

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 9

CX/GP 07/24/9

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON GENERAL PRINCIPLES
Twenty-fourth Session
Paris, France, 2 – 6 April 2007**

**CONSIDERATION OF THE STRUCTURE AND PRESENTATION OF THE PROCEDURAL
MANUAL**

Background

1. The Committee on General Principles discussed the need for a review of structure and presentation of the Procedural Manual at its 19th (Extraordinary) and 20th Session, and considered a discussion paper prepared by the Codex Secretariat at its 22nd and 23rd Sessions (ALINORM 05/28/33A, paras. 98-105 and ALINORM 06/29/33, paras. 163-176). The 23rd Session discussed how to improve the structure and contents of the Manual on the basis of the proposals made in the working document, and agreed that some questions would require further discussion. It was therefore agreed that the Secretariat would prepare an outline of a new, possible version of the Procedural Manual that would contain two parts or two volumes: 1) procedural texts of general application to the operation of the Commission and its subsidiary bodies; and 2) specific texts applying to an area of work or a Committee.
2. Since the last session of the Committee on General Principles, some amendments to the Procedural Manual have been adopted by the 29th Session of the Commission and this has resulted in additions and amendments to some sections. In addition, the proposal of the Committee to delete the year of revision or amendment in the reference to Codex standards and related texts was adopted by the Commission.
3. The present paper considers how the Procedural Manual could be reordered according to the approach taken at the 23rd Session, with specific proposals on some additional aspects that still need to be addressed.

General Organization

4. Following the discussions held at the last session of the Committee, it is proposed to retain in the first Volume (or first part) of the Manual only the procedural texts of a general nature and to include in the second Volume (or second part) the texts which are more specific to an area of work or a Committee
5. The contents of the 16th Edition of the Procedural Manual are presented in Annex 1. If it is divided into two parts, the texts currently appearing in Section I, II and IV of the Manual would remain in the first part of the Manual, and the second part would include Section III on risk analysis and other texts which are directed specifically to the work of a Committee and have not so far been included in the Procedural Manual.
6. Within the first part of the Manual some areas require further discussion, as there was no conclusion at the last session(s) of the Committee, and as there is still some need to rationalise and improve the presentation according to the subjects addressed. This might need a reorganisation of the first part into sub-sections, or additional sections, and some proposals are put forward for consideration by the Committee, as follows.

Volume I (Part I) of the Procedural Manual

Section I

7. The Statutes and Rules of Procedure would remain as the first series of provisions in that section, as they represent the institutional basis of Codex work.
8. The Elaboration Procedures might be grouped with the main texts in Section II, which explain how Codex Committees and Task Force should operate and therefore directly relate to the elaboration of standards. This would result in a new independent section including the Procedures and the relevant Guidelines and Criteria currently included in Section II. Alternatively, the current structure could be retained in order to separate the procedural and operational aspects, as was mentioned in earlier documents and discussion.
9. The Committee may also wish to consider whether the criteria for the establishment of subsidiary bodies should be retained in the present list of texts in Section II. The establishment of a committee of task force is more relevant to the overall structure of Codex than to the elaboration procedure or the operation of the committees as such, and it may be questioned whether this text should be retained in section II. The criteria for the establishment of a subsidiary body and the criteria for work priorities address two substantially different issues and the rationale for their inclusion in a sequence is not very clear. This may be because they have been developed or revised concurrently. However, it may be more logical to retain the criteria for work priorities only in conjunction with the series of texts related directly to the work of the committees.
10. The General Principles of the Codex Alimentarius are under discussion in the Committee and it is expected that specific proposals in this respect could be made under Agenda Item 7, but in view of their general nature, they would be retained in this Section.
11. Within Section I, a sub-section, or a separate section might be created to include the provisions related to International Non-Governmental Organisations and to International Non-Governmental Organisations, as these texts address the specific issue of cooperation with other organisations and are not directly linked to any other section in the Manual.
12. As regards the definitions, the last session of the Committee noted a number of proposals to transfer the definitions to other sections, partly or as a whole, but did not come to a conclusion. As the definitions are used throughout Codex and are not for exclusive use in the Procedural Manual, the Committee may consider transferring them to a Glossary, which could have the status of a Codex Guideline. If they are retained in the Procedural Manual, they might either remain at the beginning of the Manual, possibly as a separate sub-section, or as an Appendix to the first part of the Manual. The definitions related to risk analysis could also be included in a section grouping all texts on risk analysis.

