CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 10

CX/PR 12/44/13 (Rev.)
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

44th Session
Shanghai, P.R. China, 23 - 28 April 2012

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

(Prepared by the electronic working group led by Argentina and Brazil)

Governments and interested international organizations wishing to submit comments on the Risk Analysis Principles applied by the CCPR (see Annex) are invited to do so in writing 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 a 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 31 March 2012.

INTRODUCTION

1. In conformance with the mandate[1] received from the 43rd Session of the Codex Committee on Pesticide Residues (April 2011), Argentina, as leading country of the Electronic Working Group on the Revision of the Risk Analysis Principles applied by the Codex Committee on Pesticide Residues, submits this Executive Summary on the work conducted by the EWG since the 43rd Session of the CCPR.

BACKGROUND

2. The background on the discussion of the revision of the Risk Analysis Principles applied by the CCPR can be found in the reports of the 24th Session of the Codex Committee on General Principles[2], the 30th and 31st Sessions of the Codex Alimentarius Commission[3], and the 40th through the 43rd Sessions[4] of the Codex Committee on Pesticide Residues. Reports of Codex committees' meetings are available for downloading at: http://www.codexalimentarius.org.

SUMMARY OF THE WORK PERFORMED

3. In order to propose a procedure for the Periodic Reevaluation according the consensus reached at the 43rd Session of the CCPR in Beijing, China - april 2011, considering CRD 28 presented by Brazil and in accordance with the agreement at the Report of that Session, REP11/PR, paragraph 137. *The Committee therefore agreed to re-convene the electronic working group chaired by Argentina and Brazil, working in English and Spanish, to develop proposals for the revision of the periodic review as a priority and, if feasible, to review the entire text of the Risk Analysis Principles, for consideration by the next session. ……"*

4. In addressing the mandate, the Chairs separated the Risk Analysis Principles applied by the CCPR from the Evaluation and Periodic Reevaluation Procedure, working with each section in separate documents.

5. The document on the Evaluation and Periodic Reevaluation was circulated to EWG members in mid-year, and included the following aspects:

- Procedure included in CX/PR 10/42/12 submitted by the EWG;
- Original text of the 19th Procedural Manual – Codex Alimentarius Commission as base text;
- Original text of CX/PR 08/40/07;
- Proposal for Phases I and II based on CRD 28 of the meeting in 2011, other comments or amendments included in the document and new text;

1 REP11/PR, paras. 8 and 124-137.
2 ALINORM 07/30/33, paras. 27-34.
3 ALINORM 07/30/REP paras. 27-34, 158 and ALINORM 08/31/REP Appendix X.
4 ALINORM 08/31/24, paras. 129-134, ALINORM 09/32/24 paras. 177-185, ALINORM 10/33/24 paras. 139-152 and REP11/PR, paras. 124-137.

- Proposal from Australia regarding the activities of the Priorities Working Group;
- Proposals from United States on: possibility of nominating to the Priorities Working Group compounds that are in the process of registration and products not leading to detectable residues accepted by other members of the EWG with observations concerning the priorities;
- Proposals from India and Brazil, on the importance of economic aspects when substituting products with reduced toxicity risk.

6. Once comments have been received, a new text was elaborated and circulated for consensus building.

7. The document presented on the following pages is the result reached after two rounds of consultation.

8. For the rest of the document (except those regarding to the points 5.2 to 5.4.3) the Chairs' proposal took into consideration comments submitted to the 43rd session of the CCPR, referring to the document CX/PR 11/43/12.

9. The joint chairmanship of the EWG proposed a new section to address the issue of "concern form", and presents some suggestions in the text of section 6.

10. The text was circulated to the EWG members in November 2011 and comments were received until the end of December.

11. The document that was circulated as separate text is the result of the incorporation of the comments of the EWG members to the Chairs' draft text.

12. Comments submitted and their rationale for their consideration and inclusion or not in the revised proposal are given in Part III of this document.

13. The proposed Periodic Review and remaining Risk Analysis Principles applied by the Codex Committee on Pesticide Residues as revised by the EWG are presented in Parts I and II respectively.

PART I – PERIODIC REVIEW

RISK ANALYSIS PRINCIPLES APPLIED BY THE CCPR REGARDING THE EVALUATION AND REEVALUATION PROCEDURES

5.2 PREPARATION OF CCPR PRIORITY LIST OF PESTICIDES

CCPR submits a proposal to the CAC each year, as ongoing work, to re-establish the Electronic Working Group (EWG) on Priorities. The EWG on Priorities is tasked with preparing a draft CCPR Priority List of Pesticides for JMPR Evaluation (Priority List) for the consideration of CCPR.

Within two months of the CAC meeting, the Chair of the EWG issues a broadcast e-mail to all CCPR member and observers requesting nominations to the Priority List.

Each year, the CCPR finalizes the Priority List for the following year's JMPR evaluations. When feasible, tentative lists are prepared for several later years. Nominations and comments on the draft Priority List apply only to the tentative lists.

Members should send a request for evaluation to the Chair of the EWG on Priorities and the JMPR Joint Secretariat. Manufacturers and observers, when sending a request for evaluation to a nominating member, should copy the request to the Chair of the EWG on Priorities and the JMPR Joint Secretariat.

The request for evaluation shall provide a clear indication of the availability of data and national evaluations, give an indication of the number of crops and residue trials to be evaluated. The request should also indicate the current status of national registrations for the compound. For Periodic Re-evaluation, the request should also provide information on most recent evaluation, ADI and ARfD.

The due date for nominations and comments on the draft Priority List is 30 November.

The Chair of the EWG on Priorities consults closely with the JMPR Joint Secretariat before drafting a revised draft Priority List for distribution to members and observers via a Circular Letter from the Codex Secretariat no later than 1 January. Members and observers are allowed two months for comment, which must be received by the Chair of the EWG on Priorities, copied to the JMPR Joint Secretariat, by 1 March.

On the basis of comments received to the circular letter, the Chair of the EWG on Priorities prepares and submits a CCPR agenda paper to the Codex Secretariat that includes Priority List.

The draft Priority List includes six Appendices:

- Appendix 1: Tentative Lists (New Compound Evaluation, Follow-up Evaluation and Periodic Re-evaluation);
- Appendix 2: Chemicals with Extraneous Maximum Residue Limits (EMRLs) and recent deletions;
- Appendix 3: Record of periodic re-evaluations;
- Appendix 4: Periodic re-evaluation - chemicals no longer supported;
- Appendix 5: Chemical-commodity combinations for which specific GAP is no longer supported;
- Appendix 6: Periodic re-evaluation – some commodities no longer supported.

Through plenary discussions, CCPR finalizes the list of compounds to be evaluated by the JMPR in the year following the CCPR meeting and prepares tentative lists for JMPR evaluations in following years. Details of discussion and the priority lists are recorded in the CCPR report.

5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR

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

General Criteria

5.3.1 Criteria and procedures for proposing pesticides for Codex priority lists

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

I. Must be registered for use in a member by deadline of data submission for the evaluation of the toxicological and/or residues studies by the JMPR;

II. Must be available for use as a commercial product by deadline of data submission for the evaluation of the toxicological and/or residues studies by the JMPR;

III. Must not have been already accepted for consideration;

IV. 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 consumer's health concern and thus create (or have the potential to create) problems in international trade.

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

5.3.2 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.

Criteria for Prioritization

5.3.3 New Chemicals

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

I. If the chemical has a reduced acute and/or chronic toxicity risk to humans compared with other chemicals having the same function (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 member or observer 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 having the same function (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) once other aspects have been addressed, consideration must be given to agronomic variables of the chemicals.

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

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

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

V. Allocating priorities to new chemicals so that about 50% of evaluations are for new chemicals, if possible.

5.3.4 Periodic Re-Evaluation

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

I. If scientific data concerning the intake and/or toxicity profile of a compound indicates some level of consumers' health concern;

II. 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;

III. If no ARfD has been established by Codex or if established ADI or ARfD are of consumer concern and an information available from members on national registrations and/or the conclusions from national/regional evaluations indicated a consumer's health concern;

IV. The CCPR has been advised by a member that the residues from a compound has been responsible for trade disruption;

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

VI. The date the data will be submitted;

VII. If there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently;

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

   Note: The labels should be available by the time of the JMPR evaluation.

IX. Whether the data is submitted under the four-year-rule for evaluations.

   Note: The four-year-rule is applied when insufficient data have been submitted to confirm or amend an existing Codex MRL. The Codex MRL is recommended for withdrawal. However, manufacturers, members or observers 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.

