CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 11

CX/PR 11/43/12
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

43rd Session
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REVISION OF THE RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES

(Prepared by Argentina)

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 1 March 2011.

INTRODUCTION

1. In conformance with the mandate[1] received from the 42nd Session of the Codex Committee on Pesticide Residues, 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 42nd 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 42nd Sessions[4] of the Codex Committee on Pesticide Residues. Reports of Codex committees' meetings are available for downloading at: http://www.codexalimentarius.net/.

SUMMARY OF THE WORK PERFORMED

3. In addressing the mandate, the EWG rearranged the document presented at the 42nd Session of the Committee, i.e. CX/PR 10/42/12, taking into account the comments made by the Codex Committee on General Principles as included in CL 2010/1-GP.

4. In addition, CX/PR 10/42/12 has been renumbered and a new table of contents has been drafted to clearly identify comments and observations.

5. In this regard, and to facilitate understanding of the new format, the previous numbering has been included between brackets, along with the new numbering. Part of the document has been considered and agreed during the 42nd Session, whereas some sections have remained unchanged, thus any of the following comments may also appear between brackets: "agreed 2010" or "original" (original text of Procedural Manual, 17th Edition) when the text has been dealt with; or "pending" to indicate the situation of each particular section and avoid considering issues already agreed upon.

6. This year there was not enough time to circulate the document and complete two rounds of comments from member countries, since deadline for submitting conclusions has been brought forward from January 2011 to November 2010. However, to limit disagreements to the utmost, the position adopted by some countries or regions were assessed and were included as defined issues, such as the comment made by the European Union stating that EU accepted renewal of a CXL for a new period subject to certain conditions. These conditions have been included in the general text for renewal of CXL.

7. For Phase I and Phase II, a new alternative which is mid-way between the two pre-existing ones was included and identified as First Alternative Proposal.

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1 ALINORM 10/33/24 paras. 150-152.
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 and ALINORM 10/33/24 paras. 139-152.

8. This proposal includes the comments from the European Union mentioned above, the adjustments and improvements to the two existing possibilities, especially taking into consideration the requests made by Brazil, China and Thailand, among others, fulfilling the commitment to submit alternatives for the most important issues for which consensus must be reached and identified at 42nd Session of the CCPR.

9. Some proposals analyzed by the members of the EWG (in a box) are included.

I) Two proposals from India are included in sections 5.4.1 and 6.4.

II) A proposal made by Brazil as alternative to India's proposal is included in section 5.4.1.

III) At the request of some member countries the "Form for expressing concerns" has been rearranged, without content modification.

IV) Two possible alternatives on non-agreed issues are included.

a) One alternative is section 5.5.1 (Phase I) which keeps the content and layout for Phases I and II. This alternative facilitates impugnation of MRL that are not safe for consumers; allowing their deletion where applicable. This alternative has the advantage of not breaching Codex general system. In addition, maintaining unchallenged CXL for a new period is only approved when it is requested by Codex members and specific conditions are met.

The need of not breaching Codex general system refers, particularly, to:

Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, paras. 4 – 9 – 10 – 20 – 34 to 36, Procedural Manual 17th Edition (pages 112, 113, 114, 116 and 117).

Statements of Principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into consideration (para. 1) and *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle* (paras. 1 and 3), Procedural Manual 17th Edition (pages 194 and 195).

Statements of Principle Relating to the Role of Food Safety Risk Assessment (para. 2), Procedural Manual 17th Edition (page 196).

b) The other alternative fully replaces the contents of Phases I and II of CX/PR 10/42/12.

This second alternative does not observe principles of Codex general system.

However, it provides the possibility that the limit is maintained or renewed by submitting labels, prior JMPR approval of label adequacy.

SUMMARY OF COMMENTS FROM THE MEMBERS OF THE EWG

10. The members that submitted observations to the working document are as follows: Argentina, Australia, Brazil, Canada, China, Costa Rica, Haiti, Japan, Switzerland and Thailand.

11. In the section, it is defined as "original proposal" the original text of the Periodic Review Procedure with the amendments proposed, which now appear in the First Alternative proposal.

Argentina

12. In general, Argentina agrees with the document submitted by the Chair, in particular regarding not withdrawing MRLs unless for science-based reasons. Argentina supports the inclusion of India's Proposal for section 5.4.1 regarding economic aspects of new products and also supports the alternative proposal included in section 5.5.1 (7.1.2) [original proposal]. Argentina disagrees with the second Alternative Proposal.

Australia

13. Australia firmly supports the position expressed at the 42nd Session of the CCPR whereby re-evaluation of CXLs should take into account whether toxicologically they do not cause any health concern (by JMPR), the estimated dietary exposure is below the ADI and ARfD, and that relevant GAP evidence for the CXLs is submitted.

14. Australia does not support the proposal under section 5.4.1 on economic aspects of new products and considers that the EWG should first prepare a draft that faithfully describes the current Periodic Review Procedure.

15. Australia also comments on topics not addressed and which should not be opened for discussion.

Brazil

16. Brazil continued with the work carried out by the Chair of the EWG and agrees with the original proposal made by the EWG for the Periodic Review Procedure.

17. Brazil agrees with the comments made by India regarding section 5.4.1 but suggests an alternative wording for point e (see Annex).

Canada

18. Canada supports the original proposal for Periodic Review Procedure because it offers greater transparency to the suggested guidelines and does not support including India's proposal for section 5.4.1 regarding economic aspects of new products.

China

19. China recommends the second (2) alternative proposal for the Periodic Review Procedure and suggests changes to improve its contents. It agrees with the opinion that MRLs should be maintained unless there is a reason to withdraw them and on maintaining the Periodic Review Procedure.

20. China supports India's proposal for section 6.4.2 (8.6.2) regarding EMRLs for persistent products for a limited period of time.

21. In addition, China presents a number of suggestions regarding formal aspects and minor amendments.

Costa Rica:

22. In general, Costa Rica agrees with the document submitted by the Chair.

23. Costa Rica supports including India's proposal for section 5.4.1 on economic aspects of new products. In section 5.5.1, it supports including the alternative proposal in 7.1.2 [original proposal]. In section 6.4.2, it supports India's proposal on EMRLs for persistent products for a specific period of time with an evaluation by JMPR.

24. Costa Rica also proposes minor changes such as deletion of the note in section 5.4.1.

Haiti

25. Haiti supports the document submitted by the Chair. Regarding section 5.4.1, it considers that, in the case of new chemicals, secondary effects should be taken into account. Regarding the first alternative proposal, it suggests consideration be given to the effects of the new products on the environment.

Japan

26. Japan agrees with the structure of the current document, following the general principles of Codex.

27. As regards the Periodic Review Procedure, Japan suggests that CCPR should consider changing the MRLs as the GAPs evolve; MRLs for substances of animal origin according to OECD; CCPR should request JMPR for the ARfDs for the MRLs assessed in the mid 1990's. For these reasons, it supports the second alternative proposal which allows a scientific review of the MRLs. If the alternative proposal is accepted a new rule replacing the four (4)-year rule should be established.

28. Japan also makes suggestions regarding formal aspects and presents minor amendments for consideration.

Switzerland

29. Switzerland supports the second alternative proposal regarding the Periodic Review Procedure for CXLs with amendments (sections 5.5.1 and 5.5.2) which imply a system that is very similar to the one being modified. It includes in the four (4)-year rule the wording: "maintaining the CXL when there is a commitment to generate new information".

Thailand

30. Thailand prefers the second alternative proposal regarding the MRL Periodic Review Procedure. It suggests including additional text for the data requirements and an explanation of how JMPR would analyze the information provided by the countries.

31. Thailand also includes comments on the consistency of the GAPs provided by the countries with the GAP data and tests previously used to recommend the CXLs.