Section II

13. Following the proposal outlined in section I, one of the options proposed would be to group the Elaboration Procedures with the *Guidelines for Codex Committees and Intergovernmental Task Forces; Criteria for the Establishment of Work Priorities; Guidelines for the Inclusion of Specific Provisions in Codex Standards and Related Texts; Format for Commodity Standards; and Relations between Commodity Committees and General Committees.*
14. If there is no agreement to establish such a separate section and these texts are retained in the current section II, the section may be also amended to transfer all other texts which are not related directly to the operation of Committees and the elaboration of standards.
15. As regards the *Guidelines for the Inclusion of Specific Provisions in Codex Standards and Related Texts*, following the proposal of the Committee on Methods of Analysis and Sampling concerning definitions on analytical terminology, the Commission agreed that the current section should be revised as a Guideline on Analytical Terminology to be published separately when finalised. The last session of that Committee agreed to circulate a revised version of the Proposed Draft Guideline at Step 3.
16. As mentioned above, the *Criteria for the Establishment of a Subsidiary Bodies* could be transferred to the current section I.
17. The Uniform System of Reference for Codex Documents is of an administrative nature and does not result from discussion of procedures or related texts in the Committee on General Principles or the

Commission, this is only an indication of how the texts are referenced by the Codex Secretariat and may not need to be inserted in the Procedural Manual, in view of the approach outlined above whereby it should contain only the texts related to procedures. The Committee may therefore consider its deletion from the Procedural Manual.

18. The *Core Functions of Codex Contact Points* are not related to Codex procedures or the operation of Codex committees and there is no clear rationale for their inclusion in Section II. It is suggested to delete this section from the Procedural Manual and to convert it into separate Codex Guidelines, especially as they are intended to provide some useful references for governments in Codex work at the national level. If they are retained in the Manual, they could be presented as a separate section.

Section III

19. Following the decision of the last session of the Committee, section III would be transferred to the second volume or part of the Manual. However, the first text in the current section III is of a general nature as the *Working Principles* apply throughout Codex. The possible options are to retain the first text in the first part of the Manual and to transfer the other risk analysis texts to the second part; to publish all texts on risk analysis separately in the second part together with the texts applying to specific committees; or to publish separately only the texts concerning risk analysis in view of their specificity and importance.

Section IV

20. The Committee had some discussions on how to present the terms of reference of committees and the corresponding sessions but did not come to an agreement on any specific change. However, no additions or deletions to the items listed have been proposed or considered and it appears that this section would not be amended in its substance, as it is rather self contained. It is therefore proposed to retain this section as it currently appears at the end of the first part or volume of the Manual. The Committee may discuss further how each of the items should be presented if necessary.

Appendix

21. The last session of the Committee agreed to consider further how to address the general decisions of the Commission as it was noted that only the decisions taken from 1995 onwards were currently included in the Manual.

22. As these decisions provide general orientation to the work of Codex, they could be placed before Section IV that contains references and information. The Committee may wish to reconsider the inclusion of these decisions in an Appendix and insert them in other appropriate sections in the Procedural Manual. In particular, the *Statements of Principle Relating to the Role of Food Safety Risk Assessment* could be considered for inclusion in the section on risk analysis.

23. It may be noted that the Manual contains only those decisions that the Commission had specifically agreed to include in the Manual, and which had been previously discussed in the Committee with that purpose. If the Committee decided to consider retroactively previous decisions of the Commission in order to determine whether they should be included in the Manual, this might be a long term process. An example is the decision of the Commission in 2001 on the approach to be taken “when there is evidence that a risk to human health exists but scientific data are insufficient or incomplete”. This decision, which was subsequently incorporated into the Working Principle for Risk Analysis, was a general decision of the Commission. However, the Commission did not specifically decide to include it in the Procedural Manual (ALINORM 01/41, para. 84). Whether it should be included now in the Manual may need further discussion and similar issues may arise with other decisions of the Commission.

24. As regards decisions that have been taken in sessions of the Commission held prior to 1995, there does not appear to be similar cases, or decisions of a nature and scope comparable to the current decisions included in the Appendix, taking into account that some decisions relating to the interpretation of the procedures would have been superseded or integrated into various sections of the Manual itself.

Volume II (Part II) of the Procedural Manual

25. Following the decision of the last session of the Committee, this second volume would incorporate specific texts applying to an area of work or a Committee.

26. As discussed above, the Committee will need to consider whether this Volume should include risk analysis texts. If this is the case, the Volume could include a first section on risk analysis texts and as many sections as necessary to incorporate the provisions applying to specific committees. The list should be limited to guidelines or related texts that have been actually adopted by the Commission. As a result, the main texts proposed for inclusion are as follows:

Committee on Pesticide Residues

MRL Periodic Review Procedure (see Annex 3).