General note: Considering the criteria mentioned above and regarding the purpose of the Statute of the Codex Alimentarius Commission, the priority will be to protect the health of the consumers and ensure fair practices in the food trade.

5.3.5 Other evaluations

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

I. The date the request was received;

II. Commitment to provide the required data for review by the deadline of data submission for the evaluation of the toxicological and/or residues studies by the JMPR;

III. Whether the data is submitted under the 4-year rule for evaluations; and

IV. 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. In such a case the WHO Joint Secretary will schedule the request for the next JMPR;

II. A data deficiency in an evaluation noted by the JMPR. In response, members, observers or manufacturers may pledge to supply the information to the appropriate Joint Secretary of the JMPR with a copy for consideration by the CCPR secretariat. 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 members, observers or manufacturers should indicate support for the specific MRLs to the Joint Secretary of the JMPR and the Chair of the EWG on Priorities. Following scheduling in the JMPR tentative schedule, any data in support of maintenance of the MRL(s) would be submitted to the Joint Secretary of the JMPR;

IV. A member or another interested party if supported by a 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 Joint Secretary of the JMPR and submitted to the Chair of the EWG on Priorities 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 member or another interested party if supported by a 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 Joint Secretary of the JMPR with a copy to the Chair of the EWG on Priorities for consideration by the Committee CCPR. 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 FAO Joint Secretary of the JMPR will schedule the request for the next JMPR.

5.4 MRLs PERIODIC REVIEW PROCEDURE

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

5.4.1 PHASE I - Identify Periodic Review Chemicals and solicit data commitments (Year 1, CCPR meeting)

1. Listing Compounds for Periodic Re-evaluation

Compounds are listed for periodic re-evaluation according to the process and procedures described in section 5.2. The process provides members and observers a notice of a periodic re-evaluation.

When a compound is listed for periodic re-evaluation, manufacturers, members and observers are able to support it, regarding the three following possibilities:

A) The chemical and all CXLs are supported by the manufacturers with a complete data package;

B) The chemical and all CXLs are not supported by the manufacturers;

In this case, interested members or observers may support the re-evaluation of the compound and submit residue data and a national monograph on toxicological data to JMPR.

C) The chemical is supported but only one (or some) CXL is not supported by the manufacturers.

In this case, interested members or observers may support the MRL by submitting the GAP or providing new residue data and GAP to JMPR for a new recommendation.

If there is no commitment to support a compound listed for periodic re-evaluation or existing Codex MRLs or new proposed MRL for use of such a compound on particular commodities, this is highlighted in the draft Priority List distributed to members and observers by Circular Letter as well as the priorities agenda paper tabled at CCPR.

2. Commitment to Support Chemicals or existing Codex MRLs or new proposed MRL

The commitment of members to provide data for the periodic review should be addressed to the Chair of the EWG on Priorities and the JMPR Joint Secretariat. Manufacturers and observers, when addressing the commitment to a nominating member, should copy it to the Chair of the EWG on Priorities and the JMPR Joint Secretariat.

The following information must be provided in the response:

I) In the case provided for in A

- A list of chemicals and all CXLs supported by the manufacturer;
- A draft 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 and the data they commit to make complete data package submissions to the JMPR. Comments on the status of registration at the national level are encouraged;
- A brief summary of all current Good Agricultural Practices (GAPs) at the time of the notification and any potential new GAPs expected before the JMPR evaluation which they are willing to provide and which is pertinent to residue data they are willing to provide (e.g. commodities and countries for with detailed GAP summaries and representative labels can be provided).

II) In the case provided for in B

- A list of chemicals and CXLs members or observers are willing to support;
- The national monograph on toxicological data and other available scientific studies;
- Current Good Agricultural Practices (GAPs) – label (when there has been no changes in use);
- Supervised residue trial studies conducted according to current GAP, and relevant studies to support new MRLs in animal and processed commodities.

III) In the case provided for in C

- A list of CXLs members or observers are willing to support;
- Current Good Agricultural Practices (GAPs) – label (when there has been no changes in use);
- Supervised residue trial studies conducted according to current GAP, and relevant studies to support new MRLs in animal and processed commodities.

3. Repeat the Invitation and Notification

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, members and observers 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 requests but should copy addresses listed in the item above.

5.4.2 PHASE II - Status Report on Data Commitments and CCPR Follow-up

(Year 2, CCPR meeting)

1. Status report on data commitments

The Priorities EWG will provide a report and room document to the CCPR on the status of commitments received to provide data for the chemicals identified in year 1. This information will be used to schedule JMPR reviews:

A) Chemicals and CXLs that will be supported by the manufacturers with a complete data package;

B) Chemicals and CXLs that will be supported by members or observers (that is, chemical not supported by the industry);

C) CXLs that will be supported by current Good Agricultural Practices (GAPs) or new residue data and GAPs (that is, CXLs not supported by the industry, even if the chemical is supported).

Note: If there is no commitment, The Priorities EWG report will inform about the potential deleting CXLs.

2. Response to data commitments

I) Procedure for Case A

If a commitment is made to provide and identify or develop data to support the chemicals and existing CXLs, as foreseen in Case A), the complete data package will be scheduled for JMPR review. The JMPR review will be conducted consistent with one of the following scenarios:

- Sufficient toxicological data (and other studies) are submitted to support the chemical and it is therefore maintained;
- Sufficient data are submitted to confirm the existing 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 as soon as the new proposed MRL is adopted by CAC at the latest automatically after no more than 4 years;

II) Procedure for Case B

If commitments are made to provide, identify or develop data supporting the chemicals and existing CXLs, as foreseen in Case B), the JMPR review of the data will be scheduled.

The JMPR review will result in one of the following scenarios:

- A national monograph on toxicological data is submitted to evaluate the chemical;
- Current Good Agricultural Practices (GAPs) are submitted to confirm the CXL which is therefore maintained;
- Residue studies and most recent Good Agricultural Practices (GAPs) are submitted to support a new MRL proposal. It enters the process at Step 3 and the existing CXL will be automatically deleted after no more than four years.

Note: If the submitted data are insufficient, the JMPR may request additional data on a case-by-case basis.

III) Procedure for Case C

If a commitment is made to provide and identify or develop data to support the CXLs, as provided for in Case C), the review of the new data or Good Agricultural Practices (GAPs) are scheduled for review by the JMPR.

The JMPR review will result in one of the following scenarios:

- Current Good Agricultural Practices (GAPs) are submitted to confirm the CXL which is therefore maintained;
- Residue data and most recent Good Agricultural Practices (GAPs) are submitted to support the new MRL proposal. It enters the process at Step 3 and the existing CXL will be automatically deleted after four years.

Note: If the submitted data are insufficient, the JMPR may request additional data on a case-by-case basis.

IV) In any of the three procedures (A, B and C) mentioned above, three scenarios may occur:

- the data support the chemical (except procedure C);
- the data confirm the existing Codex MRL, it remains in place;
- 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;
- the data submitted is insufficient to support the chemical or the existing CXL or the new MRL;
- If no science based reason, the existing MRLs are retained, labels must be provided to demonstrate the currency of approved uses relevant to the MRLs.

3. Insufficient information to support a CXL

If insufficient data have been submitted to support the chemical or the existing CXL or the new MRL, manufacturers, members or observers are so advised by written notification from the relevant Joint Secretary of the JMPR and/or by issuance of the JMPR Report.

