

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 4

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-fifth Session, FAO Headquarters, Rome (Italy), 30 June-7 July 2003

AMENDMENTS TO THE PROCEDURAL MANUAL

PROPOSED AMENDMENTS TO THE RULES OF PROCEDURE

Clarification of Rule VI.4 (Voting and Procedures)

1. The Commission is invited to consider an amendment to the Rules of Procedure of the Codex Alimentarius Commission proposed by the 15th Session of the Committee on General Principles as a means to improve procedures for the adoption of Codex standards and to facilitate consensus (see ALINORM 01/33, paras. 67-77). Comments were requested on this proposal by means of Codex Circular Letter CL 2000/12-GP; no comments were received. The text was subsequently submitted to the 24th Session of the Commission in 2001, but the quorum required to consider amendments or additions to the Rules of Procedure was not attained¹. The proposals are therefore being resubmitted for the Commission's consideration. The full text of the proposal is provided in Appendix I.

Proposed Amendments to the Rules of Procedure concerning the Membership of Regional Economic Integration Organizations

2. Under Article II.3 of the FAO Constitution, regional economic integration organizations may be admitted to membership of FAO. Member Organizations have the right to participate in matters within their competence in any meeting of a body of FAO in which any of its Member States is entitled to participate, unless otherwise provided in rules adopted by the FAO Conference. The FAO Constitution provides further that any references to Member Nations thereunder include Member Organizations, except as otherwise expressly provided. Member Organizations of FAO are also eligible for Membership in joint bodies of FAO such as the Codex Alimentarius Commission.

¹ Report of the Twenty-fourth Session of the Codex Alimentarius Commission, ALINORM 01/41, paragraph 69, FAO/WHO, Rome, 2001.

3. Pursuant to a request dated 28 February 2001 from the Government of Sweden, the Member State then holding the Presidency of the European Union, the matter of proposed amendments to the Procedural Manual concerning the Membership of Regional Economic Integration Organizations in the Codex Alimentarius Commission was discussed by the 16th Session of the Codex Committee on General Principles. The matter was also submitted to the 24th Session of the Commission but, as the quorum was not constituted, the Commission **decided** to defer the discussion of the proposed amendments until the next session and to request the Committee on General Principles to consider them thoroughly in order to clarify relevant issues and facilitate the debate at the next session.

4. The matter was subsequently discussed at the 17th Session of the Codex Committee on General Principles when certain amendments to the proposals were made. The Director-General of FAO also sought the views of the Committee on Constitutional and Legal Matters (CCLM), a Committee of the FAO Council, on the proposed amendments to the Rules of Procedure at its Seventy-fourth Session, 2 - 3 October 2002. The CCLM had found the proposed amendments to the Rules of Procedure of the Codex Alimentarius Commission to be consistent with the provisions governing the status of Member Organizations in FAO and, as requested, offered its views and appropriate guidance on the specific issues that had been raised, but noted that the question of participation of the Member Organization in the Executive Committee depended on the nature and functions of the latter and, as such, should be dealt with by the Codex Committee on General Principles and ultimately by the Commission. The CCLM also proposed some amendments to the proposals. The report of the CCLM was endorsed by the Council of FAO at its Hundred and Twenty-third Session in November 2002.

5. The 18th Session of the Codex Committee on General Principles (April 2003) considered the revised proposals and the views of the CCLM. The following extract from the report of this session² is included at the request of the Committee:

“74. The Representative of the Legal Counsel of FAO recalled that the matter had been discussed on several previous occasions, including the Committee’s 16th Session in April 2001, 17th Session in April 2002, and the Commission in June/July 2001. The Committee’s last session (2002) noted that the Director-General of FAO would be seeking the views of the Committee on Constitutional and Legal Matters (CCLM), a Committee of the FAO Council, on the proposed amendments to the Rules of Procedure at its Seventy-fourth Session, 2 - 3 October 2002. The CCLM had found the proposed amendments to the Rules of Procedure of the Codex Alimentarius Commission to be consistent with the provisions governing the status of Member Organizations in FAO and, as requested, offered its views and appropriate guidance on the specific issues that had been raised, but noted that the question of participation of the Member Organization in the Executive Committee depended on the nature and functions of the latter and, as such, should be dealt with by the Codex Committee on General Principles and ultimately by the Commission. The CCLM also proposed some amendments to the proposals, and these were before the Committee for discussion. The report of the CCLM was endorsed by the Council of FAO at its Hundred and Twenty-third Session in November 2002.