27. This text was developed by the Committee on Pesticide Residues, forwarded to the Commission and adopted in 1997. It is included in Volume 2, Part 1. It has no separate reference and is not included in the list of Codex texts on the website.

28. As the present session of the Committee will consider the Draft Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues. This may provide an occasion to reconsider the need for this text, which describes the procedure for the review of MRLs, including recommendations on the data to be provided to JMPR. The Committee may consider recommending that the CCPR review this Procedure in order to decide whether it should be revised or abolished.

Committee on Methods of Analysis and Sampling

29. The *Recommendations for a Checklist of Information Required to Evaluate Methods of Analysis Submitted to the Codex Committee on Methods of Analysis and Sampling for Endorsement* refers to the information that should be provided to the CCMAS concerning the methods of analysis proposed by Codex Committees. This text was included in Volume 13. It has no reference and is not included in the list of Codex texts on the website.

Committee on Fish and Fishery Products

Procedure for the Inclusion of Additional Species into Standards for Fish and Fishery Products

30. This text was adopted by the Commission in 1979 (ALINORM 79/38, para. 339) and is not included in any publication. It was part of the report of the CCFFP when forwarded to the Commission for adoption and since then it has been reproduced in various working documents for that Committee, when the inclusion of new species was under consideration, and more recently when discussing the revision of the procedure.

31. As a result of the above considerations, a proposed outline of the structure of the Procedural Manual are presented in Annex 2.

CONTENTS OF THE PROCEDURAL MANUAL - 16TH EDITION

- ◆ Introduction

SECTION I

- ◆ Statutes of the Codex Alimentarius Commission
- ◆ Rules of Procedure of the Codex Alimentarius Commission
- ◆ Procedures for the Elaboration of Codex Standards and Related Texts
- ◆ General Principles of the Codex Alimentarius
- ◆ Guidelines on Cooperation between the Codex Alimentarius Commission and International Intergovernmental Organizations in the Elaboration of Standards and Related Texts
- ◆ Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission
- ◆ Definitions for the Purposes of the Codex Alimentarius

SECTION II

- ◆ Guidelines for Codex Committees and Ad hoc Intergovernmental Task Forces
- ◆ Criteria for the Establishment of Work Priorities
 - ◆ Criteria for the Prioritisation Process of Compounds for Evaluation by JMPR
- ◆ Criteria for the Establishment of Subsidiary Bodies of the Codex Alimentarius Commission
- ◆ Guidelines for the Inclusion of Specific Provisions in Codex Standards and Related Texts
- ◆ Uniform System of References for Codex Documents
- ◆ Format for Codex Commodity Standards
- ◆ Relations between Commodity Committees and General Committees
- ◆ Core Functions of Codex Contact Points

SECTION III

- ◆ Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius
- ◆ Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants
- ◆ CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups

SECTION IV

- ◆ Sessions of the Codex Alimentarius Commission
- ◆ Sessions of the Executive Committee of the Codex Alimentarius Commission
- ◆ Subsidiary Bodies of the Codex Alimentarius Commission
- ◆ Membership of the Codex Alimentarius Commission

APPENDIX

- ◆ General Decisions of the Commission

CONTENTS OF THE PROCEDURAL MANUAL: PROPOSED OUTLINE

VOLUME I or PART I

- ◆ Introduction

SECTION I

- ◆ Statutes of the Codex Alimentarius Commission
- ◆ Rules of Procedure of the Codex Alimentarius Commission
- ◆ General Principles of the Codex Alimentarius
- ◆ Criteria for the Establishment of Subsidiary Bodies of the Codex Alimentarius Commission

SECTION II (or sub-section of Section I)

- ◆ Guidelines on Cooperation between the Codex Alimentarius Commission and International Intergovernmental Organizations in the Elaboration of Standards and Related Texts
- ◆ Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission
- ◆ ~~Definitions for the Purposes of the Codex Alimentarius~~ transferred to a separate Glossary or as an Appendix

SECTION III

- ◆ Procedures for the Elaboration of Codex Standards and Related Texts
- ◆ Guidelines for Codex Committees and Ad hoc Intergovernmental Task Forces
- ◆ Criteria for the Establishment of Work Priorities
- ◆ Guidelines for the Inclusion of Specific Provisions in Codex Standards and Related Texts
- ◆ ~~Uniform System of References for Codex Documents~~
- ◆ Relations between Commodity Committees and General Committees
- ◆ Format for Codex Commodity Standards
- ◆ ~~[Core Functions of Codex Contact Points]~~ transferred to a separate Glossary or retained as a separate section

SECTION IV

- ◆ General Decisions of the Commission (or transferred to relevant sections)