DOCUMENTS USED

32. Below are the Codex documents considered in undertaking the task:

- Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius (Codex Alimentarius Commission Procedural Manual).
- Risk Analysis Principles Applied by the CCPR (Codex Alimentarius Commission Procedural Manual).
- Criteria for the Prioritization Process of Compounds for Evaluation by JMPR (Codex Alimentarius Commission Procedural Manual).
- MRL Periodic Review Procedure (Codex Alimentarius Commission Procedural Manual).
- ALINORM 06/29/24 Appendix X Form for Guidance for Expressing concern on the Advancement of an MRL or Request for Clarification (38th CCPR 2006).
- ALINORM 08/30/33 24th CCGP (2007).
- ALINORM 07/30/24 39th CCPR (2007).

- ALINORM 07/30/REP 30th CAC (2007).
- ALINORM 08/31/24 40th CCPR (2008).
- ALINORM 08/31/REP 31th CAC (2008).
- ALINORM 09/32/24 41st CCPR (2009).
- ALINORM 09/32/REP 32th CAC (2009).
- CX/PR 07/39/10 Discussion Paper about Enforcement of Codex MRLs (The Netherlands) 39th CCPR (2007).
- CX/PR 08/40/6 Discussion Paper on the Procedures for Separation Milk Fat from Whole Milk (IAEA) 40th CCPR (2008).
- CX/PR 08/40/7 Discussion Paper on the Consideration of the MRLs Periodic Review Procedure (Codex Secretariat) 40th CCPR (2008).
- CX/PR 08/40/11 Milk and Milk Fat Maximum Residue Limits (Australia) 40th CCPR (2008).
- CX/PR 08/40/13 Achieving Globally Harmonized MRLs through Codex (USA) 40th CCPR (2008).
- CRD 6 (Malaysia) 24th CCGP (2007).
- CRD 16 Proposal on MRLs in No Residue Situations - Proposal to Amend the Criteria for Nominations (USA) 39th CCPR (2007).
- CRD 25 Establishment of Codex Priority Lists of Pesticides (USA) 39th CCPR (2007).
- CRD9 (Chile) 40th CCPR (2008).
- CRD11 (Argentina) 40th CCPR (2008).
- CRD17 (Argentina) 40th CCPR (2008).
- CRD17 (Japan) 41st CCPR (2009).
- CRD19 (China) 41st CCPR (2009).
- CRD 20 (India) 42nd CCPR (2010).

ANNEX

RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES

CONTENTS

1. SCOPE

[agreed 2010 - 1.1] This document addresses the respective applications of risk analysis principles by the Codex Committee on Pesticide Residues (CCPR) as the risk management body and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) as the risk assessment body and facilitates the uniform application of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. This document should be read in conjunction with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

2. GENERAL ASPECTS

[agreed 2010] SUMMARY OF THE MRL-SETTING PROCESS

MRLs of pesticides in food and feed are based on GAP, taking into consideration information on dietary intakes.

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

[agreed 2010 - 4.1] In addressing pesticide residue issues in Codex, providing advice and taking decisions on risk management is the responsibility of the Codex Alimentarius Commission (CAC) and CCPR, [pending, original from the Procedural Manual - 8.1.1] setting maximum residue limits (LMR) of pesticide residues in food and feed; while conducting risk assessment is the responsibility of JMPR.

[agreed 2010 - 4.4] CCPR and JMPR must ensure that their respective contributions to the risk analysis process result in outputs that are scientifically based, fully transparent, thoroughly documented and available in a timely manner to members[5].

3. RISK ASSESSMENT POLICY

[agreed 2010 - 2.8] CCPR shall consider the following when preparing its priority list of compounds for JMPR evaluation:

- CCPR's Terms of Reference;
- JMPR's Terms of Reference;
- The Codex Alimentarius Commission's Strategic Plan;
- The Criteria for the Establishment of Work Priorities;
- The Criteria and Procedures for Proposing Pesticides for Codex Priority Lists;
- The Criteria for Selecting Food Commodities for which Codex MRLs or Extraneous Maximum Residue Limits (EMRLs) should be Established;
- The Criteria for Evaluation of New Chemicals;
- The Criteria for the Prioritization Process of Compounds for Evaluation by JMPR;
- A commitment to provide the necessary data for the evaluation in time.

[agreed 2010 - 2.9] When referring substances to JMPR, the CCPR shall provide background information and clearly specify the reasons for the request when chemicals are nominated for evaluation.

[agreed 2010 - 2.10] When referring substances to JMPR, the CCPR may also refer a range of risk management options, with a view toward obtaining JMPR's guidance on the attendant risks and the likely risk reductions associated with each option.

[agreed 2010 - 2.11] CCPR shall request JMPR to review any methods and guidelines being considered by CCPR for assessing maximum limits for pesticides [agreed 2010 - 2.2] considering, where appropriate, other legitimate factors that[6] are relevant such as health protection of consumers and/or promotion of fair practices in food trade.

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5 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.

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.

[agreed 2010 - 2.7] When establishing its standards, CCPR shall clearly state when it applies any considerations based on other legitimate factors in addition to JMPR's risk assessment and recommended maximum residue levels and specify its reasons for doing so.

[agreed 2010 - 3.4] JMPR applies a transparent, science based risk assessment process for establishing Acceptable Daily Intakes (ADIs) and Acute Reference Doses (ARfDs) where appropriate.

[agreed 2010 - 4.5] JMPR, in consultation with CCPR, must continue to explore developing minimum data requirements necessary for JMPR to perform risk assessments.

[agreed 2010 - 4.6] These requirements must be used by CCPR as a fundamental criterion in preparing its Priority List for JMPR. The JMPR Secretariat shall consider whether these minimum data requirements have been met when preparing the provisional agenda for meetings of JMPR.

3.1 MRLs FOR SPECIFIC COMMODITIES GROUP

3.1.1 (8.2.1) MRLs for Commodities of Animal Origin

[original - 8.2.1.1] Farm animal metabolism studies are required whenever a pesticide is applied directly to livestock, to animal premises or housing, or when significant residues remain in crops or commodities used in animal feed, in forage crops, or in plant parts that could be used in animal feeds. The results of farm animal feeding studies and residues in animal feed serve also as a primary source of information for estimating maximum residue levels in animal products.

[original - 8.2.1.2] If no adequate studies are available, no MRLs will be established for commodities of animal origin. MRLs for feeds (and the primary crops) should not be established in the absence of animal transfer data. Where the exposure of livestock to pesticides through feeds leads to residues at the limit of quantitation (LOQ), MRLs at the LOQ must be established for animal commodities. MRLs should be established for all mammalian species where pesticides on feeds are concerned and for specific species (e.g cattle, sheep) where direct treatments of pesticides are concerned.

[original - 8.2.1.3] Where the recommended maximum residue limits for animal commodities resulting from direct treatment of the animal, regardless of whether they are recommended by JMPR or JECFA, and from residues in animal feed do not agree, the higher recommendation will prevail as long this MRL is acceptable for all consumers groups.

[original - 8.2.3] 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 (8.2.4) MRLs for Fat-soluble Pesticides

[original 8.2.4.1] If a pesticide is determined as "fat soluble" after consideration of the following factors, it is indicated with the text "The residues are fat soluble" in the residue definition:

- When available, information concerning the partitioning of the residue (as defined) in muscle versus fat in the metabolism studies and livestock feeding studies that determines the designation of a residue as being "fat soluble";
- In the absence of useful information on the distribution of residues in muscle and fat, residues with log Pow > 3 are likely to be "fat soluble";
- [agreed 2008/ 2009 - 8.2.4.2] For fat-soluble pesticides analysis in milk, due to control and regulatory reasons, analysis of whole milk is recommended in all cases, comparing results obtained with MRL determined for whole milk.

[agreed 2009 - 8.2.2] 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 MRLs for processed commodities.

The Committee agrees to:

- [agreed 2009 - 8.2.2.1] establish MRLs for important processed commodities;
- [agreed 2009 -8.2.2.2] recommend MRLs for processed commodities only where there is a significant increase in residue from the raw agricultural commodity (RAC) to the processed commodity (PF > 1.3) and/or where the calculated processed commodities MRL is less than the MRL of the corresponding RAC;
- [agreed 2009 - 8.2.2.3] continue the practice of recommending MRLs for processed commodities where, due to the nature of the residues during some specific process, significant amounts of other relevant metabolites appear or increase; and
- [agreed 2009 - 8.2.2.4] 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.

