

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
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ORGANIZATION



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Agenda Item 2

CX/PR 07/39/2

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

Thirty-ninth Session

Beijing, China, 7 - 12 May 2007

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES TO THE PESTICIDE RESIDUE COMMITTEE

A. GENERAL DECISIONS OF THE 29TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION (Geneva, Switzerland, 3 – 7 July 2006)¹

1. The Commission **adopted** a number of amendments to the Rules of Procedure and other amendments to the Procedural Manual, including the splitting of the Codex Committee on Food Additives and Contaminants into the Committee on Food Additives and the Committee on Contaminants in Foods and establishing new Task Forces (see also paras 20-25 below). It also adopted other texts and standards elaborated by the Codex Committees and Task Forces. A complete list of these texts and details of their consideration could be found in ALINORM 06/41 which is available from: <http://www.codexalimentarius.net>

2. The 29th Session of the Commission endorsed the proposal of the 57th Session of the Executive Committee to recommend to Codex Committees and Task Forces:

- To prioritize work when the agenda of the Committee includes many items of work;
- To invite all Chairpersons, or host countries for adjourned committees, to provide their comments on the items of work that have been under consideration for more than five years; and
- To inform the Executive Committee and the Commission of the proposed timeframe for completion of all items that have been approved as new work prior to 2004 (ALINORM 06/29/41, para. 8 and ALINORM 06/29/3, paras. 64-65)

3. The Committee is therefore **requested to propose** a timeframe for all items under consideration in the Step Procedure while considering them at the current session.

B. DECISIONS OF THE 29TH SESSION OF THE COMMISSION RELATED TO THE WORK OF THE COMMITTEE

DRAFT STANDARDS AND RELATED TEXTS AT STEP 8 OF THE PROCEDURE (Agenda Item 4)

4. The Commission **adopted** the Draft Standards and Related Texts submitted by its subsidiary bodies at Step 8 (including those submitted at Step 5 with a recommendation to omit Steps 6 and 7 and those submitted at Step 5 of the Accelerated Procedure) as presented in Appendix IV of ALINORM 06/29/41.

¹ Full report of the 29th Session of the Commission is available from: <http://www.codexalimentarius.net>

5. The following paragraphs provide additional information on the comments made and the decisions taken on certain items.

Pesticide Residues

Draft Maximum Residue Limits for Pesticides, including Dried Chili Pepper²

6. The Commission **adopted** the MRLs as proposed in Appendices II and III of ALINORM 06/29/24 and noted the reservation expressed by the European Community and Norway on MRLs for methiocarb (132), deltamethrin (135), oxydemeton-methyl (166) and chlorpropham (201).

PROPOSED DRAFT STANDARDS AND RELATED TEXTS AT STEP 5 (Agenda Item 5)

7. The Commission **adopted** the Proposed Draft Standards and Related Texts at Step 5 submitted by its subsidiary bodies at Step 5 as presented in Appendix V to this report and advanced them to Step 6. The Commission noted that technical comments raised during the session would be referred to the relevant Committees for their consideration. The Commission encouraged members and observers that have submitted comments in writing or orally at the session to submit these comments at Step 6 of the Procedure.

8. The Commission had adopted and advanced to Step 6 the proposed draft MRL for phorate (112) for potatoes and for indoxacarb (216) for cabbages, head; lettuce, leaf; milk fats and milks as presented in Appendix VI of ALINORM 06/29/24.

9. These MRLs will be considered at Step 7 on Agenda Item 5.

REVOCATION OF EXISTING CODEX STANDARDS AND RELATED TEXTS (Agenda Item 6)³

10. The Commission **approved** the revocation of a number of pesticide MRLs as presented in Appendix VII of ALINORM 06/29/24.

PROPOSALS FOR THE ELABORATION OF NEW STANDARDS AND RELATED TEXTS AND FOR THE DISCONTINUATION OF WORK (Agenda Item 7)

11. The Commission approved new work on Priority List of Pesticides (New Pesticides and Pesticides under Periodic Review) (Ongoing) and on the Extension of the Work on the Revision of the Codex Classification of Foods and Animal Feeds (Job Code N09-2006).

