

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 2a)

CX/GP 06/23/2 Part I

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON GENERAL PRINCIPLES
Twenty-third Session
Paris, France, 10 – 14 April 2006**

MATTERS REFERRED TO THE COMMITTEE

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES

A. MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION

1. Decisions of the 28th Session of the Commission on the work of the Committee¹

Proposed Amendments to the Rules of Procedure

All proposed amendments were adopted by the Commission and entered into force following their approval by the Directors-General of FAO and WHO.

Proposed Amendment to the Statutes

The proposed amendment was adopted by the 33rd Session of the FAO Conference and will be considered by the Fifty-ninth World Health Assembly in May 2006.

Amendments Resulting from the Abolition of the Acceptance Procedure

While discussing the amendment to the *General Principles of the Codex Alimentarius*, the Delegation of Australia expressed the view that paragraph 4 of the Guidelines for the Acceptance Procedure described important principles of the Codex Alimentarius and provided guidance to member countries on how to implement or give regard to Codex standards in developing national regulations. After some discussion, the Commission agreed to delete all sections of the Procedural Manual related to acceptance and to request the Committee on General Principles to review the *General Principles* to consider how the principles reflected in paragraph 4 could be integrated into the General Principles of Codex, taking into account the written comments made by Australia and other members. This question will be discussed under **Agenda Item 7**.

Other amendments

The following amendments were adopted by the Commission and incorporated into the 15th Edition of the Procedural Manual:

- *Amendments resulting from the abolition of the Acceptance Procedure*
- *Risk Analysis Principles Applied by the Committee on Food Additives and Contaminants and CCFAC Policy for Exposure Assessment for Contaminants and Toxins in Foods and Foods Groups*
- *Revised Criteria for the Establishment of Work Priorities*
- *Guidelines on Physical Working Groups and Guidelines on Electronic Working Groups*
- *Revised Principles concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission*

¹ ALINORM 05/28/41, paras. 18-44, Appendix IV.

- *Guidelines for Cooperation between the Codex Alimentarius Commission and International Intergovernmental Organizations in the Elaboration of Standards and Related Texts*

2. Matters referred by the 28th Session of the Commission

Terms of reference of Regional Coordinating Committees

While discussing the review of the Regional Coordinating Committees, the Commission noted that the Coordinating Committee for Latin America and the Caribbean (CCLAC) had proposed to amend its mandate to include “the adoption of regional positions on strategic subjects”. The Delegation of India, supported by some delegations, expressed the view that the proposed amendment extended to the mandate of all other Coordinating Committees, pointing out that this was not in any way a contradiction to the existing mandate, but only a more precise expression of the same. Other delegations pointed out that further clarification should be required as to the implications of such an amendment, and that the proposal was already covered by the current terms of reference. The Commission therefore agreed to refer the proposed amendment to the terms of reference of the CCLAC and its possible extension to the other Coordinating Committees to the Committee on General Principles for further consideration (ALINORM 05/28/41, para. 130).

The amendment proposed by CCLAC is to include in its terms of reference an additional bullet point: (i) To promote the adoption of regional positions on strategic subjects.

The Committee is invited to consider whether this proposal is acceptable and consistent with the terms of reference of Coordinating Committees. If there is agreement in principle to this amendment, the next question will be the desirability of keeping harmonised the terms of reference of all Coordinating Committees. The Committee might address this issue as follows: (i) endorsing the amendment to the terms of reference of the CCLAC for adoption by the 29th Session of the Commission, in which case it would apply only to the CCLAC; (ii) recommending to apply the same amendment to the terms of reference of all Coordinating Committees immediately; or (iii) seeking the advice of other Coordinating Committees as to whether it should be included in their own terms of reference and reconsider the whole question at the next session of the Committee in the light of their advice.

Terms of Reference of the Committee on Food Additives and the Committee on Food Contaminants

The Delegation of the Netherlands, as host government of the Committee on Food Additives and Contaminants, stated that the current workload of the Committee was too heavy and the large number of working groups that needed to operate under the present framework raised concern from the viewpoint of transparency. The Commission requested the Secretariat to prepare the Terms of Reference for each of the new committees and present them at the next sessions of the Committee on General Principles and the Committee on Food Additives and Contaminants, with a view to their adoption and the designation of host countries at the next session of the Commission (ALINORM 05/28/41, para. 143).