75. The Observer from the European Community noted that since the previous discussions on this subject, new legislation had entered into force in the European Union that required the European Community to take into account the international food standards of Codex when introducing new or harmonizing existing food legislation. Also, in accordance with its obligations under the SPS and TBT Agreements concerning the participation of Members of the WTO in the international standards-setting bodies, the European Community that it a member of WTO was looking forward to meeting these obligations as a Member of the Codex Alimentarius Commission.

76. The Observer from the EC submitted to the Committee the following declaration concerning the participation of the European Community in the Executive Committee:

Declaration by the European Community concerning Participation in the Executive Committee of the Codex Alimentarius Commission

Although the Committee on Constitutional and Legal Matters of the FAO considered that the participation of a Member Organization in the Executive Committee depended on the functions

² ALINORM 03/33A.

and activities of this Committee, the European Community declares formally that it gives up in every case the possibility of taking part in the proceeding of the Executive Committee when a Member State of the European Community is elected for the Region of Europe and that an agenda item would be of European Community competence.

77. In response to a question, it was noted that the question referred to in the above Declaration would not arise if a non-member state of the European Union was elected to the Executive Committee.

78. In response to questions raised by Members, the Observer from the European Community assured the Committee that the proposals guaranteed that there would be no additional rights or privileges accrued to members of Regional Economic Integration Organizations as a result of the changes to the Rules. The Committee welcomed the CCLM's endorsement of the proposal to limit voting rights to the number of members of Regional Economic Integration Organizations present at the time a vote was taken (Proposed Rule II.3). At the request of several delegations, a parallel provision was drafted and included in Proposed Rule II.8 on the matter of quorum.

79. Also in response to a question, the Committee noted that where the membership of a Regional Economic Integration Organization included Members of two or more Codex regions, the Organization can participate in all relevant regional Codex Committee meetings and at these meetings the number of votes to be exercised by the Regional Economic Integration Organization would not exceed the number of member states in each region (counted separately) and not the total membership of the organization.

80. Several delegations, while welcoming the changes allowing for the membership of Regional Economic Integration Organizations in Codex, stated that there were practical considerations to be taken into account, especially in the case of mixed competence between the Regional Economic Integration Organization and its member states. It was pointed out that this would put an additional burden on the Chairpersons of Codex meetings in their efforts to assess the consensus present.

81. In this regard the Delegation of the United States, supported by the Delegation of Australia, presented the following amendments to the proposals to clarify the question of competence:

**Changes Proposed by the United States to the
Proposed Amendments to the Rules of Procedure**

II.2. A Member Organization shall have the right to participate in matters within its competence in any meetings of the Commission or its subsidiary bodies in which any of its Member States is entitled to participate. ~~This is without prejudice to the possibility for the Member States to develop or support the position of the Member Organization in areas within its competence.~~

II.5. Before any meeting of the Commission or a subsidiary body of the Commission in which a Member Organization is entitled to participate, the Member Organization or its Member States shall indicate in writing which, as between the Member Organization and its Member States, has competence in respect of any specific question to be considered in the meeting and which, as between the Member Organization and its Member States, shall exercise the right to vote in respect of each particular agenda item. Nothing in this paragraph shall prevent a Member Organization or its Member States from making a single declaration in the Commission and each subsidiary body in which a Member Organization is entitled to participate for the purposes of this paragraph, which declaration shall remain in force for questions and agenda items to be considered at all subsequent meetings, subject to such exceptions or modifications as may be indicated before any individual meeting. Should the areas of respective competence between the Member Organization and its Member States change, the Member Organization and its Member States will declare the scope and timing of such change to the Commission and each subsidiary body in which a Member Organization is entitled to participate.

II.7. In cases where an agenda item covers both matters in respect of which competence has been transferred to the Member Organization and matter which lie within the competence of its Member States, both the Member Organization and its Member States may participate in the

discussions with respect to the specific matters on which each has competence. ~~In such cases the meeting, in arriving at its decisions, shall take into account only the intervention of the party which has the right to vote.~~

82. Several delegations stated their opposition to the changes to the proposed amendments. Concern was also expressed at the submission of such proposals at this stage, and as the proposals seemed to be contradictory to the expressed wishes of the delegation presenting the proposals, to preserve the rich diversity of opinion in debates within Codex.