Proposed Draft Amendment to the Codex MRL Elaboration Procedure (in Relation to the Establishment of Interim MRLs)

12. The Delegation of the Netherlands, speaking as Chair of the Committee on Pesticide Residues, recalled that the Committee had worked on the establishment of interim MRLs for several sessions in order to expedite MRL setting and that specific interim MRLs had been adopted at the 28th Session of the Commission. The Commission, noting that the CCPR had agreed on new policies to expedite the MRL setting process, approved discontinuation of work on interim MRLs.

OTHER MATTERS

Draft Revised Criteria for Prioritization Process of Compounds for Evaluation by JMPR (ALINORM 06/29/41, paras 30-32)

13. The Delegation of India, supported by other delegations, proposed to insert an additional criterion to ensure that priority was given to pesticides and commodities of relevance for developing countries.

14. The Delegation of the Netherlands, speaking as Chair of the Committee on Pesticide Residues, recalled that the request for evaluation of compounds by JMPR was conditional on the availability of the

² ALINORM 06/29/24, Appendix II.

³ ALINORM 06/29/7

relevant data, especially supervised trials, and that the application of national and Codex MRLs at export and import was being considered by the Committee as a separate issue. The Commission also recalled that the Criteria for the Establishment of Work Priorities specifically referred to the needs of developing countries.

15. After some discussion, the Commission **adopted** the Draft Revised Criteria as proposed and **agreed to refer** to the Committee on Pesticide Residues the question of prioritization for pesticides and commodities of relevance to developing countries both in respect of new chemicals and periodic re-evaluation.

16. See also paras 26-35 from the report of the CCGP below.

MATTERS ARISING FROM REPORTS OF THE COMMISSION, CODEX COMMITTEES AND TASK FORCES (Agenda Item 11)

Committee on General Principles

Use of the term “interim”

17. The Commission recalled that the Committee on General Principles had considered the term “interim” as relates to the adoption of Codex standards and related texts, following the request of the 27th Session of the Commission. This issue was also considered at the present session in relation to pesticide residues (see Agenda Item 7).

18. The Commission **agreed** to endorse the following recommendations, as proposed by the Committee on General Principles:

- The Commission should not adopt any food safety standards at Step 8, whether they are called temporary or interim, that are not substantiated by the scientific advice of expert bodies and consultations recognized by the Commission, in accordance with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.
- Where draft standards are based on international risk assessments as mentioned above, the Commission might still wish to adopt them and at the same time commit itself to revisiting the matter in the near future; in this case, the Commission should generally refrain from using the term “interim” or “temporary”, which could introduce ambiguity as to their status, including from a legal standpoint.

19. The Commission should be very cautious in adopting standards having a limited lifetime; should the Commission choose to do so, then the time period for “automatic” expiration must be clearly defined, since all standards adopted by the Commission would be presumed to remain in force until they are revoked or replaced by new or revised standards adopted by the Commission.

Antimicrobial Resistance⁴ (ALINORM 06/29/41, paras 164-169)

20. The Commission recalled that at its 28th session it had agreed, in principle, to the establishment of an *Ad Hoc* Intergovernmental Task Force to deal with the issue related to antimicrobial resistance and that a final decision as to its establishment had to be taken at its current session. It also recalled that a Circular Letter⁵ had been issued to request proposals on Terms of Reference of such task force and on national activities and policies dealing with containment of antimicrobial resistance. The Commission noted that an in-session working group had been convened under the Chairmanship of the United States to analyze comments received and to prepare proposals for the title, objectives, terms of reference and time frame for the proposed Task Force.

21. The Commission considered the report prepared by the in-session working group presented in LIM 18 and discussed whether to establish such a task force and how to better proceed with the foreseen work.

22. Some delegations stressed that technical cooperation including information exchange was essential in order to assist developing countries in addressing the issue of antimicrobial resistance.

23. The Observer from OIE drew the attention of the Commission to the fact that OIE had recently adopted a standard on antimicrobial resistance and proposed to cross reference this standard and work in

⁴ ALINORM 05/28/41, paras 177-186; ALINORM 06/39/3A, paras 91-93

⁵ CL 2005/33-CAC.

complementary way in order to avoid duplication and conflict between the standards developed by the relevant organisations referenced under the WTO SPS Agreement.

