarding the pesticide, and indicated that current practices could serve both to support and to challenge an MRL.

World Health Organisation: Considered that it is of the utmost importance to maintain the periodic review process but admitted that the current system has some problems such as time-frames before CXLs are withdrawn, insufficient data provision by generic pesticide procedures for compounds no longer supported by the large companies, and supported the proposed procedure for compounds not leading to detectable residues.

ALINA: Considered that withdrawal of MRLs should only be science-based; agreed with the periodic review procedure but stated that many compounds have been on the market for more than 15 years without causing adverse health effects and that JMPR‘s current volume of work could increase significantly. Alina therefore suggested establishing a longer timeframe to re-evaluate the compounds, for example, 25 years.

CropLife: Considered, with regard to the withdrawal of MRLs, that the criterion to withdraw an MRL when the compound is not supported or manufactured, should be maintained; stated that the requirement

to submit labels with current approved uses is insufficient to conform to FAO specifications; supported the criterion to include in the Priority List products that were recently registered or are in the process of being registered provided a current approved label is available at the time the JMPR performs the evaluation and added that the label used to perform the re-evaluation should be the most current label to allow adequate scheduling by JMPR; and formulated comments on updating information and labels, Good Agricultural Practices and new products.

DOCUMENTS USED:

Below are the Codex documents considered in undertaking the task:

- CX/PR 08/40/7. Discussion paper on the consideration of the MRLs periodic review procedure (2008)
- Risk Analysis Principles Applied by the CCPR
- Draft Revised Criteria for Prioritization Process of Compounds for Evaluation by JMPR;
- MRL Periodic Review Procedure
- Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius
- ALINORM 06/29/24. 38ª Session CCPR (2006) – Annex X Form for Guidance for Expressing concern on the Advancement of an MRL or Request for Clarification
- ALINORM 08/30/33. 24ª Session of the Codex Committee on General Principles (2007)
- ALINORM 07/30/24. 39ª Session CCPR (2007)
- ALINORM 07/30/REP 30ª Session CAC (2007)
- CRD 6. (Comments from Malaysia) - 24ª Session CCPG (2007)
- CRD9. Chile: (2008)
- CRD11.: Comments on agenda item 1, 8 and 10 submitted Argentina (2008)
- CRD17. Comments on agenda item 8 submitted Argentina (2008)
- ALINORM 08/31/24. 40ª Session CCPR (2008)
- ALINORM 08/31/REP 31ª Session CAC (2008)
- CX/PR 08/40/6, Discussion Paper on the Procedures for Separation Milk Fat from Whole Milk (2008)
- CX/ PR 08/40/11 Milk and Milk Fat Maximum Residue Limits (2008)
- CRD17. Comments on agenda item 9 submitted by Japan (2009)
- CRD19. Comments on the Agenda Item 9 submitted by China (2009)
- ALINORM 09/32/24. 41ª Session CCPR (2009)
- ALINORM 09/32/REP 32ª Session CAC (2009)
- CX/PR07/39/10. Discussion Paper about Enforcement of Codex MRLs (Prepared by Netherlands) 2007

- CX/PR08/40/13. Achieving Globally Harmonized MRLs through Codex (Prepared by United States of America) 2008

- CRD 16. Comments on Codex Proposal on MRLs in No Residue Situations, submitted by USA. Proposal to Amend Criteria for Nominations

- CRD 25. Establishment of Codex Priority List of Pesticides (Prepared by USA)

ATTACHMENT OF OBSERVATIONS ON TOPICS NOT COVERED AND PROPOSALS MADE BY MEMBERS OF THE EWG

CropLife

1) Criteria for Inclusion of Compounds on the Priority List – limited number of uses for new compounds.