The Committee is therefore invited to consider the following proposed terms of reference for the two Committees, based on the current terms of reference of the Committee on Food Additives and Contaminants:

Codex Committee on Food Additives

Terms of reference:

- (a) to establish or endorse permitted maximum levels for individual food additives;*
- (b) to prepare priority lists of food additives for toxicological evaluation by the Joint FAO/WHO Expert Committee on Food Additives;*
- (c) to recommend specifications of identity and purity for food additives for adoption by the Commission;*
- (d) to consider methods of analysis for the determination of additives in food; and*
- (e) to consider and elaborate standards or codes for related subjects such as the labelling of food additives when sold as such [, and food irradiation].*

The Committee is invited to consider whether food irradiation should remain within the terms of reference of the Committee on Food Additives or whether it should be entrusted to the Committee on Food Hygiene as it is used to control biological hazards. The Committee could also decide to keep food irradiation within the terms of reference of the Committee on Food Additives at this stage and discuss the matter further at its next session, in order not to delay the establishment of the two Committees by the Commission. In the event the

Committee agrees to transfer food irradiation to the terms of reference of the Codex Committee on Food Hygiene, point (g) in its current terms of reference could be amended as follows:

(g) to consider microbiological risk management matters in relation to food hygiene, including food irradiation, and in relation to the risk assessment of FAO and WHO.

Codex Committee on Contaminants in Foods

Terms of reference:

- (a) to establish or endorse permitted maximum levels or guidelines levels for contaminants in food and feed;
- (b) to prepare priority lists of contaminants for toxicological evaluation by the Joint FAO/WHO Expert Committee on Food Additives;
- (c) to consider methods of analysis and sampling for the determination of contaminants in food and feed;
- (d) to develop standards or codes of practice for related subjects; and
- (e) to consider other matters assigned to it by the Commission in relation to contaminants in food and feed.

The establishment of two separate committees for additives and contaminants will entail a number of consequential changes to several sections in the Procedural Manual. These changes will not be considered in the present document as the mandate of the Committee is to finalize the terms of reference with a view to their adoption by the Commission.

However, if the terms of reference are finalized at the 23rd Session, the Secretariat could prepare an additional document with the incorporation of all consequential changes into the Procedural Manual for consideration by the Commission, as this would not require substantial discussion but would only reflect the existence of two separate committees for additives and contaminants in order to ensure consistency throughout the Manual. Other issues that would require substantial discussion, such as possible amendments to the Risk Analysis Principles Applied by the Committee on Food Additives and Contaminants, might be considered at a future session.

Procedures for the Revision of Standards

While considering the revision of Codex standards for fresh fruits and vegetables, the Commission noted the request of the Committee on Fresh Fruits and Vegetables to consider a more expeditious procedure for revising Codex standards for fresh fruits and vegetables when considering minor changes such as additions and/or deletions of some provisions (e.g. the introduction of new varieties) for which the presentation of a project document might not be considered imperative. The Commission noted that a similar situation might arise in relation to updating of other commodity standards and agreed that this matter should be considered in a general context and requested the Committee on General Principles to look into this issue at its next session. This question will be considered under **Agenda item 6b**).

Sampling Plans

The Delegation of Japan pointed out that the Principles for the Establishment or Selection of Codex Sampling Procedures in the Procedural Manual referred to the Sampling Plans for Prepackaged Foods (CAC/STAN 233), that had been superseded by the General Guidelines on Sampling adopted in 2004. The Delegation therefore proposed that the Committee on General Principles and the Committee on Methods of Analysis and Sampling consider the review and possible update of the entire section to take into account the adoption of the new Guidelines. The Commission agreed that this matter should be considered by the next session of the Committee on General Principles (ALINORM 05/28/41, para.190).

The Committee is invited to give its general advice on this issue. However, in view of the nature of the subject, it is proposed that the actual revision of the section, if needed, be initiated by the Committee on Analysis and Sampling, with the understanding that any revised text would be endorsed by CCGP.