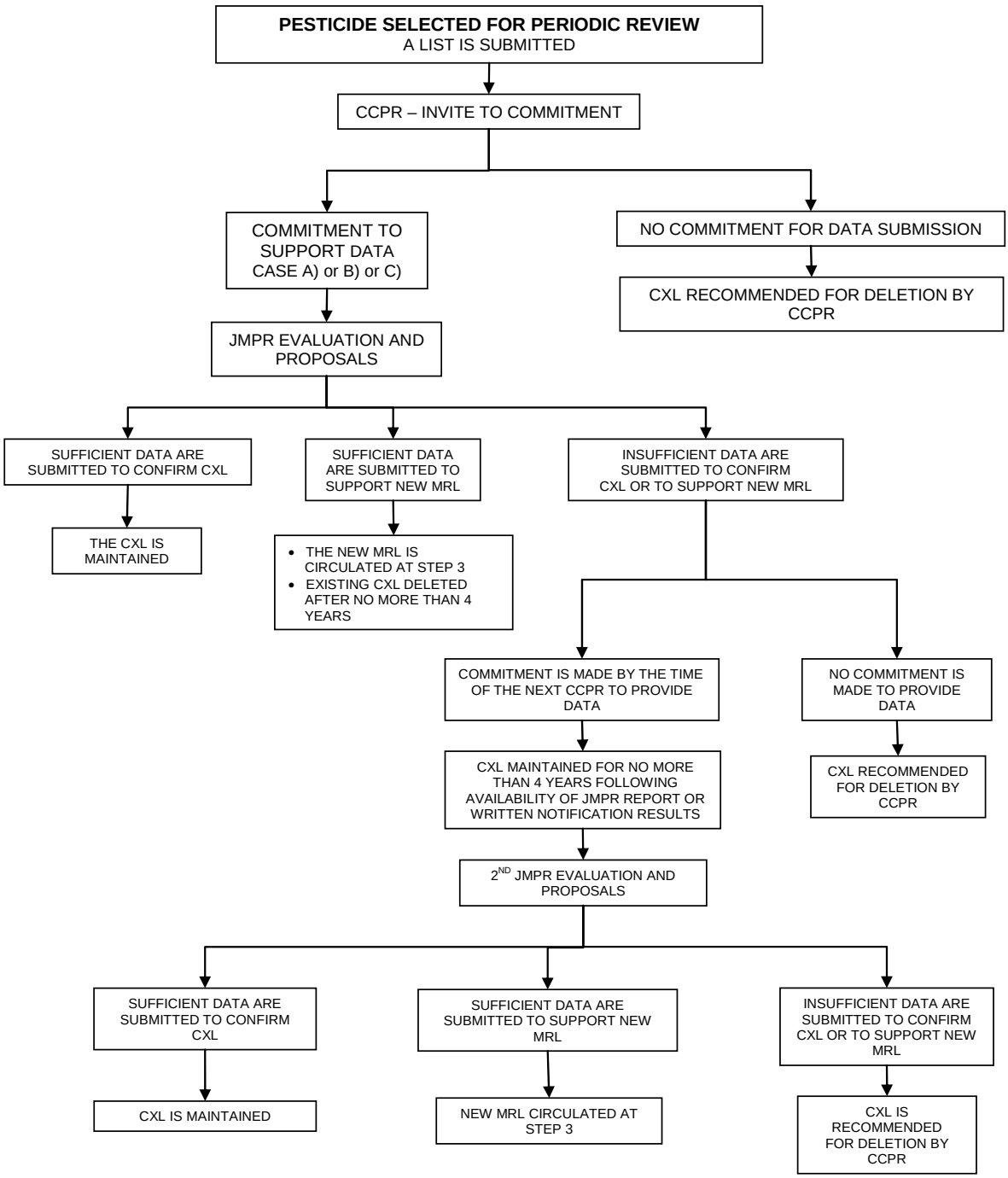
On being advised of the data inadequacy, manufacturers, members or observers may, by the next CCPR Meeting, provide to the JMPR and the CCPR Secretaries a written commitment to generate and submit a dossier of required data for review within 4 years, under the condition that no unacceptable acute/chronic risks have been identified by JMPR.

If an unacceptable acute/chronic risk has been identified by the JMPR, on a scientific base, the additional period to submit the dossier of required data will not be granted and the CXL should be proposed for deletion.

The chemical and 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.

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.

5.4.3 Summary of Periodic Review Procedure for Codex MRLs



PART II – RISK ANALYSIS PRINCIPLES EXCEPT THE PERIODIC REVIEW

RISK ANALYSIS PRINCIPLES APPLIED BY THE CCPR

(EXCEPT POINTS 5.2 TO 5.4.3)

CONTENTS

1. 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.

2. GENERAL ASPECTS

Summary of the MRL-setting process

In addressing pesticide residue issues in Codex, including setting MRLs, providing advice and taking decisions on risk management is the responsibility of the CAC and CCPR, while conducting risk assessment is the responsibility of JMPR.

The MRL-setting process begins with the response by members and other interested parties to the invitation of nominating chemicals in time for the CCPR to prioritize pesticides for review by the 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 residue definitions and 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. MRLs in or on food commodities and animal feeds are based on GAP information, taking into consideration information on dietary intakes, and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable.

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.

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

3. RISK ASSESSMENT POLICY

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 and Animal Feed 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.

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.

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.

CCPR shall request JMPR to review any risk assessment policies, methods and guidelines being considered by CCPR for assessing maximum residue limits for pesticides.

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.

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[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.

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

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

The JMPR Secretariat shall consider whether these minimum data requirements have been met when preparing the provisional agenda for meetings of JMPR.

3.1 MRLs FOR SPECIFIC COMMODITIES GROUP

3.1.1 MRLs for commodities of animal origin

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, (e.g. forage crops, plant parts that could be used in animal feeds, including also by products or coproducts of industrial productions, such as biofuels, entering into the food chain through feed). 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.

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.

Where the recommended maximum residue level 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 as this MRL does not pose unacceptable risk to populations that consume the commodity.

3.1.2 MRLs for spices

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

3.1.3 MRLs for fat-soluble pesticides

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”;

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.

3.1.4 MRLs for processed or ready-to-eat foods or Feeds

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 maximum residue levels for processed commodities.

The CCPR agreed to:

- Establish MRLs for important processed commodities;
- Establish MRL for the processed commodities only if the resulting value is higher than the MRL established for the corresponding raw agriculture commodity (RAC)[2] (PF>1.3);
- Continue the practice of establishing 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
- 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.

[2] Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant protection and Protection Paper, 197, 2009, ISBN 978-92-5-106436-8.

3.1.5 Establishment of EMRLs

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 recognized as acceptable in or on a food, agricultural commodity or animal feed.

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.

All relevant and geographically representative monitoring data (including nil-residue results) are required to make reasonable estimates to cover international trade[3]. JMPR has developed a standard format for reporting pesticide residues monitoring data.

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.

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

4. RISK ASSESSMENT

4.1 ROLE OF JMPR

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.

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.

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 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.

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 to provide safety assessments that can serve as the basis for CCPR's risk-management discussions.

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

JMPR communicates to CCPR possible sources of uncertainties in the exposure assessment and/or in the hazard characterization of the compound that, if resolved, would allow a refinement of the risk assessment.

4.2 DIETARY INTAKE

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.

In undertaking dietary exposure risk assessments to assist the CCPR, the JMPR uses the WHO Guidelines[4] and other documents[5]. The JMPR recommends Supervised Trial Median Residues (STMRs) and Highest Residues (HRs) for dietary intake purposes.

When the ADI is exceeded in one or more cluster diets, the JMPR further refines the dietary intake estimates at the international level. If further refinement is not possible, the JMPR flags this situation when recommending maximum residue levels. If further refinement is possible the CCPR should advance the MRLs to Step 8 provided that the MRLs give no longer rise to intake concerns. If further refinement is not possible or the refinement still give rise to intake concern MRLs are withdrawn

The JMPR establishes acute reference doses (ARfDs), where appropriate, and indicates cases where an ARfD is not necessary. Since 1999, the JMPR calculates the International Estimate of Short-term Intake (IESTI), following a procedure described previously (FAO, 2003). This procedure allows for the estimation of the IESTI for the General Population and for Children (less than 6 years old).

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[3] Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant protection and Protection Paper, 110, 2009, ISBN 978-92-5-106436-8.

[4] WHO Guidelines: WHO/FSF/FOS/97.7.

[5] FAO. 2003. Pesticide Residues in Food 2003- Report. FAO Plant Production and Protection Paper No. 176 FAO, Rome. Chapter 3.

Where the ARfD is exceeded for a compound/commodity, 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. 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 next year. If a GAP is provided but no field trial data, JMPR may consider a rough estimate on the safety of the use using the proportionality principle in which case the proposed MRL may be returned to Step 6 three times. The data will be evaluated by JMPR on request of CCPR as soon as they become available. If no data are supplied the CCPR should proceed to withdraw the draft MRL.

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.

5. RISK MANAGMENT

5.1 ROLE OF CCPR

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

CCPR shall base its risk management recommendations to the CAC on JMPR's risk assessments of the respective pesticides, considering, where appropriate, other legitimate factors that[6] may be relevant to health protection of consumers and/or promotion of fair practices in food trade

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.

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

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

CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by members and compiled by GEMS/Food.