2) New Chemicals – questions about certain criteria

3) MRLs IN GENERAL - IV) expected severity of effects, if the ARfD is exceeded

Japan

1) Order of Components in Risk Analysis Principle Documents

2) Issues on the Annex

3) Issues on where and how to place the MRL Periodic Review Procedure in the document

4) Other issues on the layout of the Annex

5) Criteria for preparing the priority list of compounds for JMPR evaluation

European Union

1) The MRL Periodic Re-Evaluation Procedure: Prioritization for products re-evaluation

2) The modification of the Criteria for the Prioritization with respect to compounds not leading to detectable residues - In favour of a procedure to reduce workload on the JMPR

3) Deleting Codex MRLs – Authorization in the EU

4) Need to adapt the Criteria for Priorization because in few cases the criteria for nomination of new compounds have not been strictly met.

USA

1) To add a compound to the list - in cases where a legitimate rationale exists

2) Risk management decision

CONTENTS

DOCUMENT LAYOUT

MAIN DOCUMENT

RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE

ON PESTICIDE RESIDUES

1. SCOPE

1.1. 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.

SUMMARY OF THE MRL-SETTING PROCESS

The MRL-setting process begins with the CCPR prioritizing a pesticide for review by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR). The WHO Core Assessment Group consider available data encompassing a wide range of toxicological endpoints with the aim of estimating an acceptable daily intake (ADI) and an acute reference dose (ARfD) where sufficient data are available. The FAO Panel of Experts on Pesticide Residues in Food and the Environment considers data on registered use patterns, fate of residues, animal and plant metabolism, analytical methodology and residue data derived from supervised residue trials in order to propose MRLs for the pesticide in food and feed commodities. The JMPR risk assessment includes the estimation of both short-term (single day) and long-term dietary exposures and their comparison with the relevant toxicological benchmarks. The CCPR, in a risk management role, considers the recommendations of JMPR in the light of information provided in the relevant JMPR reports and monographs. MRLs recommendations accepted by the CCPR are submitted to the Codex Alimentarius Commission (CAC) for adoption as Codex MRLs. An active periodic review program complements this process.

ROLES OF CCPR AND JMPR IN RISK ANALYSIS

2. ROLE OF CCPR

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

2.2. CCPR shall base its risk management recommendations to the CAC on JMPR's risk assessments of the respective pesticides, and considering, where appropriate, other legitimate factors that[1] are relevant to the health protection of consumers and to the promotion of fair practices in food trade.

2.3. 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.

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

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

2.6. 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

[1] Statement of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account Codex Procedural Manual 18th Edition page 171

chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by members and compiled by GEMS/Food.

2.7. 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.

2.8. 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 and Procedures for Proposing Pesticides for Codex Priority Lists;
- 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 the Prioritization Process of Compounds for Evaluation by JMPR;
- A commitment to provide the necessary data for the evaluation in time.

2.9. 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.

2.10. 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.

2.11. CCPR shall request JMPR to review any methods and guidelines being considered by CCPR for assessing maximum limits for pesticides.

3. ROLE OF JMPR

3.1. 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.

3.2. 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.

3.3. 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, and MRLs for spices based on monitoring data.

3.4. 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 assessments that can serve as the basis for CCPR's risk-management

discussions. JMPR applies a transparent, science based risk assessment process for establishing Acceptable Daily Intakes (ADIs) and Acute Reference Doses (ARfDs) where appropriate.

3.5. JMPR shall 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 sub-populations and shall, as far as possible, identify potential risks to populations of potentially enhanced vulnerability (e.g. children).

3.6. JMPR is responsible for evaluating exposure to pesticides. JMPR must 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.

3.7. JMPR communicates to CCPR the magnitude and source of uncertainties in its risk assessments. When communicating this information, JMPR provides CCPR a description of the methodology and procedures by which JMPR estimated any uncertainty in its risk assessment.

3.8. JMPR communicates to CCPR the basis for all assumptions used in its risk assessments.

4. INTERACTION BETWEEN CCPR AND JMPR

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

4.2. CCPR and JMPR recognize that good communication between risk assessors and risk managers is an essential requirement for successfully performing their risk analysis activities.

4.3. CCPR and JMPR must continue to develop procedures to enhance communication between the two bodies.

4.4. CCPR and JMPR must 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[2].

4.5. JMPR, in consultation with CCPR, must continue to explore developing minimum data requirements necessary for JMPR to perform risk assessments.