83. Some delegations stated that if the proposals were aimed at assisting delegations and Chairpersons in understanding how to evaluate consensus when the competence between the Regional Economic Integration Organization and its member states was mixed, then this might be better addressed by developing appropriate guidelines.

Status of the Proposed Amendments to the Procedural Manual

84. The Committee agreed to transmit the proposed amendments as contained in Appendix III of this report to the Commission for its consideration. It noted that this section of the present report would also be attached to the working paper to be submitted to the Commission.”

6. The amendments proposed by the Committee on General Principles are contained in Appendix II.

Procedure for the Consideration and Adoption of Amendments to the Rules of Procedure

7. A majority of the Members of the Commission shall constitute a quorum for the purposes of adopting amendments of, or additions to, the Rules of Procedure (Rule IV.6). Amendments or additions to the Rules of Procedure are adopted by a two-thirds majority of the votes cast. They come into force upon approval of the Directors-General of FAO and WHO (Rule XII.1).

PROPOSALS TO AMEND OTHER SECTIONS OF THE PROCEDURAL MANUAL

8. The Commission is invited to consider the following proposals for amendment to other Sections of the Procedural Manual. These proposals may be adopted by a simple majority and come into force immediately upon adoption.

Amendments concerning Methods of Analysis and Sampling

9. The Codex Committee on Methods of Analysis and Sampling recommends an amendment to the current *General Criteria for the Selection of Methods of Analysis Using the Criteria Approach* (adopted in 2001) to extend the application of the criteria approach to Type II methods, in addition to Type III methods. The Committee also proposes to add a new section *Working Instructions for the Implementation of the Criteria Approach in Codex*, for inclusion at the end of the *Principles for the Establishment of Codex Methods of Analysis*. These Proposed Amendments have been endorsed by the Codex Committee on General Principles and are presented in Appendix III.

Measures to facilitate consensus

10. The 49th (Extraordinary) Session of the Executive Committee (September 2001) endorsed the proposals of the Committee on General Principles in this matter³. It recommended that the proposals, as set out below, be formally adopted as decisions of the Commission at its next session. General decisions of the Commission are normally published in the Appendix to the Procedural Manual. The proposals form part of the two reports of the Executive Committee and the Committee on General Principles, and have not been drafted in the form of a Commission decision. The Secretariat has provided a short introductory text that would allow them to be published as a decision of the Commission. These proposals are contained in Appendix IV.

³ ALINORM 01/33, paras 67-70 and ALINORM 03/3, para. 35.

Terms of Reference of Codex Committees and Task Forces

11. The Codex Committee on General Principles (17th Session, 2002) endorsed the proposal of the Codex Committee on Meat and Poultry Hygiene to amend its name to “Codex Committee on Meat Hygiene” and to amend its terms of reference⁴. See Appendix V.

⁴ ALINORM 03/33, paragraph 14.

APPENDIX I**PROPOSED AMENDMENT TO THE RULES OF PROCEDURE OF THE CODEX ALIMENTARIUS
COMMISSION****CLARIFICATION OF RULE VI.4 (VOTING AND PROCEDURES)**

Amend Rule VI.4 as follows (inclusion underlined):

Subject to the provisions of paragraph 5 of this Rule and paragraph 2 of Rule X, any Member of the Commission may request a roll-call vote, in which case the vote of each Member shall be recorded.

APPENDIX II

**PROPOSED AMENDMENT TO THE RULES OF PROCEDURE OF THE CODEX ALIMENTARIUS
COMMISSION****MEMBERSHIP OF REGIONAL ECONOMIC INTEGRATION ORGANIZATIONS**

Add a new Rule 1.3 to the Rules of Procedure, and re-number current Rule 1.3 as Rule 1.4:

“Membership shall also comprise regional economic integration organizations members of either FAO or WHO that notify the Director-General of FAO or WHO of their desire to be considered Members of the Commission”.