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

(The rest of Chapter 5 is included in the special analysis of the reevaluation procedure.)

6. PROCEDURE FOR SUBMITTING CONCERN

- The members or observers must complete the Concern Form (Annex B), attach the scientific data and submit to the JMPR Secretariat, within one month after the CCPR Meeting;
- The JMPR will evaluate the concerning scientific data provided with the form and present recommendations to the next CCPR Meeting;
- The CCPR will make the decision based on the JMPR recommendations.

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 concerns based on the same data/information should be considered only once by the JMPR in relationship to any specific compound, MRL or CXL;
- only one 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;
- If the same information is submitted, JMPR should simply note that this information has already been reviewed, no other change has occurred which would affect the outcome of a new review, and therefore no review is warranted at this time.

Note 1: If the concern is about a MRL advancement and the JMPR does not change its recommendation on the MRL and the CCPR agrees, the MRL should not be prevented from advancement based on this issue.

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

[6] 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.

- 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, concerns should be officially recorded in the CCPR report and CAC informed through the CCPR report.

Note 2: If the concern in regard to a compound listed in periodic reevaluation schedule is supported by JMPR and CCPR agrees the compound will be assigned a high priority and scheduled for the next available year.

However, if a member or observer disagrees with the JMPR recommendation it must lodge additional scientific data to JMPR Secretariat one month after the CCPR Meeting. At the following CCPR Meeting, JMPR will report its recommendation. CCPR will make its final decision on prioritization.

7. ELABORATION PROCEDURE

7.1 UTILIZATION OF STEPS 5/8 FOR ELABORATION OF MRLS

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.

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;
- When the ADI is exceeded in one or more cluster diets, or the ARfD is exceeded in the one or more food commodities, the MRLs will not advance to Step 8.

7.2 DELETING CODEX MRLS

Codex MRLs are proposed for deletion in the following scenarios:

a) As a result of the periodic revaluation;

b) The active compound is no longer produced and commercialized, 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.

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.

Note: if a pesticide meets the above stated conditions and is environmentally persistent, EMRLs are needed to cover international trade after its MRLs are deleted.

8. RISK COMMUNICATION

In accordance with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*, the CCPR, in cooperation with JMPR, shall ensure that the risk analysis process is fully transparent and thoroughly documented and that results are made available in a timely manner to Members.

In order to ensure the transparency of the assessment process in JMPR, the CCPR provides comments on the guidelines related to assessment procedures being drafted and published by JMPR.

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

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

Annex A

Form for expressing concerns to the CCPR

Submitted by:		
Date:		
Pesticide/ *Pesticide Code Number*	*Commodity /* *Commodity Code Number*	*MRL* *(mg/kg)*
Is this a Request for Clarification?		
Request for Clarification (*Specific* statement of clarification requested)		
Is this a Concern?		
Is this a Continuing Concern?		
Concern (*Specific* statement of reason for concern)		
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).		

PART III

COMMENTS PRESENTED BY COUNTRIES AT THE SECOND ROUND ABOUT THE DOCUMENT "CHAIR PROPOSAL (BRAZIL - ARGENTINE) ON EVALUATION AND PERIODIC REEVALUATION ON PESTICIDES RESIDUES"

STATUS OF COMMENTS FROM AUSTRALIA, COSTA RICA, CROPLIFE INTERNATIONAL, GERMANY, JAPAN, NEW ZEALAND, THAILAND, UNITED STATES AND URUGUAY

1. AUSTRALIA

Reference in the document: "Draft text of the Risk Analysis Principles Applied by the CCPR regarding the Evaluation and Reevaluation Procedures"	Member´s Comment	Updated status and reference in the revised draft document
5.4. MRLs PERIODIC REVIEW PROCEDURE 5.4.1. PHASE I 1. Listing Compounds for Periodic Re-evaluation	Case B – the compound and all CXLs is not supported by the manufacturer for periodic re-evaluation. Australia continues to have concerns in regard to the submission of national monographs and other available studies for toxicological evaluation by JMPR. Australia believes that national monographs may not be recent evaluations and will not be accompanied by the original studies (raw data). In evaluating available data the JMPR may find a national monograph of some assistance but will often need to review the original toxicological studies. In addition, national monographs vary in the detail reported and the standard of the analysis. Data required by regulators has evolved over the years and the best use of older data often requires revisiting the original reports.	CLARIFICATION (Data requirements for submission to JMPR are already defined and submitted data are evaluated by JMPR on a case-by-case basis)
5.4. MRLs PERIODIC REVIEW PROCEDURE 5.4.1. PHASE I 2. Commitment to Support Chemicals or existing Codex MRLs or new proposed MRL	2. Inconsistent data requirements of manufacturers (Case A and C) and of members / observers (Case B) Australia continues to have concerns that in Case A and C, manufacturers are required to provide a complete data package for JMPR evaluation, whilst in Case B members / observers are required to provide national monographs and other available scientific data. This appears to place a greater burden on manufacturers. Whether or not a pesticide is supported can be decided from interventions from member countries and manufacturers, therefore we suggest the text does not need to stipulate who is responsible for providing a data package. That is, JMPR must be provided the required data package. The text on supporting a new MRL is appropriate.	CLARIFICATION (Data requirements for submission to JMPR are already defined and submitted data are evaluated by JMPR on a case-by-case basis)

2. COSTA RICA

Reference in the document: "Draft text of the Risk Analysis Principles Applied by the CCPR regarding the Evaluation and Reevaluation Procedures"	Member´s Comment	Updated status and reference in the revised draft document
5.2. PREPARACIÓN DE LA LISTA DE PRIORIDADES DEL CCPR	Párrafo 4: - "manufacturers and observers" is replaced by interested parties in this paragraph and other subsequent paragraphs. - "new" is added (new compound).	NOT ADDRESSED There are three different stakeholders in the document: manufacturers, members and observers. Depending on the case, the document will refer only to one or more of them. In the case that refers to more than one, all will be mentioned NOT ADDRESSED (See New Zealand Comment)
5.3. CRITERIOS PARA EL ESTABLECIMIENTO DE PRIORIDADES REFERENTE A LOS COMPUESTOS DESTINADOS A EVALUACIÓN POR PARTE DE LA JMPR	- In all cases "shall" is replaced by "must". - "General note" is replaced by "V". It is suggested to include it as a condition since as a note it lacks relevance in the document. It is also suggested to delete the term note from all paragraphs starting as such in the rest of the document.	NOT ADDRESSED At this point it was followed the document format with "note" of the Procedural Manual, followed by most of the members
Criterios para Priorización 5.3.3. Nuevos productos químicos	Text of item e) is amended. The highlighted text is included for better understanding of the text (as it was presented in the previous revised document). e) Once other aspects are given consideration, agronomical variables of new product as compared to other chemicals within its category must be taken into account.	NOT ADDRESSED The wording was modified base don the opinion of the majority of the members
5.3.4. Reevaluación periódica	- "manufacturers, members and observers" is replaced by "interested parties"	NOT ADDRESSED There are three different stakeholders in the document: manufacturers, members and observers. Depending on the case, the document will refer only to one or more of them. In the case that refers to more than one, all will be mentioned

5.3.5 Otras evaluaciones	- There is a request to include “other” to the title.	ADDRESSED
	- It is proposed to delete the term “note” since the content of the text is an integral part of this paragraph, which provides for other forms of evaluation.	NOT ADDRESSED At this point it was followed the document format with “note“ of the Procedural Manual, followed by most of the members
	- “Members, observers or the industry” is replaced by “interested parties” in this paragraph and in other subsequent paragraphs.	NOT ADDRESSED There are three different stakeholders in the document: manufacturers, members and observers. Depending on the case, the document will refer only to one or more of them. In the case that refers to more than one, all will be mentioned