3.1.5 (8.3) Establishment of EMRLs

[original - 8.3.1] The Extraneous Maximum Residue Limit (EMRL) refers to a pesticide residue or a contaminant arising from environmental sources (including former agricultural uses) other than the use of the pesticide or contaminant substance directly or indirectly on the commodity. It is the maximum concentration of a pesticide residue that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food, agricultural commodity or animal feed.

[original - 8.3.2] Chemicals for which EMRLs are most likely to be needed are persistent in the environment for a relatively long period after uses have been discontinued and are expected to occur in foods or feeds at levels of sufficient concern to warrant monitoring.

[original - 8.3.3] All relevant and geographically representative monitoring data (including nil-residue results) are required to make reasonable estimates to cover international trade. JMPR has developed a standard format for reporting pesticide residues monitoring data[7].

[original - 8.3.4] The JMPR compares data distribution in terms of the likely percentages of violations that might occur if a given EMRL is proposed to the CCPR.

[original - 8.3.5] 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 (3.) Role of JMPR

[agreed 2010 - 3.1] The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) consists of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. It is an independent scientific expert body convened by both Directors General of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on pesticide residues.

[agreed 2010 - 3.2] This guidance document applies to the work of JMPR in the context of Codex and in particular as it relates to advice requests from CCPR.

[agreed 2010 - 3.3] JMPR is primarily responsible for performing the risk assessments and proposing MRLs upon which CCPR and ultimately the CAC base their risk management decisions. JMPR also proposes MRLs based on Good Agricultural Practices (GAPs)/ registered uses or in specific cases, such as EMRLs, and MRLs for spices based on monitoring data.

[agreed 2010 - 3.4] JMPR provides CCPR with science-based risk assessments that include the four components of risk assessment as defined by CAC, namely hazard identification, hazard characterization, exposure assessment and risk characterization, and safety assessments that can serve as the basis for CCPR's risk-management discussions.

[agreed 2010 - 3.5] JMPR shall identify and communicate to CCPR in its assessments any information on the applicability and any constraints of the risk assessment in regard to the general population and to particular sub-populations and shall, as far as possible, identify potential risks to populations of potentially enhanced vulnerability (e.g. children).

[agreed 2010 - 3.7] JMPR communicates to CCPR the magnitude and source of uncertainties in its risk assessments. When communicating this information, JMPR provides CCPR a description of the methodology and procedures by which JMPR estimated any uncertainty in its risk assessment.

4.2 Dietary Intake

[original - 3.6] JMPR is responsible for evaluating exposure to pesticides. JMPR must strive to base its exposure assessment and hence the dietary risk assessments on global data, including that from developing countries. In addition to GEMS/Food data, monitoring data and exposure studies may be used. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the available high percentile consumption data as provided by members and compiled by GEMS/Food.

[original - 8.1.1] In undertaking dietary exposure risk assessments to assist the CCPR, the JMPR uses the WHO Guidelines for predicting dietary intake of pesticides residues[8]. The JMPR is recommending MRLs establishing Supervised Trial Median Residues (STMRs) for new and periodic review compounds for dietary intake purposes. In cases the intake exceeds the Acceptable Daily Intake (ADI) in one or more of the thirteen GEMs/Food Compsumption cluster diets, the JMPR, when recommending MRLs, flags this situation indicating the type of data which may be useful to further refine the dietary intake estimate.

[original - 8.1.2] When the ADI is exceeded in one or more regional diets, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level. If further refinement is not possible then MRLs are withdrawn until the remaining MRLs give no longer rise to intake concerns.

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7 Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant protection and Protection Paper, 170, 2002, ISBN 92-5-104759-6.

8 Programme of Food Safety and Food Aid, World Health Organization, WHO/FSF/FOS/97.7.

[pending - 8.1.3] The JMPR is currently routinely establishing acute reference doses (ARfDs), where appropriate, and indicates cases where an ARfD is not necessary. The 1999 JMPR for the first time calculated the short-term dietary intake estimates following an approach using the International and National Estimates of Short-term Intake (IESTI, NESTI). The procedure allows for estimating the short-term risk for relevant subgroups of the population, like children. The JMPR flags cases when the IESTI for a given commodity exceeds the acute RfD.

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

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

[pending - 8.1.4] Under the "retrospective" procedure, when a Draft MRL has been returned to Step 6 three times, the CCPR should ask JMPR to examine residue data from other appropriate GAPs and to recommend MRLs which cause no dietary intake concerns, if possible.

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

[original - 8.1.6] The estimate of the short-term dietary intake requires substantial food consumption data that currently are only sparsely available. Governments are urged to generate relevant consumption data and to submit these data to the WHO.

[original - 8.7.1] JMPR needs data and information for their evaluations. Among these are methods of analysis. Methods should include specialized methods used in supervised trials and enforcement methods.

4.3 GOOD AGRICULTURAL PRACTICES

[pending – original from the Procedural Manual] Good agricultural practices (GAP) in the use of pesticides translate into a series of conditions to be observed when applying these products, which must be authorised and assessed at national level to allow effective pest control. The range of authorised product dose must be such that a higher pesticide concentration applied in the crop or product/pest ratio delivers lower residue concentration at the time the crop is available for human or animal consumption, without posing a risk.

5. RISK MANAGMENT

5.1 (2.) ROLE OF CCPR

[agreed 2010 - 2.1] CCPR is primarily responsible for recommending risk management proposals, such as MRLs, for adoption by the CAC.

[agreed 2010 - 2.2] CCPR shall base its risk management recommendations to the CAC on JMPR's risk assessments of the respective pesticides.

[agreed 2010 - 2.3] In cases where JMPR has performed a risk assessment and CCPR or the CAC determines that additional scientific guidance is necessary, CCPR or CAC may make a specific request to JMPR to provide further scientific guidance necessary for a risk management decision.

[agreed 2010 - 2.4] CCPR's risk management recommendations to the CAC shall take into account the relevant uncertainties as described by JMPR.

[agreed 2010 - 2.5] CCPR shall consider maximum residue limits (MRLs) only for those pesticides for which JMPR has completed an appropriate safety evaluation.

[agreed 2010 - 2.6] CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns on a global scale when recommending MRLs in food. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by members and compiled by GEMS/Food.

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

5.2 PROCEDURE TO ESTABLISH PRIORITY LISTS

[agreed 2010 - 5.1] 5.2.1 Identification of Candidate Chemicals for Re-evaluation

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

- pesticide chemicals for which MRLs were first estimated more than 15 years ago; or
- pesticide chemicals for which a periodic review was conducted more than 15 years ago.

Tentative lists for several years may be prepared when feasible.

[agreed 2010 - 5.2] 5.2.2 Preparation of Priority Lists

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

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

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

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

The Chair of the EWG on Priorities will prepare a circular letter including a draft paper on "Establishment of Codex Priority List of Pesticides" by 21 December.

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

On the basis of comments to the circular letter received, the Chair of the EWG on Priorities will prepare a draft CCPR agenda paper that will include Codex Priority Lists of Pesticides and submit to Codex Secretariat.

The Codex Priority Lists of Pesticides will comprise four appendices: Appendix 1 – Codex Priority List of Pesticides, Appendix 2 - Periodic Re-evaluations (summarized in 3 lists)[9], Appendix 3: Chemical-commodity combinations for which specific GAP is no longer supported and Appendix 4: Chemicals with extraneous MRLs and recent deletions.