SECTION V

- ◆ Sessions of the Codex Alimentarius Commission
- ◆ Sessions of the Executive Committee of the Codex Alimentarius Commission
- ◆ Subsidiary Bodies of the Codex Alimentarius Commission
- ◆ Membership of the Codex Alimentarius Commission

VOLUME II or PART II

SECTION I – Risk Analysis

Section I A - General aspects

- ◆ Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius

Section 1B - Food Additives and Contaminants

- ◆ Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants
- ◆ CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups

Section 1C - Pesticide Residues

- ◆ Criteria for Prioritisation Process of Compounds for Evaluation by JMPR (for inclusion in the section on risk analysis for Pesticide Residues, when finalised)

Other sections and texts to be added when adopted by the Commission

SECTION II – Provisions applying to specific areas of work

Section II-A Pesticide Residues

MRL Periodic Review Procedure

Section II-B Methods of Analysis and Sampling

Recommendations for a Checklist of Information Required to Evaluate Methods of Analysis Submitted to the Codex Committee on Methods of Analysis and Sampling for Endorsement

Section II-C Fish and Fishery Products

Procedure for the Inclusion of Additional Species into Standards for Fish and Fishery Products

MRL PERIODIC REVIEW PROCEDURE

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

PHASE I

IDENTIFY PERIODIC REVIEW CHEMICALS AND SOLICIT DATA COMMITMENTS (Year 1, CCPR Meeting)

1. Identify Candidate Chemicals for Re-evaluation

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

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

Tentative lists for several years may be prepared when feasible.

2. Notify Data Owners or Other Parties of Candidate List

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

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

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

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

- Chairman, CCPR
 - Chairman, Priorities Working Group
 - JMPR Secretariats
 - the requester (government or international organization representative)
- (Names, titles and addresses will be provided)

The invitation will request that the following information be provided in the response:

- a. A list of all commodities for which interested parties are willing to support CXLs.
- b. A brief summary of all current Good Agricultural Practice (GAP) which they are willing to provide and which is pertinent to residue data they are willing to provide (e.g. commodities and countries for which detailed GAP summaries and representative labels can be provided).
- c. A list of all chemistry (residue, metabolism, animal transfer, processing, analytical sample storage stability, analytical methods etc.) and toxicology studies and other data that they are willing to provide (regardless of whether previously provided) and the data they commit to make complete data package submissions to the JMPR. Comments on the status of registrations for the chemicals at the national level are encouraged. Data for which a submission is committed should be identified in the response by study or report title and number, author, date.

4. Repeat the Notification and Invitation

By means of a Codex Circular Letter to accompany the report of the Meeting the Secretariat will repeat the notification and request. On receipt of the request by the Circular Letter, governments and international organizations will immediately repeat their notification and invitation to identified interested parties who may not have been represented at the CCPR (they would not have received the report of the Meeting and the accompanying Circular Letter). Interested parties need only respond to one of the request, but should copy addresses listed in item 3 above.

PHASE II

STATUS REPORT ON DATA COMMITMENTS AND CCPR FOLLOW-UP
(Year 2, CCPR Meeting)

1. Status Report on Data Commitments - The Priorities Working Group will provide a report and room document to the CCPR on the status of commitments received to provide data for each compound identified in year 1. This information will be used to schedule JMPR reviews or to make other recommendations such as withdrawal of CXLs.

2. Response to Data Commitments

a. If there is no commitment - to provide and identify or develop data to support current CXLs, the CXL(s) will be recommended by the CCPR for withdrawal by the next session of the Codex Commission.

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

- Sufficient data are submitted to confirm the CXL and it remains in place.
- Sufficient data are submitted to support a new proposed MRL, it enters the process at Step 3 and the existing CXL is deleted automatically after no more than 4 years.