3. CROPLIFE

Reference in the document: "Draft text of the Risk Analysis Principles Applied by the CCPR regarding the Evaluation and Reevaluation Procedures"	Member´s Comment	Updated status and reference in the revised draft document
5.2. Preparation of Priority Lists	Members should send a request for evaluation to the Chair of the EWG on Priorities and the JMPR Joint Secretariat~~. Manufacturers and observers~~ Other interested parties, when sending a request for evaluation to a nominating member, should copy the request to the Chair of the EWG on Priorities and the JMPR Joint Secretariat. ~~Members should send a request for evaluation to the Chair of the EWG on Priorities and the JMPR Joint Secretariat.~~	PARTIALLY ADDRESSED (It is ok to change the sentences order in the paragraph. But, as mentioned in the previously round of comments, there are three different stakeholders in the document: manufacturers, members and observers. Depending on the case, the document will refer only to one or more of them. In the case that refers to more than one, all will be mentioned. A new language is proposed: *"Members should send a request for evaluation to the Chair of the EWG on Priorities and the JMPR Joint Secretariat. Manufacturers and observers, when sending a request for evaluation to a nominating member, should copy the request to the Chair of the EWG on Priorities and the JMPR Joint Secretariat.")*
5.2. Preparation of Priority Lists	The due date for nominations ~~and comments~~ on the draft Priority List is 30 November.	NOT ADDRESSED (It is customary to forward comments on the draft list, for example, indicating an error)

5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR General Criteria 5.3.1. Criteria and procedures for proposing pesticides for Codex priority lists	I. Must be registered for use in a member country by the time the toxicological and/or residues studies are evaluated by the JMPR.	NOT ADDRESSED (In the Procedure Manual is possible to find the terms "member", "member country", "government member", etc. For this document, the term "member" was chosen as it is the most common in the Manual)
5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.3. New Chemicals	~~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;~~ b) a statement that due to the toxicological profile of the substance it would not be classified as highly or extremely hazardous; Corplife comment: These calculations are made by the JMPR but not by the data submitter, information not available by the time of the priority list establishment.	NOT ADDRESSED To analyze that the proposed new chemical is a “safer” or “reduced risk” replacement chemical requires comparison and dietary exposure calculations
5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.5. Other Evaluations	II. A data deficiency in an evaluation noted by the JMPR. In response, members, observers or manufacturers may pledge to supply the information to the appropriate Joint Secretary of the JMPR with a copy for consideration by the CCPR. secretariat and the Chairperson. Following scheduling in the JMPR tentative schedule, the data should be submitted subsequently to the appropriate Joint Secretary of the JMPR;	PARTIALLY ADDRESSED (It should be enough to inform the JMPR and CCPR Secretariats.)
5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.5. Other Evaluations	III. The CCPR may place a chemical under the four-year rule, in which case members, observers or manufacturers should indicate support for the specific MRLs to the Joint Secretary of the JMPR. and the Chair of the EWG on Priorities. Following scheduling in the JMPR tentative schedule, any data in support of maintenance of the MRL(s) would be submitted to the Joint Secretary of the JMPR.	ADDRESSED

5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.5. Other Evaluations	IV. A member or another interested party if supported by a 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 Joint Secretary of the JMPR and submitted to the Chair of the EWG on Priorities for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data would be submitted to the Joint Secretary of the JMPR;	ADDRESSED
5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.5. Other Evaluations	V. A member or another interested party if supported by a 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 Joint Secretary of the JMPR with a copy to the Chair of the EWG on Priorities for consideration by the ~~Committee~~ CCPR. Following scheduling in the JMPR tentative schedule, the data would be submitted to the Joint Secretary of the JMPR;	ADDRESSED
5.4. MRLs PERIODIC REVIEW PROCEDURE 5.4.1. PHASE I 1. Listing Compounds for Periodic Re-evaluation	A) The chemical and all CXLs are supported by ~~the manufacturers~~ an interested party with a complete data package as required by the FAO/WHO; ~~B)~~ The chemical and all CXLs are ~~not~~ no longer supported by ~~the manufacturers~~. B) ~~In this case~~,previously interested party. In this case, interested members or ~~or observers~~ other interested parties may support the re-evaluation of the compound and submit ~~residue~~ all relevant data required by FAO and ~~the national monograph on~~ all new relevant toxicological data ~~to~~ not previously evaluated by the JMPR to the JMPR. C) The chemical is supported but only one (or some) CXL is not supported ~~by the manufacturers~~ previously interested party. In this case, interested members or ~~observers~~ other interested parties may support the MRL by submitting the GAP or providing new residue data and GAP to JMPR for a new recommendation.	NOT ADDRESSED (See the 43th CCPR Report, specially para 131 and 132)

5.4. MRLs PERIODIC REVIEW PROCEDURE 5.4.1. PHASE I 2. Commitment to Support Chemicals or existing Codex MRLs or new proposed MRL	The commitment of members ~~or observers~~ to provide data for the periodic review should be addressed to the chair of the EWG on Priorities and the JMPR Joint Secretariat. ~~Manufacturers~~ Other interested parties , when addressing the commitment to a nominating member, should copy it to the Chair of the EWG on Priorities and the JMPR Joint Secretariat.	PARTIALLY ADDRESSED (A new language is proposed: "The commitment of members to provide data for the periodic review should be addressed to the chair of the EWG on Priorities and the JMPR Joint Secretariat. Manufacturers and observers, when addressing the commitment to a nominating member, should copy it to the Chair of the EWG on Priorities and the JMPR Joint Secretariat.")
5.4. MRLs PERIODIC REVIEW PROCEDURE 5.4.1. PHASE I 2. Commitment to Support Chemicals or existing Codex MRLs or new proposed MRL	I) In the case provided for in A – A list of chemicals and all ~~CXL~~CXLs supported; (...)	ADDRESSED
5.4. MRLs PERIODIC REVIEW PROCEDURE 5.4.1. PHASE I 2. Commitment to Support Chemicals or existing Codex MRLs or new proposed MRL	II) In the case provided for in B (...) – ~~The national monograph on~~ A study list of new relevant toxicological data and other available scientific studies; or a justification that no new data have to be submitted. – Supervised residue trial studies and all other relevant data (e.g. metabolism , analytical methods, storage stability) conducted according to current GAP, and relevant studies to support new MRLs in animal and processed commodities.	NOT ADDRESSED (See the 43th CCPR Report, specially para 131 and 132)
5.4.2. PHASE II 1. Status report on data commitments	The Priorities EWG will provide a report and room document to the CCPR on the status of commitments received to provide data for the chemicals identified in year 1. This information will be used to schedule JMPR reviews: A) Chemicals and CXLs that will be supported by ~~the manufacturers~~ same interested parties with a complete data package; B) Chemicals and CXLs that will be supported by members or ~~observers (that is, chemical not supported by the industry)~~; interested parties other than previous supporters. C) CXLs that will be supported by current Good Agricultural Practices (GAPs) or new residue data and GAPs (that is, CXLs not supported ~~by the industry~~, previously interested party even if the chemical is supported).	NOT ADDRESSED (See the 43th CCPR Report, specially para 131 and 132)

5.4.2. PHASE II 1. Status report on data commitments II) Procedure for Case B	~~A national monograph on~~ The submitted new, not previously evaluated, toxicological data ~~is submitted~~ are considered as sufficient by the JMPR to ~~evaluate~~ support the chemical;.	NOT ADDRESSED (See the 43th CCPR Report, specially para 131 and 132)
5.4.2. PHASE II 1. Status report on data commitments II) Procedure for Case B III) Procedure for Case C	Note: If the submitted data ~~is~~ are insufficient, the JMPR may request additional data on a case-by-case basis.	ADDRESSED
5.4.2. PHASE II 3. Insufficient information to support a CXL (first and second paragraph)	If insufficient data have been submitted to support the chemical or the existing CXL or the new MRL, ~~manufacturers, members or observers~~ members and all interested parties who had submitted relevant information are so advised by written notification from the relevant Joint Secretary of the JMPR and/or by issuance of the JMPR Report. On being advised of the data inadequacy, ~~manufacturers,~~ members ~~or observers~~ and other interested parties may, by the next CCPR Meeting, provide to the JMPR and the CCPR Secretaries a written commitment to generate and submit a dossier of required data for review within 4 years, under the condition that no acute/chronic risks have been identified by any interested member.	NOT ADDRESSED (As mentioned in the previously round of comments, there are three different stakeholders in the document: manufacturers, members and observers. Depending on the case, the document will refer only to one or more of them. In the case that refers to more than one, all will be mentioned).
5.4.2. PHASE II 3. Insufficient information to support a CXL (third and fourth paragraph)	.... and submit a dossier of required data for review within 4 years, under the condition that no unacceptable acute/chronic risks have been identified by any interested member. During this period if an unacceptable acute/chronic risk has been identified, on a scientific base, and presented by a member, the additional period to submit the dossier of required data will not be granted and the CXL should be proposed for deletion.	ADDRESSED