[agreed 2010 - 6] 5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR

[agreed 2010 - 6.1] 5.3.1 General Criteria

[agreed 2010 - 6.1.1] Criteria and Procedures for proposing Pesticides for Codex Priority Lists

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

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

- [agreed 2010 - 6.1.1.1] must be registered for use in a member country; or be expected to be registered in a member country by the time the MRLs are considered at the JMPR;
- [agreed 2010 - 6.1.1.2] must be available for use as a commercial product; or be expected to be registered for use as a commercial product by the time the MRLs are considered at the JMPR;
- [agreed 2010 - 6.1.1.3] must not have been already accepted for consideration;
- [agreed 2010 - 6.1.1.4] must, in general, give rise to residues in or on a food or feed commodity moving in international trade, the presence of which is (or may be) a matter of public health concern and thus create (or have the potential to create) problems in international trade; however, a pesticide can also be considered if it may give rise to residues that are not detectable (if it is deemed appropriate to establish Codex standards which demonstrate that no residues are expected to avoid the potential for creating problems in international trade as the result of the lack of a standard) (6.2.1.6) If use of the compound does not give rise to detectable residues in foods and feeds, in which case it will be afforded a lower priority to those compounds that do give rise to measurable residues in foods or feeds.

[agreed 2010 - 6.1.2] 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.

[agreed 2010 - 6.2] 5.4 SPECIFIC CRITERIA AND PROCEDURES FOR NEW EVALUATION OR PERIODIC RE-EVALUATION

[pending - 6.2.1] 5.4.1 New chemicals

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

9 In case any of the alternatives for re-evaluation proceedings is approved, four lists must be issued.

– [agreed up to point d - 6.2.1.1] If the chemical has a reduced acute and/or chronic toxicity risk to humans compared with other chemicals in its classification (insecticide, fungicide, herbicide, etc);

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

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

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

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

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

e. [pending] *take into account the economic aspects* ***

**Proposal from India*

… including comparative cost economics for use of proposed chemical and the other chemicals in its classification for which the proposed chemical is likely to be an alternative.

*** Brazil proposal*

e) Once other aspects have been addressed, consideration must be given to economic and agronomic variables of the chemicals.

– [agreed 2010 - 6.2.1.2] The date when the chemical was nominated for evaluation;

– [agreed 2010 - 6.2.1.3] Commitment by the sponsor of the compound to provide supporting data for review with a firm date for data submission;

– [agreed 2010 - 6.2.1.4] The availability of regional/national reviews and risk assessments, and coordination with other regional/national lists;

– [agreed 2010 - 6.2.1.5] Allocating priorities to new chemicals, so that at least 50% of evaluations are for new chemicals, if possible;

– [agreed 2010 - 6.2.1.6] If use of the compound does not give rise to detectable residues in foods and feeds, in which case it will be afforded a lower priority to those compounds that do give rise to measurable residues in foods or feeds.

5.4.2 (6.2.2) Periodic Re-evaluation

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

– [agreed 2010 - 6.2.2.1] If the intake and/or toxicity profile indicates, through scientific and/or technical data, some level of public health concern;

– [original - 6.2.2.2] Chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits for 15 years;

– [original - 6.2.2.3] Whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;

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

– [original - 6.2.2.5] The date that data will be submitted;

– [original - 6.2.2.6] If there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently;

– [original - 6.2.2.7] The availability of current labels arising from recent national re-evaluations;

– [original - 6.2.2.8] Whether the data is submitted under the 4-year rule for evaluations.

[original - 6.2.3] 5.4.3 Other Criteria for Evaluations

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

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

[original - 6.2.3.2] The JMPR may note a data deficiency in a Periodic Re-evaluation or New Chemical evaluation. In response, national governments or other interested parties may pledge to supply the information to the appropriate Joint Secretary of the JMPR with a copy for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data should be submitted subsequently to the appropriate Joint Secretary of the JMPR.

[agreed 2008/2009 - 6.2.3.3] Where new scientific data becomes available to support a change in MRLs, the CCPR may place a chemical under the re-evaluations procedure.

[original - 6.2.3.4] A government member may seek to expand the use of an existing Codex chemical: that is, obtain MRLs for one or more new commodities where some MRLs already exist for other commodities. Such requests should be directed to the FAO Joint Secretary of the JMPR and submitted for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.

[original - 6.2.3.5] A government member may seek to review a MRL due to a change in GAP. For example a new GAP may necessitate a larger MRL. In this case the request shall be made to the FAO Joint Secretary with a copy for consideration by the Committee. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.

[original - 6.2.3.6] The CCPR may request a clarification or reconsideration of a recommendation from the JMPR. In such cases the relevant Joint Secretary will schedule the request for the next JMPR.

[original - 6.2.3.7] A serious public health concern may emerge in relation to a particular pesticide for which MRLs exist. In such cases government members should notify the WHO Joint Secretary of the JMPR promptly and provide appropriate data to the WHO Joint Secretary.

5.5 (7.) MRLs PERIODIC REVIEW PROCEDURE

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

[pending completely] 5.5.1 (7.1) Phase I

Identify Periodic Review Chemicals and Solicit Data Commitments

(Year 1, CCPR Meeting)

Invitation and Notification to Support or Challenge MRLs

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

(7.1.1) Notify Data Owners or Other Parties of Candidate List

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

(7.1.2) Invite Commitment to Challenge or Support Continued (or New) Codex Maximum Residue Limits (CXLs)

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

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

- Chair, CCPR;
- Chair, Priorities Working Group;
- JMPR Secretariats;
- The requester (government or international organization representative) (Names, titles and addresses will be provided).

The following information must be provided in the response:

A. When CXL of a product is challenged, inform whether:

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

   b. The challenge is based on the product posing a risk to public health.

      In that case, interested parties are required to submit a preliminary risk profile.

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

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

(7.1.3) Repeat the Notification and Invitation

By means of a Codex Circular Letter to accompany the report of the Meeting the Secretariat will repeat the notification and request. On receipt of the request by the Circular Letter, governments and international organizations will immediately repeat their notification and invitation to identified interested parties who may not have been represented at the CCPR (they would not have received the report of the Meeting and the accompanying Circular Letter). Interested parties need only respond to one of the request, but should copy addresses listed in section 7.1.2 above.

5.5.2 (7.2) Phase II

Status Report on Data Commitments and CCPR Follow-up

(Year 2, CCPR Meeting)

(7.2.1) Status Report on Data Commitments

The Priorities Working Group will provide a report and room document to the CCPR on the status of commitments received to provide data for each compound identified in year 1.

– A list of not challenged CXL;

– A list of challenged CXL with a list of governments and international organizations interested in support them;

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

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

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

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

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

Dissent: (*) Croplife

(7.2.2) Response to data commitments

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

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

    – Delete current CXL that have been challenged;

    – Modify challenged CXL, starting the new proposal at Step 3;

    – Maintain current CXL.

b. Insufficient data have been submitted to challenge or to support a new MRL or to confirm the existing CXL, data submitters are so advised by written notification from the FAO Joint Secretary and/or by issuance of the JMPR Report. On being advised of the data inadequacy, data submitters may by the next CCPR Meeting, provide to the FAO and the CCPR Secretaries a written commitment to generate and submit a dossier of required data for review within 4 years.

    – If there is a commitment to provide new data, the CXL is maintained for no more than 4 years following advice of data inadequacy (by direct notification or by issuance of the JMPR Report). The 4 year period may be extended by the CCPR only to the extent necessary for the JMPR to schedule and complete review of the available new data. The new data are scheduled for the second JMPR review and the first part of the PHASE II procedure is repeated;