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

LIST OF RISK MANAGEMENT POLICIES USED BY CCPR IN ESTABLISHMENT OF MRLs/EMRLs

5. PREPARATION OF THE CODEX PRIORITY LIST OF PESTICIDES FOR JMPR EVALUATION

5.1. 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 15 years ago; or

[2] 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

- pesticide chemicals for which a periodic review was conducted more than 15 years ago.

Tentative lists for several years may be prepared when feasible.

5.2. Preparation of Priority Lists

CCPR will submit a proposal to the CAC each year, as ongoing work, to re-establish the Electronic Working Group (EWG) on Priorities. The EWG on

Priorities will be tasked with preparing a draft 'Codex Priority List of Pesticides for JMPR evaluation' for the consideration of CCPR.

Within two months of the CAC meeting, the Chair of the EWG will issue a broadcast email to all CCPR member countries and observers requesting nominations to the new chemicals priority list and proposing additions to the periodic re-evaluation schedule.

Each CCPR meeting will have finalised the Priority Lists of Pesticides for the following year's JMPR evaluations. Therefore, nominations and comments on the Codex Priority Lists of Pesticides will apply to subsequent years to the forthcoming CCPR meeting.

The due date for nominations and comments on the draft priority list of compounds will be 30 November.

The Chair of the EWG on Priorities will prepare a draft CCPR agenda paper 'Establishment of Codex Priority Lists of Pesticides' by 21 December.

The draft agenda paper will be submitted to the Codex Secretariat for circulation to all member countries and observers as a circular letter on 1 January with comments due on 1 March.

The Chair of the EWG on Priorities will finalise the CCPR agenda paper which includes the Codex Priority Lists of Pesticides and submit to Codex Secretariat.

The Codex Priority Lists of Pesticides will comprise four appendices: Appendix 1 – Codex Priority List of Pesticides, Appendix 2 - Periodic Re-evaluations (summarized in 3 lists), Appendix 3: Chemical-commodity combinations for which specific GAP is no longer supported and Appendix 4: Chemicals with extraneous MRLs and recent deletions.

6. CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR

6.1. General Criteria

6.1.1. Criteria and procedures for proposing pesticides for Codex priority lists

Before proposing a pesticide/commodity for prioritization, it is recommended that governments check if the pesticide is already in the Codex system.

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

6.1.1.1. 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 considered at the JMPR;

6.1.1.2. must be available for use as a commercial product (*); or be expected to be registered for use as a commercial product by the time the MRLs are considered at the JMPR;

6.1.1.3. must not have been already accepted for consideration;

6.1.1.4. 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 create (or have 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 (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) **(**, ***).**

Dissents

(*) Crop Life

Proposal

(**) Brasil

(***) EU

6.1.2. 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, shall 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.

6.2. Specific Criteria and Procedures for New evaluation or Periodic Re-evaluation

6.2.1. New chemicals

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

6.2.1.1. If the chemical has a reduced acute and/or chronic toxicity risk to humans compared with other chemicals in its classification (insecticide, fungicide, herbicide, etc);

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:*

a) the name(s) of the chemicals for which the proposed chemical is likely to be an alternative;

b) a comparison of the acute and chronic toxicities of the proposed chemical with other chemicals in its classification (insecticide, fungicide, herbicide);

c) a summary of acute and chronic dietary exposure calculations encompassing the range of diets considered by CCPR;

d) other relevant information to support classification of the proposed chemical as a safer alternative chemical; and

e) take into account the economic aspects

6.2.1.2. The date when the chemical was nominated for evaluation;

6.2.1.3. Commitment by the sponsor of the compound to provide supporting data for review with a firm date for data submission;

6.2.1.4. The availability of regional/national reviews and risk assessments, and coordination with other regional/national lists;

6.2.1.5. Allocating priorities to new chemicals, so that at least 50% of evaluations are for new chemicals, if possible;

6.2.1.6. If use of the compound does not give rise to detectable residues in foods and feeds, in which case it will be afforded a lower priority to those compounds that do give rise to measurable residues in foods or feeds.