4. GERMANY

Reference in the document: "Draft text of the Risk Analysis Principles Applied by the CCPR regarding the Evaluation and Reevaluation Procedures"	Member´s Comment	Updated status and reference in the revised draft document
5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.3. New Chemicals	5.3.3. New Chemicals When prioritizing new chemicals for evaluation by the JMPR, the Committee will consider the following criteria: I. If the chemical has a reduced acute and/or chronic toxicity risk to humans compared with other chemicals *having the same function (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 member or observer 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 *having the same function (insecticide, fungicide, herbicide);*	ADDRESSED
5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.3. New Chemicals	V. Allocating priorities to new chemicals so that about 50% of evaluations are for new chemicals, if possible;	ADDRESSED
5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.4 Periodic Re-Evaluation	III. If no ARfD has been established by Codex or if established ADI or ARfD are of consumer concern and an information available from members on national registrations and/or the conclusions from national/regional evaluations indicated a consumer's health concern; *Commment: No case exists where an active substance having MRLs has no ADI*	ADDRESSED

5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.4 Periodic Re-Evaluation	IX.Whether the data is submitted under the four-year-rule for evaluations.(…) *Comment: I propose to delete this point (IX) here. It is addressed in chapter 5.3.5.*	NOT ADDRESSED (The four-year-rule is not only applied to others evaluations, but also in the periodic re-evaluation procedure, as mentioned in the Procedure Manual.
5.4.1. PHASE I - Identify Periodic Review Chemicals and solicit data commitments (Year 1, CCPR meeting) 1. Listing Compounds for Periodic Re-evaluation	C) The chemical is supported but only one (or some) CXL is not supported by the manufacturers. In this case, interested members or observers may support the MRL by submitting the GAP and providing (new) residue data to JMPR for a new recommendation. *Comment: Clarification necessary to indicate the basis of a MRL for that GAP*	NOT ADDRESSED (It is important to clarify that there are two different situations: 1) No changes in good agricultural practices since the last time the JMPR evaluated the residue studies. So in this case, only the GAP should be submitted. It is not necessary to resubmit the same residue studies the JMPR has evaluated to maintain the (already existing) Codex MRLs. 2) There were some changes in good agricultural practices since the last time the JMPR evaluated the residue studies. So in this case, it is necessary to submit the new residue studies and the latest GAP to the JMPR evaluation and new recommendation)
5.4.1. PHASE I - Identify Periodic Review Chemicals and solicit data commitments (Year 1, CCPR meeting) 2. Commitment to Support Chemicals or existing Codex MRLs or new proposed MRL	I) In the case provided for in A – A list of chemicals and all CXL supported by the manufacturer; (…) II) In the case provided for in B – A list of chemicals and CXLs members or observers are willing to support; (…) III) In the case provided for in C – A list of CXLs members or observers are willing to support; (…)	ADDRESSED

5.4.1. PHASE I - Identify Periodic Review Chemicals and solicit data commitments (Year 1, CCPR meeting) 2. Commitment to Support Chemicals or existing Codex MRLs or new proposed MRL	II) In the case provided for in B – Current Good Agricultural Practices (GAPs) – label; ~~(when there has been no changes in use);~~ III) In the case provided for in C – Current Good Agricultural Practices (GAPs) – label; ~~(when there has been no changes in use);~~ Comment: What does this mean? Changes compared to...? And when changes have happened compared to ...?	NOT ADDRESSED (It is important to clarify that there are two different situations: 1) No changes in good agricultural practices since the last time the JMPR evaluated the residue studies. So in this case, only the GAP should be submitted. It is not necessary to resubmit the same residue studies the JMPR has evaluated to maintain the (already existing) Codex MRLs. 2) There were some changes in good agricultural practices since the last time the JMPR evaluated the residue studies. So in this case, it is necessary to submit the new residue studies and the latest GAP to the JMPR evaluation and new recommendation)

5.4.2. PHASE II - Status Report on Data Commitments and CCPR Follow-up (Year 2, CCPR meeting) 1. Status report on data commitments	C) CXLs that will be supported by current Good Agricultural Practices (GAPs) and (new) residue data (that is, CXLs not supported by the industry, even if the chemical is supported).	NOT ADDRESSED (It is important to clarify that there are two different situations: 1) No changes in good agricultural practices since the last time the JMPR evaluated the residue studies. So in this case, only the GAP should be submitted. It is not necessary to resubmit the same residue studies the JMPR has evaluated to maintain the (already existing) Codex MRLs. 2) There were some changes in good agricultural practices since the last time the JMPR evaluated the residue studies. So in this case, it is necessary to submit the new residue studies and the latest GAP to the JMPR evaluation and new recommendation)
5.4.2. PHASE II - Status Report on Data Commitments and CCPR Follow-up (Year 2, CCPR meeting) 2. Response to data commitments	I) Procedure for Case A (…) - Sufficient data are submitted to confirm the existing CXL; ~~and it remains in place;~~ it enters the process at Step 3	NOT ADDRESSED (The CXL already exist. It is already a Codex MRL. No changes)
5.4.2. PHASE II - Status Report on Data Commitments and CCPR Follow-up (Year 2, CCPR meeting) 2. Response to data commitments	I) Procedure for Case A (…) - Sufficient data are submitted to support a new proposed MRL, it enters the process at Step 3 and the existing CXL is deleted as soon as the new proposed MRL is adopted by CAC, at the latest automatically after no more than 4 years;	ADDRESSED *(Almost the same wording proposed. It is exactly what happen nowadays)*

5.4.2. PHASE II - Status Report on Data Commitments and CCPR Follow-up (Year 2, CCPR meeting) 2. Response to data commitments II) Procedure for Case B III) Procedure for Case C	(…) ~~Current~~ Good Agricultural Practices (GAPs) are submitted ~~to confirm the CXL which is therefore maintained;~~ – Residue studies (existing or new) ~~and most recent Good Agricultural Practices (GAPs)~~ are submitted to support a new MRL proposal. It enters the process at Step 3 and the existing CXL is deleted as soon as the new proposed MRL is adopted by CAC, at the latest it will be automatically deleted after no more than four years.	NOT ADDRESSED (It is important to clarify that there are two different situations: 1) No changes in good agricultural practices since the last time the JMPR evaluated the residue studies. So in this case, only the GAP should be submitted. It is not necessary to resubmit the same residue studies the JMPR has evaluated to maintain the (already existing) Codex MRLs. 2) There were some changes in good agricultural practices since the last time the JMPR evaluated the residue studies. So in this case, it is necessary to submit the new residue studies and the latest GAP to the JMPR evaluation and new recommendation)
5.4.2. PHASE II - Status Report on Data Commitments and CCPR Follow-up (Year 2, CCPR meeting) 2. Response to data commitments IV)	IV) In any of the three procedures (A, B and C) mentioned above, three scenarios may occur in case the data support the chemical (except procedure C): - the data confirm the existing Codex MRL, the confirmed CXL enter the system at Step 3; *Comments: Proposed change to be in line with three scenarios and chapter 5.4.3.*	NOT ADDRESSED (The CXL already exist. It is already a Codex MRL. No changes, so it is not necessary to enter the system at step 3)
5.4.2. PHASE II - Status Report on Data Commitments and CCPR Follow-up (Year 2, CCPR meeting) 2. Response to data commitments IV)	IV) (…) - 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 - the data submitted is insufficient to support the chemical or the existing CXL or the new MRL *Comments: Repetition of text above*	NOT ADDRESSED (It is a repetition, but the intention is to summarize all the situations above)

5.4.2. PHASE II - Status Report on Data Commitments and CCPR Follow-up (Year 2, CCPR meeting) 3. Insufficient information to support a CXL third paragraph)	~~During this period~~ if If an acute/chronic risk has been identified, on a scientific base, and presented by a member, the additional period to submit the dossier of required data will not be granted and the CXL should be proposed for deletion.	ADDRESSED

5. JAPAN

Reference in the document: "Draft text of the Risk Analysis Principles Applied by the CCPR regarding the Evaluation and Reevaluation Procedures"	Member´s Comment	Updated status and reference in the revised draft document
5.2. Preparation of Priority Lists (fifth paragraph)	The request for evaluation should indicate the current status of national registrations, accompany a clear indication of the availability of data and national evaluations, and give an indication of the number of crops and residue trials to be evaluated. For Periodic Re-evaluation, the request should also provide information on most recent evaluation, ADI and ARfD.	PARTIALLY ADDRESSED (See new language proposed by New Zealand)
5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR General Criteria 5.3.1. Criteria and procedures for proposing pesticides for Codex priority lists	Before a pesticide can be considered for the Priority List it: V. Must be registered for use in a member by the deadline of data submission for the evaluation of the toxicological and/or residues studies by the JMPR. VI. Must be available for use as a commercial product by the deadline of data submission for the evaluation of the toxicological and/or residues studies by the JMPR.	NOT ADDRESSED