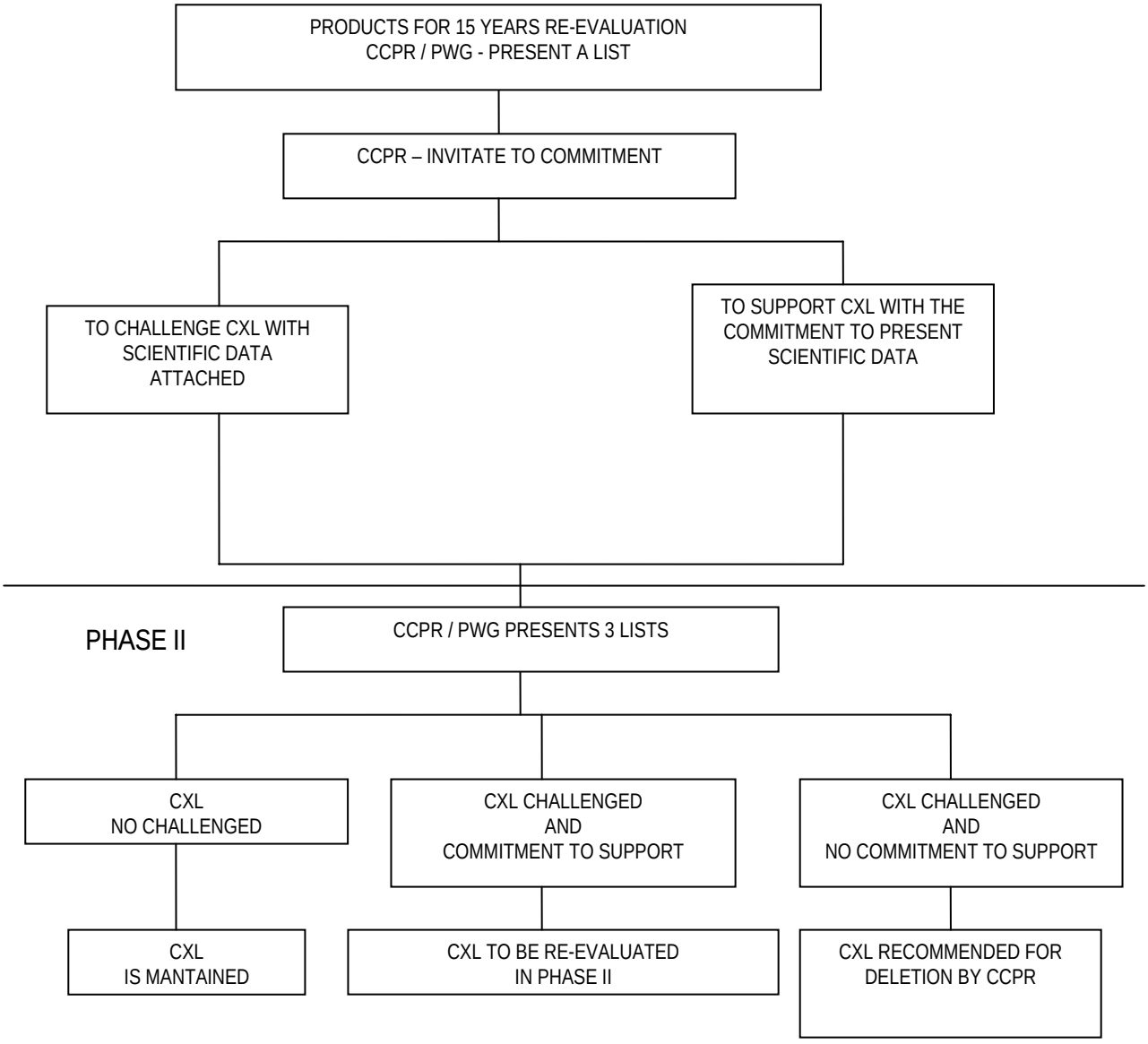
    – If there is not commitment to provide new data for challenging MRLs, the CCPR will recommend to mantain the CXL;

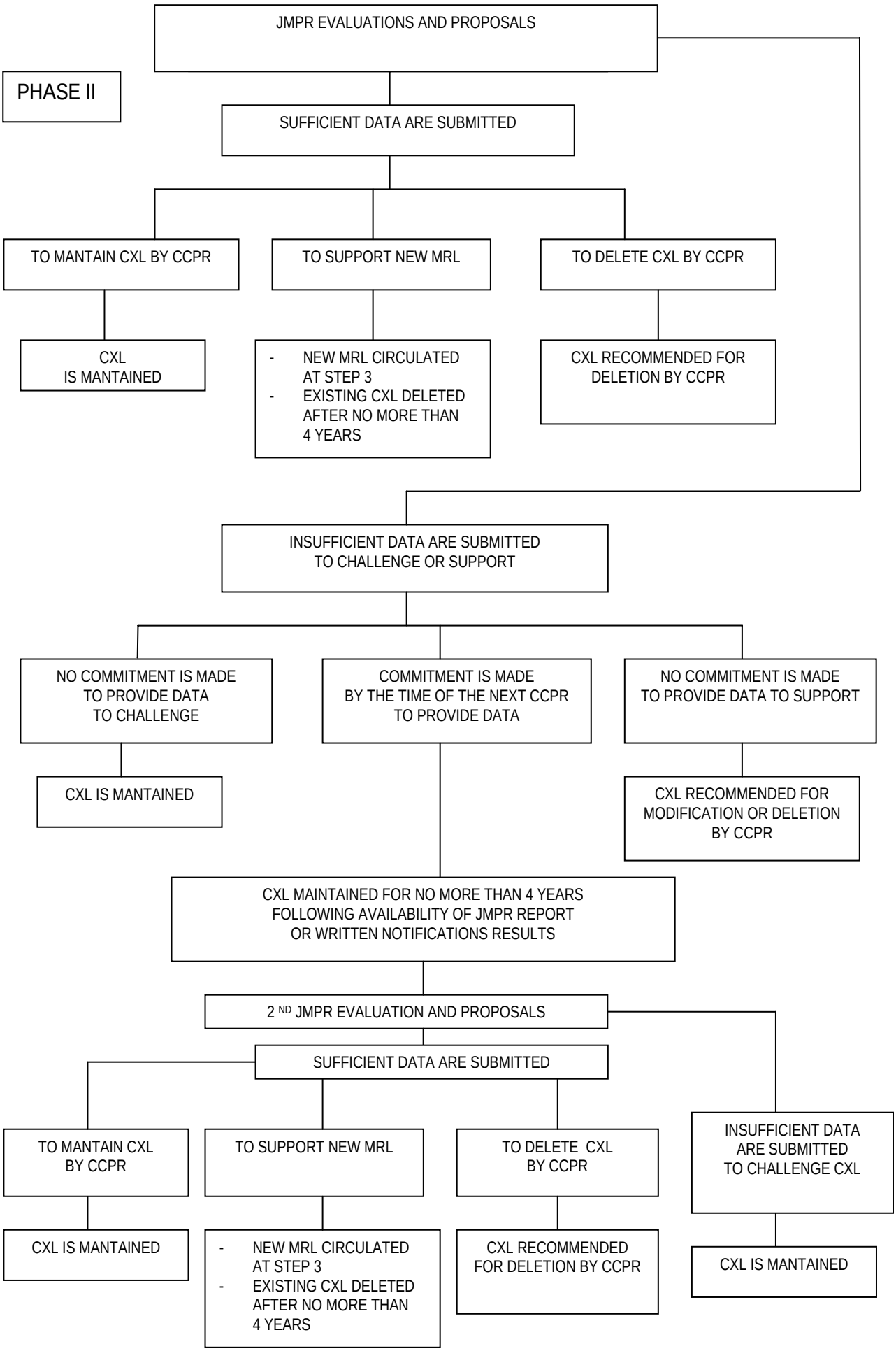
    – If there is not commitment to provide new data for supporting MRLs, with an adequate challenge defined by the JMPR, the CCPR will recommend to modify or delete the CXL;

    – If insufficient information are submitted to challenge MRLs, the CCPR will recommend to mantain the CXL.

5.3.3 (7.3) Summary of reevaluation procedure for Codex MRLs

PHASE I




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

FIRST ALTERNATIVE PROPOSAL MRLs PERIODIC REVIEW PROCEDURE

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

5.5.1 (7.1) Phase I

Identify Periodic Review Chemicals and Solicit Data Commitments

(Year 1, CCPR Meeting)

Invitation and notification to support or challenge MRLs

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

(7.1.1) Notify Data Owners or Other Parties of Candidate List

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

(7.1.2) Invite Commitment to Challenge or Support Continued (or New) Codex Maximum Residue Limits (CXLs)

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

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

- Chair, CCPR;
- Chair, Priorities Working Group;
- JMPR Secretariats;
- The requester (government or international organization representative) (Names, titles and addresses will be provided).