6.2.2. Periodic re-evaluation

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

6.2.2.1. If the intake and/or toxicity profile indicates, through scientific and/or technical data, some level of public health concern;

6.2.2.2. 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;

6.2.2.3. Whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;

6.2.2.4. The year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation – Not Yet Scheduled;

6.2.2.5. The date that data will be submitted;

6.2.2.6. If there is a closely related chemical that is a candidate for periodic reevaluation that can be evaluated concurrently;

6.2.2.7. The availability of current labels arising from recent national re-evaluations;

6.2.2.8. Whether the data is submitted under the 4-year rule for evaluations.

6.2.3. Other criteria for evaluations

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:

6.2.3.1. New toxicological data becomes available to indicate a significant change in the ADI or ARfD.

6.2.3.2. The JMPR may note a data deficiency in a Periodic Reevaluation 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.

6.2.3.3. Where new scientific data becomes available to support a change in MRLs, the CCPR may place a chemical under the re-evaluations procedure.

6.2.3.4. 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.

6.2.3.5. 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 shall 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.

6.2.3.6. 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.

6.2.3.7. 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.

7. MRLs PERIODIC REVIEW PROCEDURE

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

7.1. PHASE I

Identify Periodic Review Chemicals and Solicit Data Commitments

(Year 1, CCPR Meeting)

I. Invitation and notification to support or challenge MRLs

Once Identified Candidate Chemicals for Re-evaluation by the CCPR Priorities Working Group, the Secretariat will circulate an invitation with the list of MRLs Candidates.

7.1.1. 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.

7.1.2. Invite Commitment to Challenge or 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 support or challenge MRLs 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 following information must be provided in the response:

- When CXL of a product is challenged, inform whether:

  a) The challenge is due to scientific data not considered in the previous evaluation/re-evaluation. In that case, interested party(ies) are required to provide detailed information on the scientific data and the manner in which it may modify the process of product risk analysis.

  b) The challenge is based on the product posing a risk to public health. In that case, interested parties are required to submit a preliminary risk profile

c) It involves a different type of challenge. In that case, the required rationale shall consist in scientifically-based definition of risk and considered proof.

- In case of supporting CXLs for a given product, interested parties need to notify their intention of doing so and answer, if applicable, to the challenges providing adequate scientific data

7.1.3. 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 7.1.2. above.

7.2. PHASE II

Status Report on Data Commitments and CCPR Follow-up

(Year 2, CCPR Meeting)

7.2.1. 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.

- A list of not challenged CXL

- A list of challenged CXL with a list of governments and international organizations interested in support them.

- A list of challenged CXL with no commitment to support them.

CCPR Meeting

If there is no challenge to the CXLs with the adequate scientific data, the CCPR will recommend to maintain them for another period of 15 years (or less). **(*)**

If there is a challenge to the CXLs, with the adequate scientific data and a commitment to support the product, the CCPR will recommend to reevaluate them.

If there is a challenge to the CXLs with the adequate scientific data and there is no commitment to support ir the CXL(s) the CCPR will recommend to re-evaluate them. **(**) (***)**

CXL reevaluations shall be conducted only on challenged aspects related to a risk to public health and/or scientific breakthrough not covered in previous evaluations.

Dissent

(*) CropLife

Proposal

(**) EU

(***) USA

7.2.2. Response to data commitments

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

a) Sufficient data have been submitted for JMPR review of current CXL that have been challenged. The JMPR shall assess data submitted in support or challenge of each position and recommends the CCPR to:

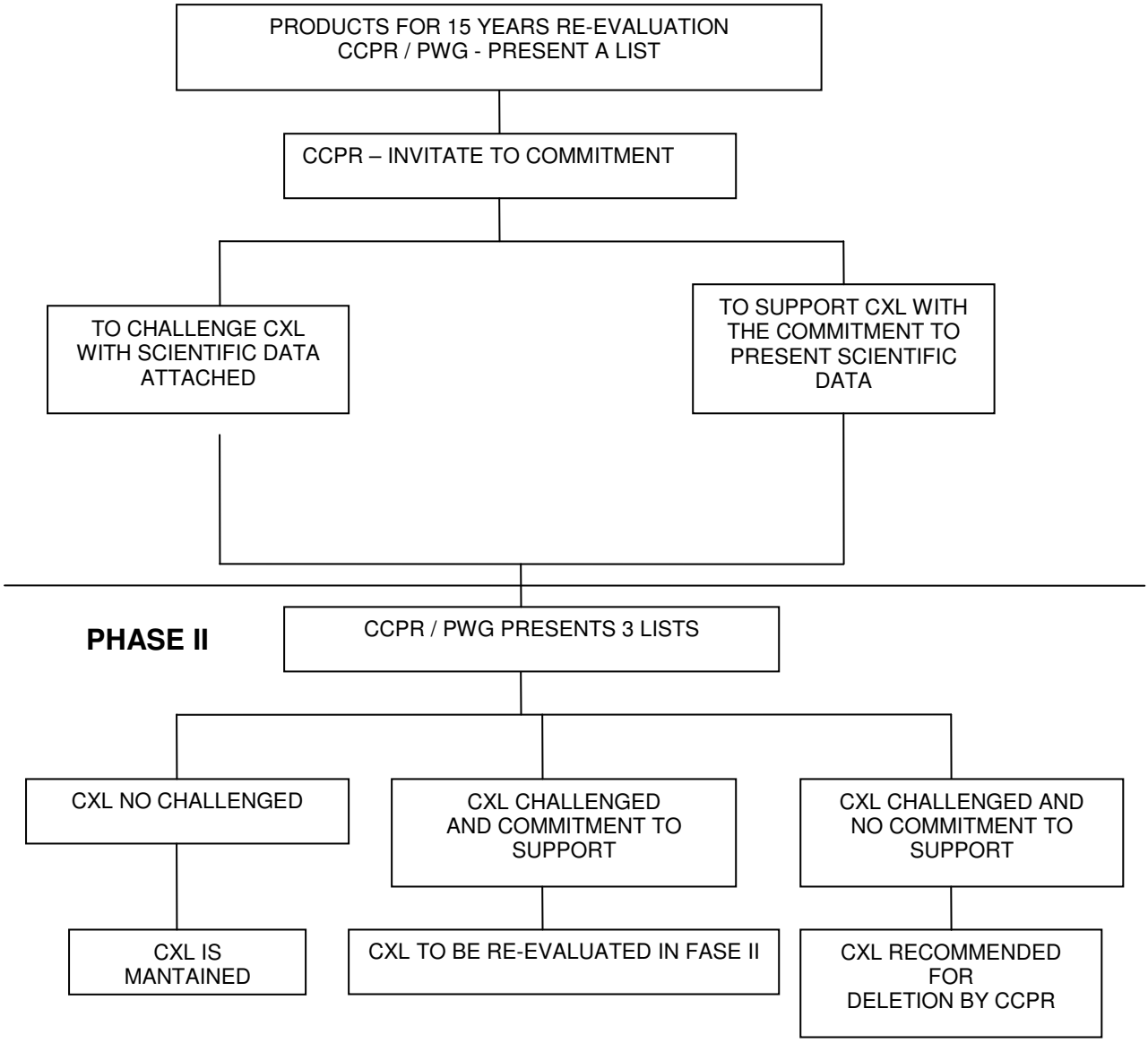
- Delete current CXL that have been challenged.
- Modify challenged CXL, starting the new proposal at step 3.
- Maintain current CXL.

b) Insufficient data have been submitted to challenge or 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 by the next CCPR Meeting, provide to the FAO and the CCPR Secretaries a written commitment to generate and submit a dossier of required data for review within 4 years.