B. MATTERS REFERRED BY OTHER COMMITTEES

Committee on Pesticide Residues

The Committee on Pesticide Residues agreed to send the draft revised Criteria for Prioritization Process to the Committee on General Principles for their review with the understanding that the revised version would be forwarded to the Commission for adoption and be included in the Codex Alimentarius Procedural Manual (ALINORM 05/28/24, para. 256 and Appendix XV). The Draft Criteria are attached as **Annex 1**.

The Secretariat would like to draw the attention of the Committee to the following aspects of the Draft Criteria:

The Committee on Pesticide Residues is currently using Criteria for prioritization of compounds that are included in a Circular Letter on the establishment of priorities sent prior to each session. The CCPR agreed that these criteria should be reviewed and considered for inclusion in the Procedural Manual.

As these Criteria address the prioritization for evaluation by JMPR but also the prioritization of work within the Committee since compounds that have been evaluated by JMPR are circulated as Proposed Draft MRLs, it is proposed to include them, when finalized, in the section of the Manual on *Criteria for the Establishment of Work Priorities*.

The Criteria, as they have been drafted, include several references to the Chair of the Working Group on Priorities. This may imply that this working Group has a permanent status, which would not be consistent with the *Guidelines for Physical Working Groups*. It is therefore suggested that the text refer only to the Committee where applicable, with the understanding that the Committee may convene a Working Group to facilitate its work on the establishment of priorities. This would also allow more flexibility in the organisation of work, as the Committee might be unable to hold a working group before a particular session for practical reasons, and should be allowed to proceed on a case by case basis.

As regards the terminology used in the document, it is suggested to use the wording of the Elaboration Procedures and to refer to MRLs or Proposed or Draft MRLs, instead of the term CXL, which is not used in the Procedural Manual. This expression may be used in the database, but it would be preferable to ensure consistency in the texts presented in the Procedural Manual.

The Committee is invited to consider the Criteria in the light of the *Criteria for the Establishment of Work Priorities* and the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.

It may be noted that the CCPR is currently developing *Draft Risk Analysis Principles Applied by the CCPR* (adopted at Step 5 by the 28th Session of the Commission) that will describe the roles of CCPR and JMPR in Risk Analysis and will be forwarded to the Committee on General Principles when finalized.

Some editorial changes are proposed in **Annex 2**.

Committee on Methods of Analysis and Sampling

The Committee on Methods of Analysis and Sampling developed a guidance document on *The Use of Analytical Results : Sampling Plans, Relationship between the Analytical Results, the Measurement Uncertainty, Recovery Factors and Provisions in Codex Standards* with the understanding that it would be used by commodity committees, and included in the Procedural Manual as it was intended for use in the framework of Codex. The document was forwarded to all commodity committees for consideration and was finalized taking into account the comments made by several committees.

The Committee agreed to forward the recommendations on *The Use of Analytical Results* to the Committee on General Principles for endorsement and to the 29th Session of the Commission for adoption and inclusion in the Procedural Manual, at the end of the sections on methods of analysis and sampling in the *Guidelines for the Inclusion of Specific Provisions in Codex Standards and Related Text*.(ALINORM 05/28/23, para. 107, Appendix II). A few editorial amendments are suggested to the text attached as **Annex 3**.

DRAFT 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, governments are recommended to 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 nominated to the Chair, Priorities Working Group;
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 new chemicals to be evaluated on at least a 50:50 basis, if possible, with periodic re-evaluation chemicals to be evaluated.

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 to the Chair of the Working Group on Priorities. 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 CXLs to the FAO Joint Secretary of the JMPR, with a copy to the Chair of the Working Group on Priorities. Following scheduling in the JMPR tentative schedule, any data in support of maintenance of the CXL(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 CXLs already exist for other commodities. Such requests should be directed to the FAO Joint Secretary of the JMPR and copied to the Chair of the Working Group on Priorities. 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 CXL 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 to the Chair of the Working Group on Priorities. 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 Codex pesticide. In such cases government members should notify the WHO Joint Secretary of the JMPR promptly and provide appropriate data to the WHO Joint Secretary.