Add a new Rule to the Rules of Procedure after Rule I to read as follows:

“Rule II - Member Organizations

1. A Member Organization shall exercise membership rights on an alternative basis with its Member States that are Members of the Commission in the areas of their respective competence.
2. A Member Organization shall have the right to participate in matters within its competence in any meetings of the Commission or its subsidiary bodies in which any of its Member States is entitled to participate. This is without prejudice to the possibility for the Member States to develop or support the position of the Member Organization in areas within its competence.
3. A Member Organization may exercise on matters within its competence, in any meetings of the Commission or any subsidiary body of the Commission in which it is entitled to participate in accordance with paragraph 2, a number of votes equal to the number of its Member States which are entitled to vote in such meetings and present at the time the vote is taken. Whenever a Member Organization exercises its right to vote, its Member States shall not exercise theirs, and conversely.
4. A Member Organization shall not be eligible for election or designation, nor to hold office in the Commission or any subsidiary body. A Member Organization shall not participate in voting for any elective places in the Commission and its subsidiary bodies.
5. Before any meeting of the Commission or a subsidiary body of the Commission in which a Member Organization is entitled to participate, the Member Organization or its Member States shall indicate in writing which, as between the Member Organization and its Member States, has competence in respect of any specific question to be considered in the meeting and which, as between the Member Organization and its Member States, shall exercise the right to vote in respect of each particular agenda item. Nothing in this paragraph shall prevent a Member Organization or its Member States from making a single declaration in the Commission and each subsidiary body in which a Member Organization is entitled to participate for the purposes of this paragraph, which declaration shall remain in force for questions and agenda items to be considered at all subsequent meetings, subject to such exceptions or modifications as may be indicated before any individual meeting.
6. Any Member of the Commission may request a Member Organization or its Member States to provide information as to which, as between the Member Organization and its Member States, has competence in respect of any specific question. The Member Organization or the Member States concerned shall provide this information on such request.
7. In cases where an agenda item covers both matters in respect of which competence has been transferred to the Member Organization and matters which lie within the competence of its Member States, both the Member Organization and its Member States may participate in the discussions. In such

cases the meeting, in arriving at its decisions,⁵ shall take into account only the intervention of the party which has the right to vote.⁶

8. For the purpose of determining a quorum, as specified in paragraph 6 of Rule IV, the delegation of a Member Organization shall be counted for a number equal to the number of its Member States which are entitled to participate in the meeting and are present at the time the quorum is sought, to the extent that it is entitled to vote under the relevant agenda item.”

Renumber the subsequent Rules accordingly.

⁵ The word ‘decisions’ should be understood to mean both voting and situations where a decision is taken by consensus.

⁶ The above is without prejudice to the question of whether or not the views of the party not having the right to vote shall be reflected in the report of the meeting. Where the views of the party not having the right to vote are reflected in the report, the fact that they are the views of the party not having the right to vote shall also be reflected in the report.

APPENDIX III

PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL

AMENDMENTS TO THE GUIDELINES FOR THE INCLUSION OF SPECIFIC PROVISIONS IN
CODEX STANDARDS AND RELATED TEXTS**1. AMENDMENT TO THE GENERAL CRITERIA FOR THE SELECTION OF METHODS OF ANALYSIS USING THE CRITERIA APPROACH**

In the case of Codex **Type II and** Type III methods, method criteria may be identified and values quantified for incorporation into the appropriate Codex commodity standard. Method criteria which are developed will include the criteria in section Methods of Analysis, paragraph (c) above together with other appropriate criteria, e.g., recovery factors.”

2. WORKING INSTRUCTIONS FOR THE IMPLEMENTATION OF THE CRITERIA APPROACH IN CODEX

(for inclusion at the end of the *Principles for the Establishment of Codex Methods of Analysis* after the above *General Criteria*)

Any Codex Commodity Committee may continue to propose an appropriate method of analysis for determining the chemical entity, or develop a set of criteria to which a method used for the determination must comply. In some cases a Codex Commodity Committee may find it easier to recommend a specific method and request the Codex Committee on Methods of Analysis and Sampling (CCMAS) to “convert” that method into appropriate criteria. The Criteria will then be considered by the CCMAS for endorsement and will, after the endorsement, form part of the commodity standard replacing the recommended method of analysis. If a Codex Commodity Committee wishes to develop the criteria by itself rather than allowing the CCMAS to do so, it should follow instructions given for the development of specific criteria as outlined below. These criteria must be approved for the determination in question.

However, the primary responsibility for supplying methods of analysis and criteria resides with the Commodity Committee. If the Commodity Committee fails to provide a method of analysis or criteria despite numerous requests, then the CCMAS may supply an appropriate method and “convert” that method into appropriate criteria.

The minimum “approved” Codex analytical characteristics will include the following numeric criteria as well as the general criteria for methods laid down in the Analytical Terminology for Codex Use (see page 66):

- precision (within and between laboratories, but generated from collaborative trial data rather than measurement uncertainty considerations)
- recovery
- selectivity (interference effects etc.)
- applicability (matrix, concentration range and preference given to 'general' methods)
- detection/determination limits if appropriate for the determination being considered
- linearity

CCMAS will generate the data corresponding to the above criteria.