The following information must be provided in the response:

A. When CXL of a product is challenged, inform whether:

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

   b. The challenge is based on the product posing a risk to public health. CXL shall not be maintained when posing a risk to human health.

The public health may be affected when:

The estimation of the intake, with base in the Codex criteria, exceed the ADI and ARfD with a non acceptable effect in the risk analysis; and

I. the definition of residue of Active by Codex has been modified, and the data of the studies does not reflect this new definition; or

II. the dietary risk assessment is not updated according to changes in the thirteen GEMS/Food Consumption cluster diets.

In that case, interested parties are required to submit data in support.

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

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

C. In case of maintaining a CXL for a given unchallenged product, interested members need only to notify their intention to do so, provided the product poses no risk to human health (see 7.1.2 A) b) – of this alternative proposal), or that there are no viable methods such as resistant varieties, rotation, less toxic products (see 5.4.1 Note) and that they are comparable in effectiveness according to agronomic particularities of each region.

(7.1.3) Repeat the Notification and Invitation

By means of a Codex Circular Letter to accompany the report of the Meeting the Secretariat will repeat the notification and request. On receipt of the request by the Circular Letter, governments and international organizations will immediately repeat their notification and invitation to identified interested parties who may not have been represented at the CCPR (they would not have received the report of the Meeting and the accompanying Circular Letter). Interested parties need only respond to one of the request, but should copy addresses listed in section 7.1.2 above.

5.5.2 (7.2) Phase II

Status Report on Data Commitments and CCPR Follow-up

(Year 2, CCPR Meeting)

(7.2.1) Status Report on Data Commitments

The Priorities Working Group will provide a report and room document to the CCPR on the status of commitments received to provide data for each compound identified in year 1.

- A list of not challenged CXL;
- A list of not challenged CXL that countries require to maintain;
- A list of challenged CXL with a list of governments and international organizations interested in support them;
- A list of challenged CXL with no commitment to support them.

If there is no challenge to the CXL with relevant scientific data, and no member requests that the CXL is maintain, the CCPR will recommend that the CXL is deleted.

If there is no challenge to the CXLs with the adequate scientific data, and it was required that the CXL be maintained, the CCPR will recommend to maintain the CXL for a new period, according to the guidelines set forth in section 7.1.2 C).

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

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

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

(7.2.2) Response to data commitments

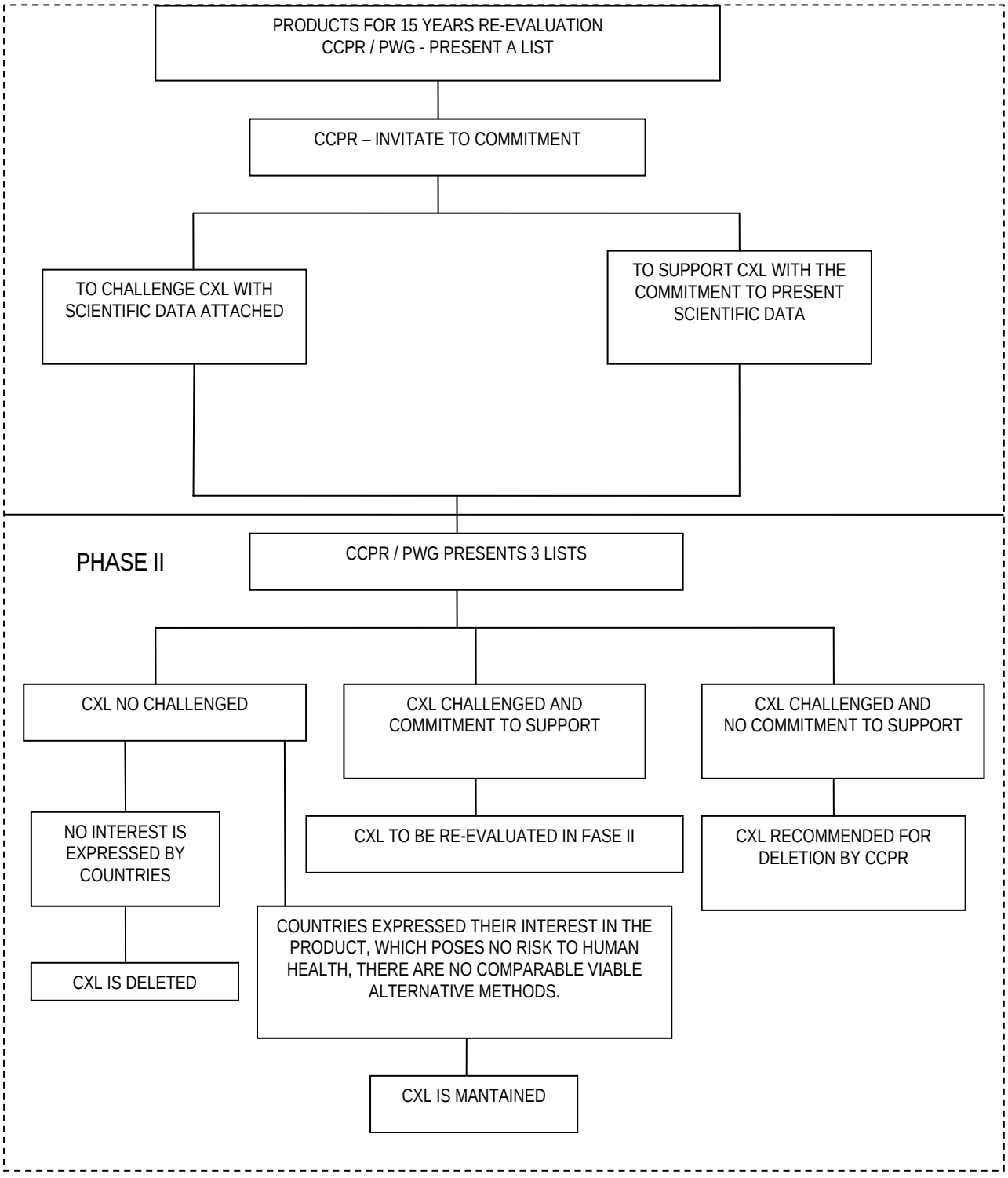
If a commitment is made to provide and identify or develop data to support current CXLs, that have been challenged with scientific support, the MRL(s) are scheduled for JMPR review. The JMPR review will result in one of the following scenarios