DRAFT REVISED CRITERIA FOR PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR

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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 to the Chair, Priorities Working Group**; ~~to the Chair, Priorities Working Group~~;
3. Commitment by the sponsor of the compound to provide supporting data for review with a firm date for data submission;
5. The availability of regional/national reviews and risk assessments, and coordination with other regional/national lists; and
5. Allocating **priorities to new chemicals and to chemicals for periodic re-evaluation to be evaluated** ~~with periodic re-evaluation chemicals to be evaluated~~ on at least a 50:50 basis, 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:

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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:

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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** ~~to the Chair of the Working Group on Priorities~~. 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** ~~EXLs~~ to the FAO Joint Secretary of the JMPR, ~~with a copy to the Chair of the Working Group on Priorities~~. Following scheduling in the JMPR tentative schedule, any data in support of maintenance of the ~~EXL~~ **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 ~~EXLs~~ **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** ~~copied to the Chair of the Working Group on Priorities~~. 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 ~~EXL~~ **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** ~~to the Chair of the Working Group on Priorities~~. 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 ~~Codex~~ 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.

THE USE OF ANALYTICAL RESULTS: SAMPLING PLANS, RELATIONSHIP BETWEEN THE ANALYTICAL RESULTS, THE MEASUREMENT UNCERTAINTY, RECOVERY FACTORS AND PROVISIONS IN CODEX STANDARDS

(To be included in the Codex Procedural Manual at the end of the sections on methods of analysis and sampling in the *Guidelines for the Inclusion of Specific Provisions in Codex Standards and Related Texts*)

ISSUES INVOLVED

There are a number of analytical and sampling considerations which prevent the uniform implementation of legislative standards. In particular, different approaches may be taken regarding sampling procedures, the use of measurement uncertainty and recovery corrections.

At present there is no official guidance on how to interpret analytical results in the framework of Codex. Significantly different decisions may be taken after analysis of the “same sample”. For example some countries use an “every-item-must-comply” sampling regime, others use an “average of a lot” regime, some deduct the measurement uncertainty associated with the result, others do not, some countries correct analytical results for recovery, others do not. This interpretation may also be affected by the number of significant figures included in any commodity specification.

It is essential **that** analytical results ~~be are~~ interpreted in the same way if there is to be harmonization in the framework of Codex.

It is stressed that this is not an analysis or sampling problem as such but an administrative problem which has been highlighted as the result of recent activities in the analytical sector, most notably the development of International Guidelines on the Use of Recovery Factors when Reporting Analytical Results and various Guides prepared dealing with Measurement Uncertainty.

RECOMMENDATIONS

It is recommended that when a Codex Commodity Committee discusses and agrees on a commodity specification and the analytical methods concerned, it states the following information in the Codex Standard:

1. Sampling Plans

The appropriate sampling plan, as outlined in the Guidelines for Sampling (CAC/GL 50-2004), Section 2.1.2 Guidelines on Sampling to control conformity of products with the specification. This should state:

- whether the specification applies to every item in a lot; **or** to the average in a lot, or the proportion non-conforming;
- the appropriate acceptable quality level to be used;
- the acceptance conditions of a lot controlled, in relation to the qualitative/quantitative characteristic determined on the sample.

2. Measurement Uncertainty

An allowance is to be made for the measurement uncertainty when deciding whether or not an analytical result falls within the specification. This requirement may not apply in situations when a direct health hazard is concerned, such as for food pathogens.

3. Recovery

Analytical results are to be expressed on a recovery corrected basis where appropriate and relevant, **and when corrected it has to be so stated.**

~~In all cases it has to be stated when the result is corrected for recovery.~~

If a result has been corrected for recovery, the method by which the recovery was taken into account should be stated. The recovery rate is to be quoted ~~where ever~~ **wherever** possible.

When laying down provisions for standards, it will be necessary to state whether the result obtained by a method used for analysis within conformity checks shall be expressed on an recovery-corrected basis or not..

4. Significant Figures

The units in which the results are to be expressed and the number of significant figures to be included in the reported result.