5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR General Criteria 5.3.1. Criteria and procedures for proposing pesticides for Codex priority lists	General note: If use of the compound does not give rise to detectable residues in foods and feeds, except when some toxicological concerns are identified for the compound, it will be afforded a lower priority to those compounds that do give rise to measurable residues in foods or feeds.	NOT ADDRESSED (In the re-evaluations this is the first analyzed point.)
5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.3. New Chemicals	Comment of Japan The meaning of the term “agronomic variables” in paragraph e) should be clarified, because it is difficult to determine whether or not to include this paragraph without sufficient explanation. Then paragraph e) should be deleted unless this paragraph is proved to be one of the factors to determine if the proposed new chemical is a “safer” or “reduced risk” replacement chemical.	CLARIFICATION (The term "agronomic variables" is related to some characteristics of a country or a region: weather, soil type, pests and diseases pressure, among others.)
5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.5 Other evaluations	II. Commitment to provide the required data for review by the deadline of data submission for the evaluation of the toxicological and/or residues studies by the JMPR;	ADDRESSED
5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.5 Other evaluations	Japan eliminates item IX and its note “5.3.4. Periodic Re-Evaluation”, and at the same time incorporates in item III “5.3.5 Other evaluations”	NOT ADDRESSED (The four-year-rule is not applied only to others evaluations, but also in the periodic re-evaluation procedure, as mentioned in the Procedure Manual. Moreover, IX could be a relevant priority criterion for periodic re-evaluations, when, for example, JMPR has identified data gaps on a consumer’s health concern. So, it is necessary to prioritize the assessment of these data).

5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.5 Other evaluations	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: New toxicological data becomes available to indicate a significant change in the ADI or ARfD. In such a case the WHO Joint Secretary will schedule the request for the next JMPR	ADDRESSED
5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.5 Other evaluations	VII. A serious consumers' health concern may emerge in relation to a particular pesticide for which MRLs exist. In such cases members should notify the WHO Joint Secretary of the JMPR promptly and provide appropriate data. In such a case the WHO Joint Secretary will schedule the request for the next JMPR. The CCPR shall immediately start procedures to delete the existing MRLs without awaiting a result of the evaluation by JMPR.	NOT ADDRESSED (JMPR assessment shall be awaited)
5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.5 Other evaluations Paragraph IV, V, and VII under Note	The terms "the Joint Secretary of the JMPR" should be replaced with "the FAO Joint Secretary of the JMPR" or "the WHO Joint Secretary of the JMPR" where this term indicates either of the two secretaries.	ADDRESSED
5.4.1. PHASE I - Identify Periodic Review Chemicals and solicit data commitments (Year 1, CCPR meeting) 1. Listing Compounds for Periodic Re-evaluation	In the cases B) and C) suggested adding the following sentence at the end: If the submitted data are insufficient, the JMPR may request additional data on a case-by-case basis.	NOT ADDRESSED (The text suggested is included in the section 5.4.2 Phase II, 2)
5.4.1. PHASE I - Identify Periodic Review Chemicals and solicit data commitments (Year 1, CCPR meeting) 2. Commitment to Support Chemicals or existing Codex MRLs or new proposed MRL	Adds at the final of points II) In the case provided for in B y III) In the case provided for in C The following sentence: – Sufficient data for JMPR evaluation other than those mentioned above.	NOT ADDRESSED (Other data than those mentioned in section 5.4.1 may be requested by JMPR on a case-by-case basis, as mentioned in section 5.4.2)

5.4.2. PHASE II - Status Report on Data Commitments and CCPR Follow-up (Year 2, CCPR meeting) 2. Response to data commitments	II) Procedure for Case B (…) Note: If the submitted data are insufficient, the JMPR may request additional data on a case-by-case basis. III) Procedure for Case C (…) Note: If the submitted data are insufficient, the JMPR may request additional data on a case-by-case basis.	ADDRESSED
5.4.2. PHASE II - Status Report on Data Commitments and CCPR Follow-up (Year 2, CCPR meeting) 2. Response to data commitments Paragraph 3 and 4 of Section IV)	On being advised of the data inadequacy, manufacturers, members or observers may, by the next CCPR Meeting, provide to the JMPR and the CCPR Secretaries a written commitment to generate and submit a dossier of required data for review within 4 years, under the condition that no acute/chronic risks have been identified by the JMPR. During this period if an acute/chronic risk has been identified, on a scientific base, and presented by the JMPR, the additional period to submit the dossier of required data will not be granted and the CXL should be proposed for deletion.	ADDRESSED

6. NEW ZEALAND

Reference in the document: "Draft text of the Risk Analysis Principles Applied by the CCPR regarding the Evaluation and Reevaluation Procedures"	Member´s Comment	Updated status and reference in the revised draft document
5.2. PREPARATION OF CCPR PRIORITY LIST OF PESTICIDES (fifth paragraph)	In the fifth paragraph, it may read better if 'For new compound evaluation,' is deleted as information on the status of national registrations is required for all evaluation types.	ADDRESSED
5.2. PREPARATION OF CCPR PRIORITY LIST OF PESTICIDES (ninth paragraph)	To assist with flow, the Appendices should be listed as bullet points.	ADDRESSED
5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR General Criteria 5.3.1. Criteria and procedures for proposing pesticides for Codex priority lists	Under I and II, it may be appropriate to provide guidance on how this will operate in practice. This section describes the criteria to be used by CCPR for setting the priority for JMPR assessments. At the time a compound is proposed for inclusion on the Priority List, it may not yet be registered for use. While CCPR will have some information on when a national registration is expected, and can schedule the compounds accordingly, there have been several cases in the past where these anticipated registrations have been delayed and the JMPR assessments have been postponed. Therefore, it is suggested that an additional 'General note' be added to outline how CCPR will manage this situation.	NOT ADDRESSED The compound must be registered for use in a member, this is responsibility of the member

5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.3. New Chemicals and 5.3.4 Periodic Re-Evaluation and 5.3.5 Other evaluations	We consider the format of these sections needs some tidying up. In particular, some of the criteria suggested, in our view describe what the section is covering, rather than being priority criteria. For example, under section 5.3.4 criteria I to IV are outlining what a periodic re-evaluation covers and not priorities. The priority criteria are from V onwards. In section 5.3.5 the second points I to VII are in the main describing what is covered in this section. Therefore, for clarity purposes and to provide some consistency in these sections we propose that a definition or description of the activity under each heading is provided to explain what is covered in the section and this is followed by the criteria for priority. The following comments are made in light of the above comments.	NOT ADDRESSED
5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.3. New Chemicals	It is unclear what the criterion 'agronomic variables' in 1(e) means and therefore its relevancy.	NOT ADDRESSED (The term "agronomic variables" is related to some characteristics of a country or a region: weather, soil type, pests and diseases pressure, among others.)
5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.4 Periodic Re-Evaluation	We consider IX is not a relevant priority criterion for periodic re-evaluations. Data submitted under the four-year-rule would only occur once a Periodic Re-evaluation has been completed and JMPR has identified data gaps that need to be addressed. Prioritizing the assessment of these data is adequately covered in 5.3.5 (III).	NOT ADDRESSED (IX could be a relevant priority criterion for periodic re-evaluations, when, for example, JMPR has identified data gaps on a consumer's health concern. So, it is necessary to prioritize the assessment of these data)
5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.5 Other evaluations	Under III, the words 'for evaluations' are not necessary and can be deleted. We would also suggest that the explanatory note describing the four-year-rule, currently part of 5.3.4 (IX) be moved to this paragraph.	NOT ADDRESSED (See the above comment)