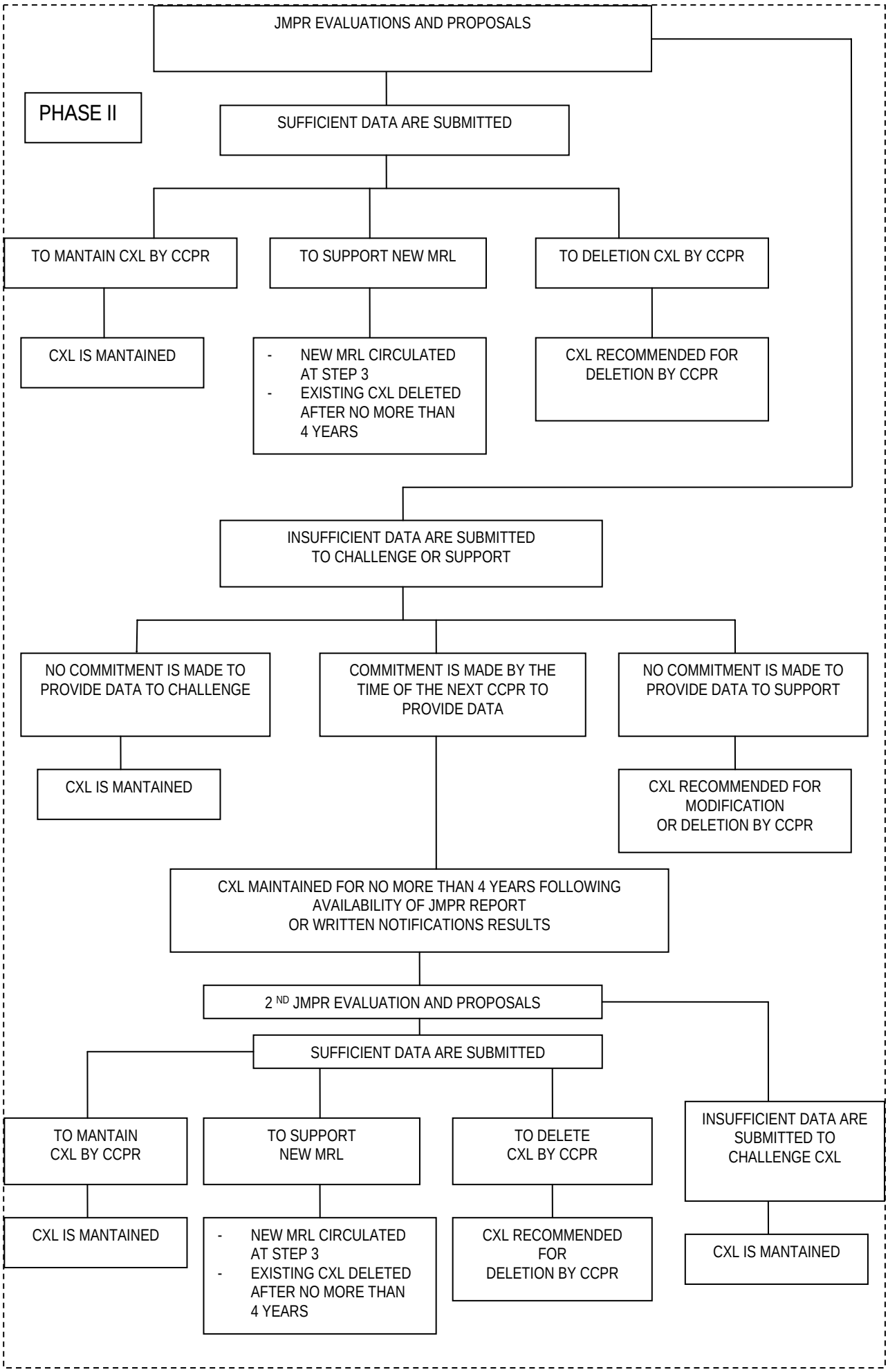
a. Sufficient data have been submitted for JMPR review of current CXL that have been challenged. The JMPR shall assess data submitted in support or challenge of each position and recommends the CCPR to:
    - Delete current CXL that have been challenged;
    - Modify challenged CXL, starting the new proposal at Step 3;
    - Maintain current CXL.

b. Insufficient data have been submitted to challenge or to support a new MRL or to confirm the existing CXL, data submitters are so advised by written notification from the FAO Joint Secretary and/or by issuance of the JMPR Report. On being advised of the data inadequacy, data submitters may by the next CCPR Meeting, provide to the FAO and the CCPR Secretaries a written commitment to generate and submit a dossier of required data for review within 4 years.
    - If there is a commitment to provide new data, the CXL is maintained for no more than 4 years following advice of data inadequacy (by direct notification or by issuance of the JMPR Report). The 4 year period may be extended by the CCPR only to the extent necessary for the JMPR to schedule and complete review of the available new data. The new data are scheduled for the second JMPR review and the first part of the PHASE II procedure is repeated.
    - If there is not commitment to provide new data for challenging MRLs, the CCPR will recommend to maintain the CXL, provided there is a request to do so according to section 7.1.2 C.
    - If there is not commitment to provide new data for supporting MRLs, with an adequate challenge defined by the JMPR, the CCPR will recommend to modify or delete the CXL.
    - If insufficient information are submitted to challenge MRLs, the CCPR will recommend to maintain the CXL, provided there is a request to do so according to section 7.1.2 C.

5.3.3 (7.3) Summary of reevaluation procedure for Codex MRLs

PHASE **I**

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CXL RECOMMENDED FOR DELETION BY CCPR
CXL IS MANTAINED

SECOND ALTERNATIVE PROPOSAL

MRL PERIODIC REVIEW PROCEDURE

MRL PERIODIC REVIEW PROCEDURE

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

PHASE I

IDENTIFY PERIODIC REVIEW CHEMICALS AND SOLICIT DATA COMMITMENTS

(Year 1, CCPR Meeting)

After the CCPR Working Group on Priorities identifies the candidate chemicals, the Secretariat will circulate an invitation including the list of MRLs proposed for review.

1. Notify Data Owners or Other Parties of Candidate List

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

2. Invite Commitment to Submit Data to Support Existing or New Codex Maximum Residue Limits (CXLs)

After notifying data owners (or other interested parties) of the list of chemicals requiring periodic review, governments and international organizations shall inquire of these parties their willingness to provide data for that review and shall advise them of the implications if they choose not to.

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

- Chair, CCPR;
- Chair, Priorities Working Group;
- JMPR Secretariats;
- The requester (government or international organization representative) (Names, titles and addresses will be provided).

If interested in supporting CXLs for a given product, interested members shall notify their intention of doing so.

3. Repeat the Notification and Invitation

By means of a Codex Circular Letter to accompany the report of the Meeting, the Secretariat will repeat the notification and request. On receipt of the Circular Letter with the request, governments and international organizations will immediately repeat their notification and invitation to identified interested parties who may not have been represented at the CCPR (they would not have received the report of the Meeting and the accompanying Circular Letter).

Interested parties need only respond to one of the request, but should copy addresses listed in section above.

PHASE II

Status Report on Data Commitments and CCPR Follow-up

(Year 2, CCPR Meeting)

1. Status Report on Data Commitments - The Priorities Working Group shall present a report and room document to the CCPR on the status of commitments received to provide data for each compound identified in year 1, including the following information:

- A list of CXLs supported by the manufacturers;
- A list of CXLs supported by governments and international organizations;
- A list of CXLs for which the manufacturer made no commitment to support them and the governments expressed no interest.

2. Response to data commitments

2.1 If the manufacturer made a commitment to provide and identify or develop data to support current CXLs, the MRLs are scheduled for JMPR review.