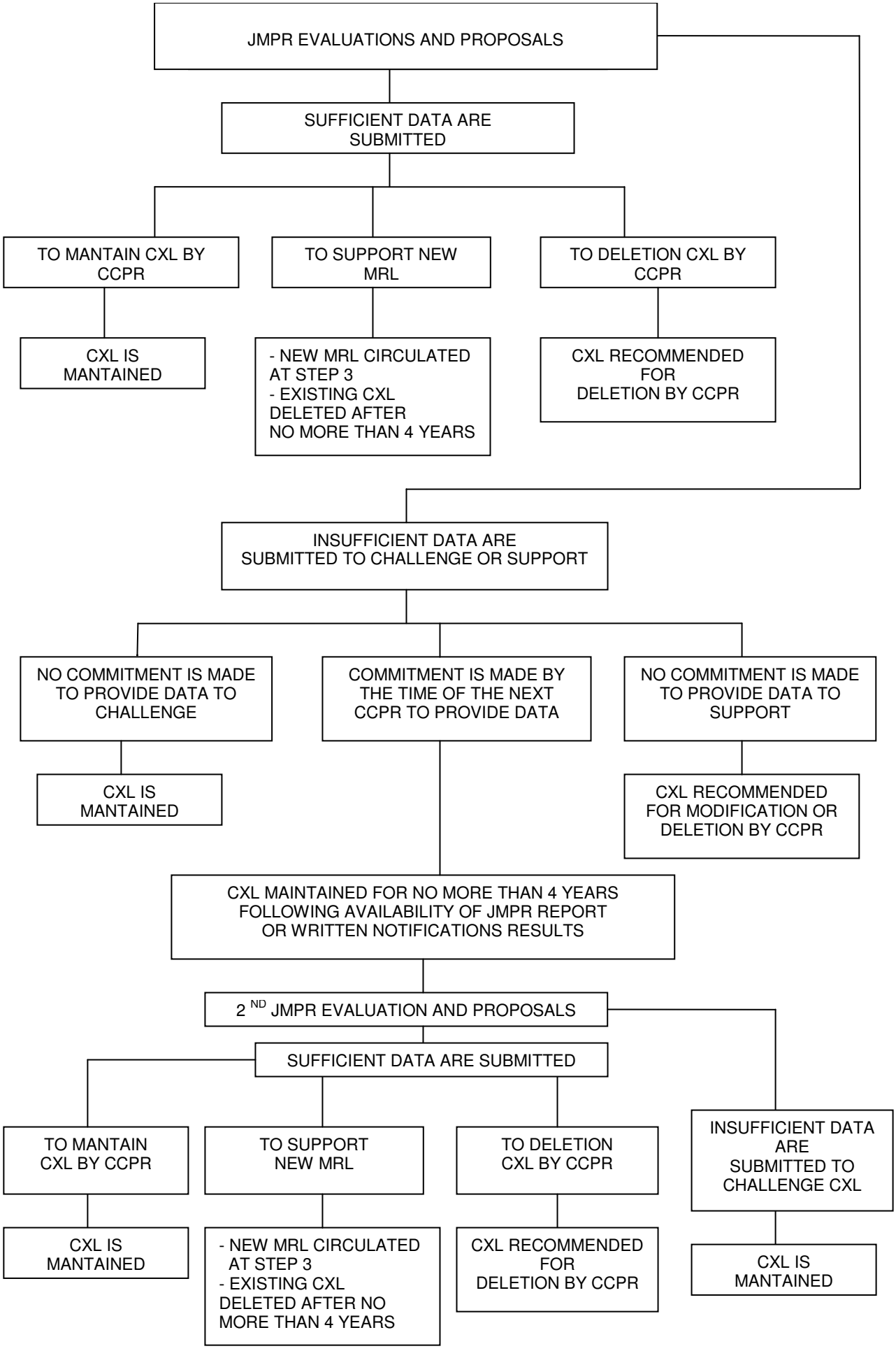
- If there is a commitment to provide new data, the CXL is maintained for no more than 4 years following advice of data inadequacy (by direct notification or by issuance of the JMPR Report). The 4 year period may be extended by the CCPR only to the extent necessary for the JMPR to schedule and complete review of the available new data. The new data are scheduled for the second JMPR review and the first part of the PHASE II procedure is repeated
- If there is not commitment to provide new data for challenging MRLs, the CCPR will recommend to mantain the CXL.
- If there is not commitment to provide new data for supporting MRLs, with an adequate challenge defined by the JMPR, the CCPR will recommend to modify or delete the CXL.
- If insufficient information are submitted to challenge MRLs, the CCPR will recommend to mantain the CXL.