5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.5 Other evaluations	Bearing in mind our above comments, we consider VII is similar to I under Section 5.3.4. Hence we are unclear on the differentiation between the two situations. Specifically, where there is a toxicological concern what prompts a periodic re-evaluation of the compound compared to the compound falling into the other evaluation category.	ADDRESSED Point VII is deleted in Section 5.3.5.
5.4.1. PHASE I - Identify Periodic Review Chemicals and solicit data commitments (Year 1, CCPR meeting) 1. Listing Compounds for Periodic Re-evaluation	Under B) in the section 1, replace 'the' with 'a' before 'national monograph'.	ADDRESSED
5.4.1. PHASE I - Identify Periodic Review Chemicals and solicit data commitments (Year 1, CCPR meeting) 2. Commitment to Support Chemicals or existing Codex MRLs or new proposed MRL	Under Section 2, I) i) Amend 'a list' to read 'a draft list' (2 places). ii) Add 'at the time of notification and any potential new GAPs expected before the JMPR evaluation' after 'A brief summary of all Good Agricultural Practices (GAPs)'.	ADDRESSED

5.4.1. PHASE I - Identify Periodic Review Chemicals and solicit data commitments (Year 1, CCPR meeting) 1. Listing Compounds for Periodic Re-evaluation	Under Section 1, II) and III) add 'or anticipated' after 'current'.	NOT ADDRESSED (It is important to clarify that there are two different situations: 1) No changes in good agricultural practices since the last time the JMPR evaluated the residue studies. So in this case, only the current GAP should be submitted. It is not necessary to resubmit the same residue studies the JMPR has evaluated to maintain the (already existing) Codex MRLs. 2) There were some changes in good agricultural practices since the last time the JMPR evaluated the residue studies. So in this case, it is necessary to submit the new residue studies and the latest GAP to the JMPR evaluation and new recommendation)

5.4.2. PHASE II - Status Report on Data Commitments and CCPR Follow-up (Year 2, CCPR meeting) 2. Response to data commitments	This section, as drafted, seems to include a mixture of activities (e.g. data submission), outcomes (e.g. JMPR and CCPR decisions). For clarity, we would suggest that the section first identifies possible JMPR outcomes and then describes what procedures would be followed by CCPR. The following replacement text (mostly editorial changes) is suggested: "2. Response to data commitments I) Procedure for Case A: If a commitment is made to provide and identify or develop data to support the chemicals and existing CXLs, as foreseen in Case A), the complete data package will be scheduled for JMPR review. The JMPR review will result in one of the following scenarios: - Toxicological data (and other studies) are sufficient to support the chemical and it is therefore maintained (ADIs and/or ARfDs are reconfirmed, revised, or established); - Residue data, GAP information and other relevant studies are sufficient to confirm the existing CXL and it remains in place provided there are no dietary intake concerns; - Residue data, GAP information and other relevant studies are sufficient to support a new proposed MRL, it enters the process at Step 3 and if there are no dietary intake concerns, the new proposed MRL is advanced to step 8 with the subsequent deletion of the existing CXL; II) Procedure for Case B If commitments are made to provide, identify or develop data supporting the chemicals and existing CXLs, as foreseen in Case B), the JMPR review of the data will be scheduled. The JMPR review will result in one of the following scenarios: - A national monograph on toxicological data is sufficient to evaluate the chemical and to establish/revise/confirm ADIs and ARfDs; - Current Good Agricultural Practices (GAPs) are sufficient to confirm the CXL which is therefore maintained provided there are no dietary intake concerns; - Residue data and GAP information are sufficient to support a new MRL proposal. It enters the process at Step 3 and if there are no dietary intake concerns, the new proposed MRL is advanced to step 8 with the subsequent deletion of the existing CXL; III) Procedure for Case C If a commitment is made to provide and identify or develop data to support the CXLs, as provided for in Case C), the review of the new data or Good Agricultural Practices (GAPs) is scheduled for review by the JMPR. The JMPR review will result in one of the following scenarios: - Current Good Agricultural Practices (GAPs) are sufficient to confirm the CXL which is therefore maintained provided there are no dietary intake concerns; Residue data and GAP information are sufficient to support a new MRL proposal. It enters the process at Step 3 and provided there are no dietary intake concerns, the new proposed MRL is advanced to step 8 with the subsequent deletion of the existing CXL; Note: If the submitted data are insufficient, the JMPR may request additional data on a case-by-case basis."	NOT ADDRESSED While the comments are not against the proposal procedure, we consider that the procedures are clear to be followed by the CCPR, and are in line with the mandate of the 43th CCPR Report, specially para 131 and 132

5.4.2. PHASE II 2. Response to data commitments IV) (first paragraph)	Section 5.4.2, Part 2. paragraph IV: We consider this paragraph, identifying the four scenarios that might occur is a duplication of the information in previous sections and could be deleted.	NOT ADDRESSED (It is a repetition, but the intention is to summarize all the situations above)
5.4.2. PHASE II - Status Report on Data Commitments and CCPR Follow-up (Year 2, CCPR meeting) 2. Response to data commitments IV) (last five paragraphs)	Insufficient data to support CXLs section: The last five paragraphs of the text (page 9) outline the procedures to be followed if there are insufficient data to support the compound or existing CXLs, and in order to differentiate this information from the previous sections, we propose a new section heading for this text – possibly "5.4.3 Insufficient Information to Support a CXL'.	PARTIALLY ADDRESSED New section heading is included

7. THAILAND

Reference in the document: "Draft text of the Risk Analysis Principles Applied by the CCPR regarding the Evaluation and Reevaluation Procedures"	Member´s Comment	Updated status and reference in the revised draft document
5.4.2. PHASE II 2. Response to data commitments II) Procedure for case B III) Procedure for case C IV)	We wonder whether the Notes "If the submitted data is insufficient, the JMPR may request additional data on a case-by-case basis" in both subsections are repetition to the second paragraph of IV) started with "If insufficient data have been submitted..." If this is the case, we can delete both notes in II) and III) otherwise we need to clarify why the case-by-case basis are needed for II) and III).	CLARIFICATION (The note was included in both procedures (B and C), given that, in these cases the data submitted could be insufficient and thus the JMPR may request additional data on a case-by-case basis.)
5.4.2. PHASE II 3. Insufficient information to support a CXL (second paragraph)	We do not fully agree with the additional text to the last sentence of the 3rd para. The acute/chronic risks used to prevent the additional period for data submission must be raised by JMPR and not by an interested member. We can agree to have this text in but changing " by any interested member" to "by JMPR".	ADDRESSED

5.4.2. PHASE II 3. Insufficient information to support a CXL (third paragraph)	We also think that the 4th para is not needed and should be deleted since the last sentence of the 3rd para is sufficient. Also, since the scenario can be A, B or C, it is not always the case that the CXL have to be deleted. If this para is retained, we would suggest amending the last part to read " During this period if an acute/chronic risk has been identified by JMPR, the additional period to submit the dossier of required data will not be granted and the CXL with unacceptable risk should be proposed for deletion.	PARTIALLY ADDRESSED (A New redaction is proposed *If an unacceptable acute/chronic risk has been identified by the JMPR, on a scientific base, the additional period to submit the dossier of required data will not be granted and the CXL should be proposed for deletion.)*

8. UNITED STATES

Reference in the document: "Draft text of the Risk Analysis Principles Applied by the CCPR regarding the Evaluation and Reevaluation Procedures"	Member´s Comment	Updated status and reference in the revised draft document
5.2. PREPARATION OF CCPR PRIORITY LIST OF PESTICIDES (third paragraph)	The U.S. proposes to revise the first sentence in the third paragraph in section 5.2 to read: ~~Manufacturers and observers, when sending a request for evaluation to a nominating member should copy the request to the Chair of the EWG on Priorities and the JMPR Joint Secretariat.~~ Manufacturers and observers should send a request for evaluation to a nominating member. Members should send a request for evaluation to the Chair of the EWG on Priorities and the JMPR Joint Secretariat. Rationale: The U.S Delegations believes that it will be confusing to have manufacturers and observers copy their initial requests to the Chair of the EWG and the JMPR Joint Secretariat this early in the process. Once the U.S. Delegation receives such requests they work to determine if the required data are available for submission to the JMPR for review and whether it is appropriate for the U.S. Delegation to make such a nomination. Therefore it is possible that a request submitted to a Delegation may not be nominated for review by the JMPR.	NOT ADDRESSED (See the new language proposed in the Croplife comments section)

5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR Criteria for Prioritization 5.3.3. New Chemicals l) e)	The U.S. would like clarification as to what is meant by and the type of information that would need to be provided under section 5.3.3 l. e) regarding agronomic variables. Further clarification or a definition is needed for the term agronomic variables.	CLARIFICATION (The term "agronomic variables" is related to some characteristics of a country or a region: weather, soil type, pests and diseases pressure, among others.)

9. URUGUAY

Uruguay did not find objections and continues to support the work done.