24. The Commission **agreed** to establish a Codex *Ad Hoc* Intergovernmental Task Force on Antimicrobial Resistance and, on the basis of the discussion on the proposals in LIM 18 and with the necessary adjustments, **agreed** on its objectives, terms of reference and timeline as presented in Appendix XI to this report.

25. The Commission **agreed** that a Circular Letter be sent to request concrete proposals for new work, preferably in the form of draft project documents, which would be compiled in a working document to be circulated for comments and consideration by the first meeting of the Task Force. The Commission also **agreed** to use the text listing elements and activities presented in LIM 18 as background information for the above Circular Letter.

C. MATTERS ARISING FROM OTHER CODEX COMMITTEES AND TASK FORCES

23RD SESSION OF THE CODEX COMMITTEE ON GENERAL PRINCIPLES (ALINORM 06/29/33, PARAS 31-39)

Draft revised Criteria for Prioritization Process of Compounds for Evaluation by JMPR

26. The Committee recalled that the Committee on Pesticide Residues (CCPR) currently used criteria for the prioritization of compounds that were part of the Circular Letter distributed prior to each session to request comments on the establishment of priorities for evaluation by JMPR. The 37th Session of the CCPR finalized the Draft Criteria and forwarded them to the Committee on General Principles for endorsement and to the Commission for adoption. The Secretariat indicated that some editorial amendments had been proposed in Annex 2 of the working document in order to harmonise terminology with current Codex terminology or for clarification purposes. The Committee considered the draft Criteria section by section and made the following comments and amendments.

27. The Delegation of Brazil, supported by other delegations, proposed to insert a new criterion to the effect that in order to be considered for inclusion in the priority list, the CCPR “must take into account the identified needs of developing countries”

28. The Delegation of the United States expressed the view that, as the “General Criterion” in the Criteria for the Establishment of Work Priorities referring to the needs of developing countries applied to all Codex subsidiary bodies, there was no need to repeat general statements in the criteria applied by CCPR.

29. The Delegation of the Netherlands, speaking as host country for the CCPR, recalled that the problems of developing countries in relation to MRL setting were regularly considered in that Committee; however the establishment of MRLs for specific compounds and commodities was conditional on the submission of relevant data, including the results of supervised trials and JMPR could not carry out risk assessment in the absence of such data.

30. In section 2.1 Criteria for Selecting Food Commodities, the Delegation of Colombia pointed out that the absence of Codex MRLs for commodities produced in developing countries caused considerable trade problems as importing countries applied a zero tolerance when no specific MRL existed. In order to address this problem, the Delegation proposed to add a reference to commodities originating from developing countries, as priority should be given to the establishment of MRLs for these products. This proposal was supported by some delegations.

31. The Committee noted that as MRLs were established on the basis of the data on substances and commodities provided to a large extent by developed countries, the CCPR had been considering how to address the difficulties and needs of developing countries. The Secretariat informed the Committee that the last session of the CCPR had decided to undertake a comprehensive revision of the Classification of Foods and Feeds and that one of the issues to be addressed in the process was how to take into account the commodities of importance to developing countries; in the same perspective, the CCPR had recently established MRLs for spices.

32. The Committee noted that the proposed 50% minimum ratio for new compounds for allocating priorities to new chemicals as compared to chemicals for periodic reevaluation resulted from an evolution in

the priorities for evaluation of pesticides. For many years priority had been given to the periodic reevaluation of pesticides that were already on the market and a large number of MRLs had been reevaluated in order to take into account updated scientific evidence and risk assessment methodologies. In more recent years several new compounds had appeared on the market and the CCPR had recognized that their evaluation should be carried out as a matter of priority. The Committee had therefore agreed that the proportion of new evaluations to periodic reevaluations should be significantly increased and introduced the 50% minimum ratio for new compounds, if possible, in the criteria for the prioritization of compounds. It was also noted that the Draft Criteria placed special emphasis on the evaluation of new compounds with reduced acute and/or chronic toxicity.

33. The Committee agreed to retain the 50% minimum ratio for new compounds, if possible, and to reword paragraph 5 of section 2.1 for clarification purposes.