7.3. Summary of reevaluation procedure for Codex MRLs

PHASE I



PHASE II


JMPR EVALUATIONS AND PROPOSALS
SUFFICIENT DATA ARE SUBMITTED
TO MANTAIN CXL BY CCPR
TO SUPPORT NEW MRL
TO DELETION CXL BY CCPR
CXL IS MANTAINED
- NEW MRL CIRCULATED AT STEP 3
- EXISTING CXL DELETED AFTER NO MORE THAN 4 YEARS
CXL RECOMMENDED FOR DELETION BY CCPR
INSUFFICIENT DATA ARE SUBMITTED TO CHALLENGE OR SUPPORT
NO COMMITMENT IS MADE TO PROVIDE DATA TO CHALLENGE
COMMITMENT IS MADE BY THE TIME OF THE NEXT CCPR TO PROVIDE DATA
NO COMMITMENT IS MADE TO PROVIDE DATA TO SUPPORT
CXL IS MANTAINED
CXL RECOMMENDED FOR MODIFICATION OR DELETION BY CCPR
CXL MAINTAINED FOR NO MORE THAN 4 YEARS FOLLOWING AVAILABILITY OF JMPR REPORT OR WRITTEN NOTIFICATIONS RESULTS
2 ND JMPR EVALUATION AND PROPOSALS
SUFFICIENT DATA ARE SUBMITTED
TO MANTAIN CXL BY CCPR
TO SUPPORT NEW MRL
TO DELETION CXL BY CCPR
INSUFFICIENT DATA ARE SUBMITTED TO CHALLENGE CXL
CXL IS MANTAINED
- NEW MRL CIRCULATED AT STEP 3
- EXISTING CXL DELETED AFTER NO MORE THAN 4 YEARS
CXL RECOMMENDED FOR DELETION BY CCPR
CXL IS MANTAINED

8. PROCEDURES FOR ESTABLISHMENT OF MRLs /EMRLs

8.1 Dietary Exposure Assessments in the Risk Assessment Process

8.1.1. The CCPR is entrusted with the elaboration of Maximum Residue Limits (MRLs) of pesticide residues in food and feed. In undertaking dietary exposure risk assessments to assist the CCPR, the JMPR uses 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 thirteen GEMs/Food Compsumption cluster 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.

8.1.2. 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.

8.1.3. 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 if the exceedances of the ARfD are seen as unacceptable adverse effect, 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

8.1.4. 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.

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

8.1.6. 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.

8.2. Consideration of MRLs for Specific Commodity Groups

8.2.1. MRLs for commodities of animal origin

8.2.1.1. 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

[3] Programme of Food Safety and Food Aid, World Health Organization, WHO/FSF/FOS/97.7

studies and residues in animal feed serve also as a primary source of information for estimating maximum residue levels in animal products.

8.2.1.2. 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 (LOQ), 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.

8.2.1.3. 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 as long this MRL is acceptable for all consumers groups.

8.2.2. MRLs for processed or ready-to-eat foods or Feeds

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.

The JMPR evaluates processing studies to derive processing factors used to estimate residues concentrations in processed commodities for dietary risk assessments and, if necessary, recommended MRLs for processed commodities.

The Committee has agreed to:

8.2.2.1. Establish MRLs for important processed commodities,

8.2.2.2. Recommend MRLs for processed commodities only where there is a significant increase in residue from the raw agricultural commodity (RAC) to the processed commodity (PF >1.3) and/or where the calculated processed commodities MRL is less than the MRL of the corresponding RAC,

8.2.2.3.continue the practice of recommending MRLs for processed commodities where, due to the nature of the residues during some specific process, significant amounts of other relevant metabolites appear or increase; and

8.2.2.4.to support the current JMPR practice of evaluating all processing studies provided and including in each *Evaluation/Review* a summary table of all validated processing factors.