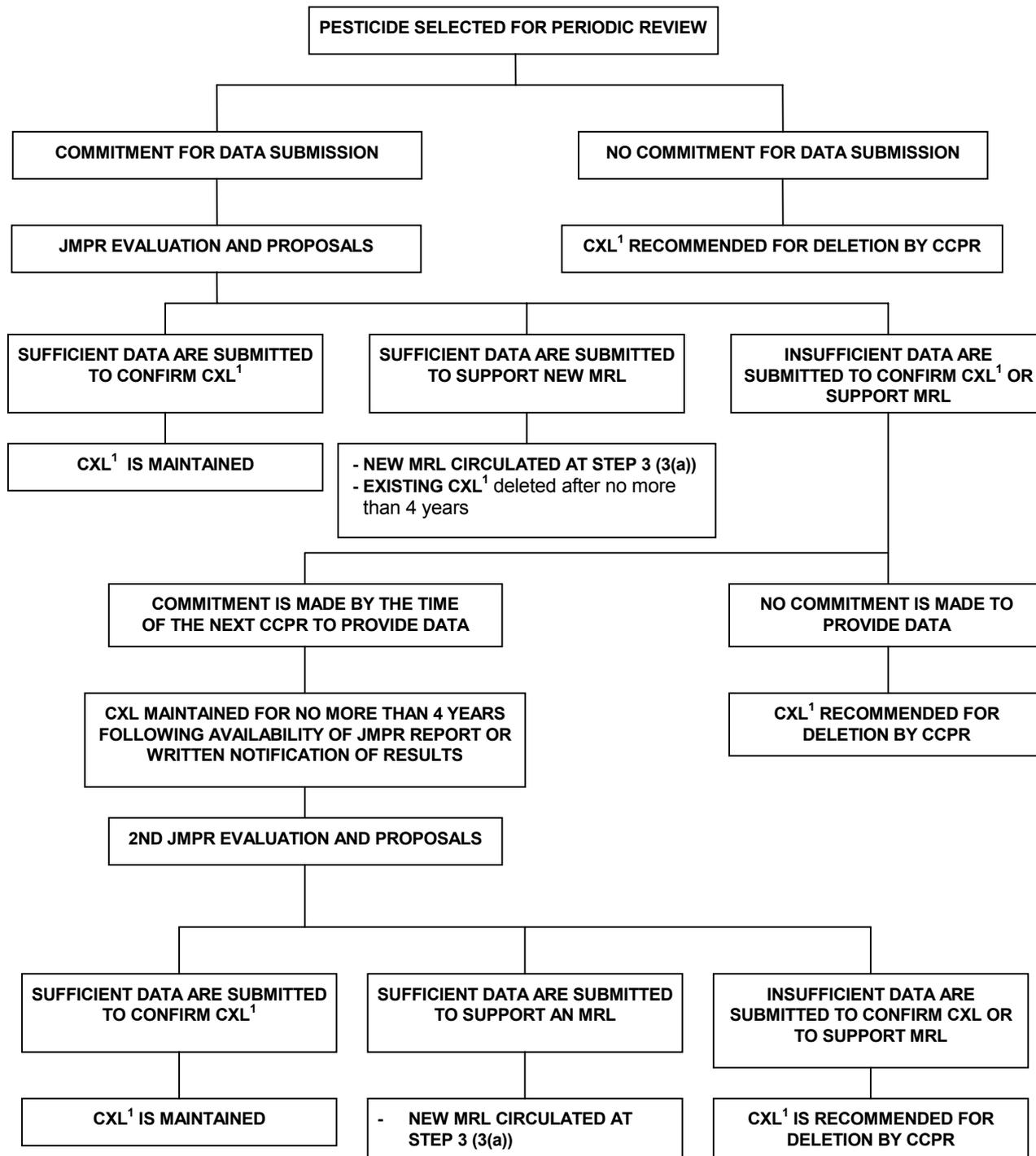
Insufficient data have been submitted to support a new MRL or to confirm the existing CXL, data submitters are so advised by written notification from the FAO Joint Secretary and/or by issuance of the JMPR Report.

On being advised of the data inadequacy, data submitters may by the next CCPR Meeting, provide to the FAO and CCPR Secretaries a written commitment to generate and submit a complete dossier of required data for review within 4 years. The CXL is maintained for no more than 4 years following advice of data inadequacy (by direct notification or by issuance of the JMPR Report). The 4 year period may be extended by the CCPR only to the extent necessary for the JMPR to schedule and complete review of the available new data.

The new data are scheduled for the second JMPR review and the first part of the PHASE II 2b procedure is repeated:

- Sufficient data are submitted to confirm the CXL and it remains in place.
 - Sufficient data are submitted to support a new proposed MRL, it enters the process at Step 3. The CXL is automatically deleted no more than the 4 years after the new proposal enters the process.
 - Insufficient data are submitted to confirm the CXL or support a proposed MRL the CCPR recommends deletion of the CXL.
- c. If the committed data are not submitted, or if the data submitted for the initial periodic review are insufficient and no commitment is made by the next CCPR Meeting to generate new data, the CCPR recommends deletion of the CXL.

SUMMARY OF PERIODIC REVIEW PROCEDURE FOR CODEX MRLS



1 Codex MRL adopted by the Codex Alimentarius Commission. The Codex Alimentarius Commission may decide to delete certain MRLs based on the recommendations made to it by the Codex Committee on Pesticide Residues.