34. The Committee **agreed to endorse** the Draft Revised Criteria and to forward them for adoption to the 29th Session of the Commission, and including in the Procedural Manual after the Criteria for the Establishment of Work Priorities (see Appendix). The Committee also **agreed to draw the attention** of the Committee on Pesticide Residues to the concern expressed by developing countries at the present session, regarding the need for CCPR to give priority to setting MRLs for commodities originating from developing countries. (See also paras 13-16)

35. The Committee is **invited** to use the above criteria while prioritizing compounds for evaluation by JMPR.

APPENDIX

**REVISED CRITERIA FOR PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION
BY JMPR****1. GENERAL CRITERIA****1.1 Criteria for Inclusion of Compounds on the Priority List**

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

- i must be registered for use in a member country;
- ii must be available for use as a commercial product;
- iii must not have been already accepted for consideration; and
- iv must give rise to residues in or on a food or feed commodity moving in international trade, the presence of which is (or may be) a matter of public health concern and thus create (or have the potential to create) problems in international trade.

1.2 Criteria for Selecting Food Commodities for which Codex MRLs or EMRLs should be Established

The commodity for which the establishment of a Codex MRL or EMRL is sought should be such that it may form a component in international trade. A higher priority will be given to commodities that represent a significant proportion of the diet.

Note:

Before proposing a pesticide/commodity for prioritization, it is recommended that governments check if the pesticide is already in the Codex system. Pesticide/commodity combinations that are already included in the Codex system or under consideration are found in a working document prepared for and used as a basis of discussion at each Session of the Codex Committee on Pesticide Residues. Consult the document of the latest session to see whether or not a given pesticide has already been considered.

2. CRITERIA FOR PRIORITISATION**2.1 New Chemicals**

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

1. If the chemical has a reduced acute and/or chronic toxicity risk to humans compared with other chemicals in its classification (insecticide, fungicide, herbicide);
2. The date when the chemical was nominated for evaluation;
3. Commitment by the sponsor of the compound to provide supporting data for review with a firm date for data submission;
4. The availability of regional/national reviews and risk assessments, and coordination with other regional/national lists; and
5. Allocating priorities to new chemicals, so that at least 50% of evaluations are for new chemicals, if possible.

Note

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

- i the name(s) of the chemicals for which the proposed chemical is likely to be an alternative;
- ii a comparison of the acute and chronic toxicities of the proposed chemical with other chemicals in its classification (insecticide, fungicide, herbicide);

- iii a summary of acute and chronic dietary exposure calculations encompassing the range of diets considered by CCPR; and
- iv other relevant information to support classification of the proposed chemical as a safer alternative chemical.

2.2 Periodic Re-Evaluation

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

1. If the intake and/or toxicity profile indicate some level of public health concern;
2. Chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits for 15 years;
3. The year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation –Not Yet Scheduled;
4. The date that data will be submitted;
5. Whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;
6. If there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently; and
7. The availability of current labels arising from recent national re-evaluations.

2.3 Evaluations

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

1. The date the request was received;
2. Commitment by the sponsor to provide the required data for review with a firm date of submission;
3. Whether the data is submitted under the 4-year rule for evaluations; and
4. The nature of the data to be submitted, and the reason for its submission; for example, a request from CCPR.

Note:

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

- i New toxicological data becomes available to indicate a significant change in the ADI or ARfD.
- ii The JMPR may note a data deficiency in a Periodic Re-evaluation or New Chemical evaluation. In response, national governments or other interested parties may pledge to supply the information to the appropriate Joint Secretary of the JMPR with a copy for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data should be submitted subsequently to the appropriate Joint Secretary of the JMPR.
- iii The CCPR may place a chemical under the four-year rule, in which case the government or industry should indicate support for the specific MRLs to the FAO Joint Secretary of the JMPR. Following scheduling in the JMPR tentative schedule, any data in support of maintenance of the MRL(s) would be submitted to the FAO Joint Secretary of the JMPR.
- iv A government member may seek to expand the use of an existing Codex chemical: that is, obtain MRLs for one or more new commodities where some MRLs already exist for other commodities. Such requests should be directed to the FAO Joint Secretary of the JMPR and submitted for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.

- v A government member may seek to review a MRL due to a change in GAP. For example a new GAP may necessitate a larger MRL. In this case the request should be made to the FAO Joint Secretary with a copy for consideration by the Committee. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.
- vi The CCPR may request a clarification or reconsideration of a recommendation from the JMPR. In such cases the relevant Joint Secretary will schedule the request for the next JMPR.
- vii 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.