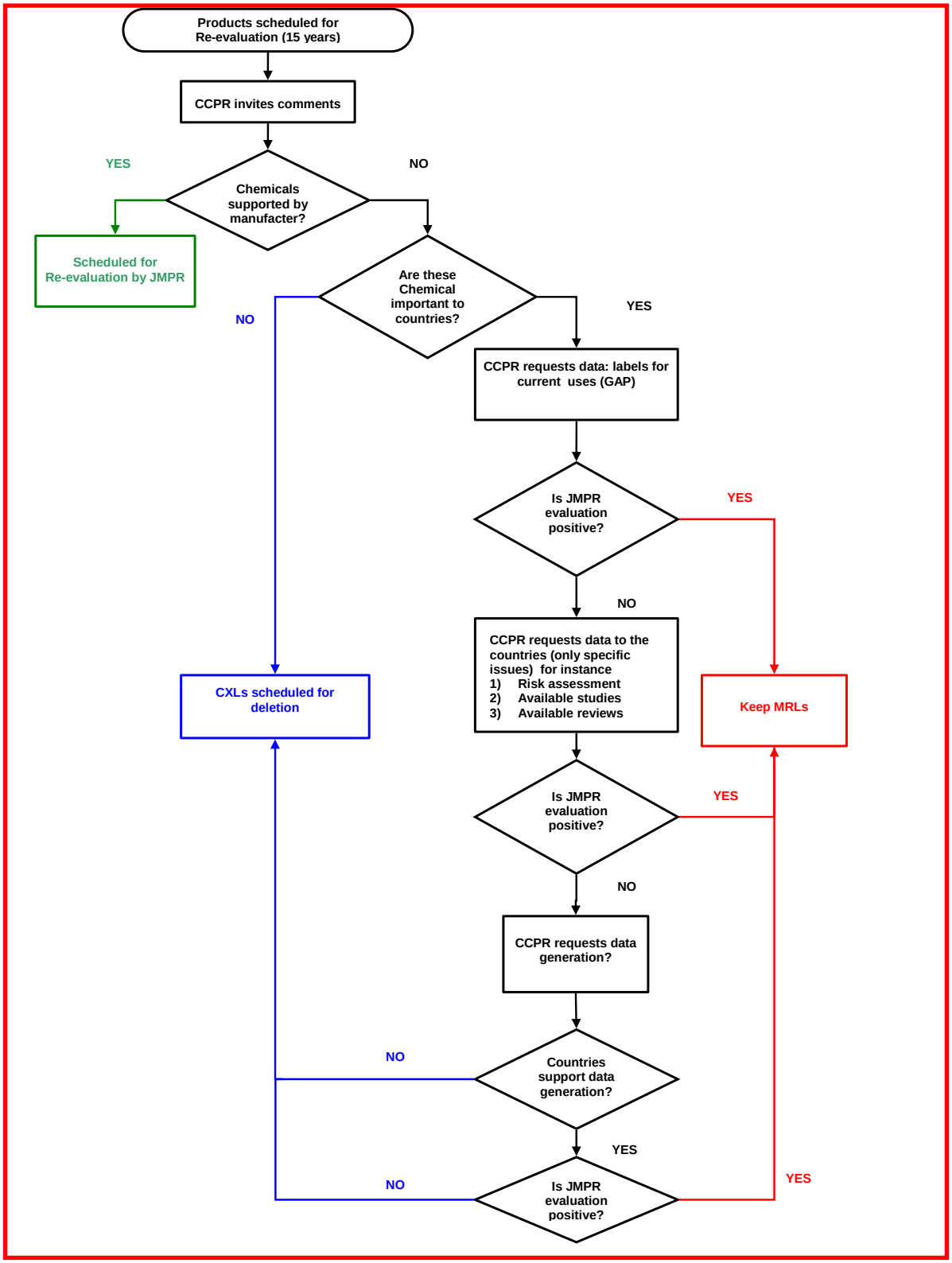
2.2 If the countries made a commitment but the manufacturer made no commitment to submit and identify or develop data to support current CXLs, the MRLs are scheduled for JMPR review. In this case, CCPR requests countries to provide current labels (GAP) for the evaluation by JMPR.

- JMPR reviews the information submitted by the countries and, if sufficient, maintains the CXL.
- If in the opinion of JMPR the information is insufficient, JMPR informs CCPR of the need for additional data. CCPR then invites interested parties to provide information on the following specific issues: available studies and reviews (risk assessment).
- On being advised of the data inadequacy, data submitters may by the next CCPR Meeting, provide to the FAO and the CCPR Secretaries a written commitment to generate and submit a dossier of required data for review within 4 years.
- If there is a commitment to provide new data, the CXL is maintained for no more than 4 years following advice of data inadequacy (by direct notification or by issuance of the JMPR Report). The 4 year period may be extended by the CCPR only to the extent necessary for the JMPR to schedule and complete review of the available new data.
- If the JMPR review of the new information is favorable, the CXL is maintained.
- If the JMPR review is not favorable, CCPR requests interested parties to generate more data. If no member is interested in submitting additional information the CXL is revoked.

The following chart has been prepared informally during the 42 CCPR session in Xian; it was decided not to adapt it to keep its original layout, and, if approved, it will be adapted to the layout of the other two charts for Phase I and II of Periodic Re-evaluation in its different alternative proposals.

SECOND ALTERNATIVE PROPOSAL

MRL PERIODIC REVIEW PROCEDURE



6. ELABORATION PROCEDURE

[original - 8.4] 6.1 UTILIZATION OF STEPS 5/8 FOR ELABORATION OF MRLS

[original - 8.4.1] *Preconditions for utilization of Step 5/8 Procedure*

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

[original - 8.4.2] *Steps 5/8 Procedure (Recommendation to omit Steps 6 and 7 and adopt the MRL at Step 8)*

- If the preconditions listed above are met.
- If a delegation has a concern with advancing a given MRL, a concern form must be completed detailing the concern along with a description of the data that will be submitted to substantiate the concern preferably as comments at Step 3, or at the latest, one month after the CCPR session at which the concern was raised.
- If the JMPR Secretariat or the CCPR can address that concern at the upcoming CCPR session, and the JMPR position remains unchanged, the CCPR will decide if the MRL will be advanced to Step 5/8.
- If the concern cannot be addressed at the meeting, the MRL will be advanced to Step 5 at the CCPR session and the concern will be addressed by the JMPR as soon as possible. Any other draft MRLs for the pesticide, satisfying the above conditions, should be advanced to Step 5/8.
- The result of the consideration of the concern by the JMPR will be considered at the next CCPR session. If the JMPR position remains unchanged, the CCPR will decide if the MRL will be advanced to Step 8.

[pending - 8.5] 6.2 PROCEDURE FOR SUBMITTING CONCERN FORM AGAINST PROPOSED/DRAFT MRL SETTLED BY CCPR

When considering concerns expressed by members:

- CCPR should recognize the position taken by the JMPR as the best available science (applicable at the international level) until and if a different position is indicated.
- science based objections based on the same data/information should be considered only once by the JMPR in relationship to any specific MRL. If the objection does not result in JMPR changing its recommendation on the MRL then the MRL should not be prevented from advancement based on this issue.
- once only review of the same data/information applies to science-based issues with JMPR methods and procedures as well as issues with MRL specific data/information.
- members are encouraged not to submit the same data/information on more than one occasion. If the same information is submitted to JMPR then JMPR should simply note that this information has already been reviewed, no other changed have occurred which would affect the outcome of a new review, and therefore no review is warranted at this time. The subject MRL should not be prevented from advancement based in this issue.
- while MRLs should not be prevented from advancement because of objections concerning current JMPR procedures, it is imperative that CCPR appropriately address any continuing objections, i.e. repeated objections related to the same science-based issue. This may also be relevant to issues closely associated with risk management. Appropriate action could be:
    - referring the issue to JMPR if there is additional or new information, or if the CCPR wishes to provide risk management input to JMPR on the conduct of risk assessments;
    - referring the issue to national governments or regional authorities for input with a discussion and decision at the next CCPR; and/or
    - where justified by the nature of the issue, referring the issue to a scientific consultation if the budget is available from FAO and/or WHO, with JMPR and/or CCPR to make adjustments based on the recommendations of that consultation. Members recommending any such action by CCPR should provide documentary information supporting their recommendation for the consideration of the Committee;
    - in the interim, according to the above recommendations, subject MRLs should be advanced.
- if desired by the objecting member, objections should be officially recorded in the CCPR report
- the members should use the “Form for Guidance for Expressing concern on the Advancement of an MRL or Request for Clarification” as follows.

[pending] 6.3 FORM FOR EXPRESSING CONCERNS WITH ADVANCEMENT OF AN MRL/OR REQUEST FOR CLARIFICATION OF CONCERNS

Submitted by:			
Date:			
Pesticide/ *Pesticida Code Number*	*Commodity /* *Commodity Code Number*	*MRL* *(mg/kg)*	*Present step*
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 to the advancement of the proposed MRL).			
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).			

[pending - 8.6] 6.4 DELETING CODEX MRLS

[pending - 8.6.1] The Codex MRL deletion is stipulated in the following scenarios:

a. Where new scientific data, following a risk analysis, indicate that active compound use may compromise human health;

b. The active compound is no longer produced and there is no remaining stock;

c. The active compound is produced but is not used in food or feed;

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

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

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

**Proposal from India*

However, if a pesticide meeting the above stated condition is of environmentally persistent type, EMRLs are elaborated for a specified limited period.

7. RISK COMMUNICATION

[pending, original from the Procedural Manual] 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. The CCRR recognises that communication between risk assessors and risk managers is critical to the success of risk analysis activities.

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 or published by JMPR.

[agreed 2010 - 4.2] CCPR and JMPR recognize that good communication between risk assessors and risk managers is an essential requirement for successfully performing their risk analysis activities.

[agreed 2010 - 4.3] CCPR and JMPR must continue to develop procedures to enhance communication between the two bodies.