8.3. MRLs for spices

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

8.4. MRLs for fat-soluble pesticides

8.4.1. 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, information concerning 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 logPow>3 are likely to be “fat soluble”

8.4.2. For fat-soluble pesticides analysis in milk, due to control and regulatory reasons, analysis of whole milk is recommended in all cases, comparing results obtained with MRL determined for whole milk.

8.3. Establishment of EMRLs

8.3.1. 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.

8.3.2. 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.

8.3.3. 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 [4].

8.3.4. 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.

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

8.3.6. 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.

8.4. Utilization of Steps 5/8 for elaboration of MRLs

8.4.1. 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

8.4.2. 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 must 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 at which the concern was raised.

- 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. Any other draft MRLs for the pesticide, satisfying the above conditions, 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.

[4] 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.

8.5. Procedure for Submitting Concern Form against Proposed/Draft MRL Settled by CCPR

When considering concerns expressed by members, the CCPR has agreed;

- CCPR should recognize the position taken by the JMPR as the best available science (applicable at the international level) until and if a different position is indicated.

- science based objections based on the same data/information should be considered only once by the JMPR in relationship to any specific MRL. If the objection does not result in JMPR changing its recommendation on the MRL then the MRL should not be prevented from advancement based on this issue.

- once only review of the same data/information applies to science-based issues with JMPR methods and procedures as well as issues with MRL specific data/information.

- members are encouraged not to submit the same data/information on more than one occasion. If the same information is submitted to JMPR then JMPR should simply note that this information has already been reviewed, no other changed have occurred which would affect the outcome of a new review, and therefore no review is warranted at this time. The subject MRL should not be prevented from advancement based in this issue.

- while MRLs should not be prevented from advancement because of objections concerning current JMPR procedures, it is imperative that CCPR appropriately address any continuing objections, i.e. repeated objections related to the same science-based issue. This may also be relevant to issues closely associated with risk management. Appropriate action could be:

    - referring the issue to JMPR if there is additional or new information, or if the CCPR wishes to provide risk management input to JMPR on the conduct of risk assessments;

    - referring the issue to national governments or regional authorities for input with a discussion and decision at the next CCPR; and/or

    - where justified by the nature of the issue, referring the issue to a scientific consultation if the budget is available from FAO and/or WHO, with JMPR and/or CCPR to make adjustments based on the recommendations of that consultation. Members recommending any such action by CCPR should provide documentary information supporting their recommendation for the consideration of the Committee

    - in the interim, according to the above recommendations, subject MRLs should be advanced

- if desired by the objecting member, objections should be officially recorded in the CCPR report

- The members should use the “Form for Guidance for Expressing concern on the Advancement of an MRL or Request for Clarification” as follows.

Form for expressing concerns with advancement of an MRL/or request for clarification of concerns

Submitted by:			
Date:			
Pesticide/ **Pesticide Code Number**	**Commodity/** **Commodity Code Number**	**MRL** **(mg/kg)**	**Present Step**
Is this a Request for Clarification?			
Is this a Concern?			
Is this a Continuing Concern?			
Concern (Specific statement of reason for concern to the advancement of the proposed MRL).			
Request for Clarification (Specific statement of clarification requested).			
Do you wish this Concern to be Noted in the CCPR Report?			
Data/Information (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.)			

8.6. DELETING CODEX MRLs

8.6.1. The Codex MRL deletion is stipulated in the following scenarios: (*):

a) Where new scientific data, following a risk analysis, indicate that active compound use may compromise human health, (**)

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 or feed.

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

e) If no residue data submitted to support uses of a pesticide scheduled for periodic re-evaluation, the existing MRLs are retained unless there is a science-based reason to warrant withdrawal, providing labels are submitted to demonstrate the currency of approved uses relevant to the MRLs.

8.6.2. When a compound meets one or more of conditions (a-d), its MRL list will be included in the agenda for the next CCPR session for the Committee to consider a recommendation to the CAC for withdrawal of the MRLs. Decisions of the CAC on deletion of MRLs will take effect a year after the close of the session of the CAC where such decisions were made.

Dissents

(*) Crop Life

(**) Japan

8.7. MRLs AND METHODS OF ANALYSIS

8.7.1. 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.

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