Conversion of Specific Methods of Analysis to Method Criteria by the CCMAS

When a Codex Commodity Committee submits a Type II or Type III method to CCMAS for endorsement, it should also submit information on the criteria listed below to enable the CCMAS to convert it into suitable generalized analytical characteristics:

- accuracy
- applicability (matrix, concentration range and preference given to 'general' methods)
- detection limit
- determination limit
- precision; repeatability intra-laboratory (within laboratory), reproducibility inter-laboratory (within laboratory and between laboratories), but generated from collaborative trial data rather than measurement uncertainty considerations
- recovery
- selectivity
- sensitivity
- linearity

These terms are defined in the Analytical Terminology for Codex Use (see page 66), as are other terms of importance.

The CCMAS will assess the actual analytical performance of the method which has been determined in its validation. This will take account of the appropriate precision characteristics obtained in collaborative trials which may have been carried out on the method together with results from other development work carried out during the course of the method development. The set of criteria that are developed will form part of the report of the CCMAS and will be inserted in the appropriate Codex Commodity Standard.

In addition, the CCMAS will identify numeric values for the criteria for which it would wish such methods to comply.

Assessment of the Acceptability of the Precision Characteristics of a Method of Analysis

The calculated repeatability and reproducibility values can be compared with existing methods and a comparison made. If these are satisfactory then the method can be used as a validated method. If there is no method with which to compare the precision parameters then theoretical repeatability and reproducibility values can be calculated from the Horwitz equation. (M. Thompson, *Analyst*, 2000, **125**, 385-386).

Additions to ANALYTICAL TERMINOLOGY FOR CODEX USE⁷

Terms to Be Used in the Criteria Approach

a) Detection Limit

The detection limit is conventionally defined as field blank + 3σ , where σ is the standard deviation of the field blank value signal (IUPAC definition).

However, an alternative definition which overcomes most of the objections to the above approach (i.e. the high variability at the limit of measurement can never be overcome) is to base it on the rounded value of the reproducibility relative standard deviation when it goes out of control (where $3\sigma_R = 100\%$; $\sigma_R = 33\%$, rounded to 50% because of the high variability). Such a value is directly related to the analyte and to the measurement system and is not based on the local measurement system.

b) Determination limit

As for detection limit except that 6σ or 10σ is required rather than 3σ .

⁷ These Definitions are proposed on an interim basis: they are subject to modification as a result of further harmonization.

However, an alternative definition that corresponds to that proposed for the detection limit is to use $\sigma_R = 25\%$. This value does not differ much from that assigned to the detection limit because the upper limit of the detection limit merges indistinguishably into the lower limit of the determination limit.

c) *Recovery*

Proportion of the amount of analyte present or added to the test material which is extracted and presented for measurement.

d) *Selectivity*

Selectivity is the extent to which a method can determine particular analyte(s) in mixtures or matrices without interferences from other components.

Selectivity is the recommended term in analytical chemistry to express the extent to which a particular method can determine analyte(s) in the presence of interferences from other components. Selectivity can be graded. The use of the term specificity for the same concept is to be discouraged as this often leads to confusion.

e) *Linearity*

The ability of a method of analysis, within a certain range, to provide an instrumental response or results proportional to the quantity of analyte to be determined in the laboratory sample. This proportionality is expressed by an a priori defined mathematical expression. The linearity limits are the experimental limits of concentrations between which a linear calibration model can be applied with a known confidence level (generally taken to be equal to 1%).

APPENDIX IV**PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL****ADDITION TO APPENDIX TO THE PROCEDURAL MANUAL: GENERAL DECISIONS OF THE COMMISSION****MEASURES TO FACILITATE CONSENSUS**

The Codex Alimentarius Commission, desiring that every effort should be made to reach agreement on the adoption or amendment of standards by consensus, recommends the following measures to facilitate consensus:

- Refraining from submitting proposals in the step process where the scientific basis is not well established on current data and, where necessary, carry out further studies in order to clarify controversial issues;
 - Providing for thorough discussions and documentation of the issues at meetings of the committees concerned;
 - Organizing informal meetings of the parties concerned where disagreements arise, provided that the objectives of any such meetings are clearly defined by the Committee concerned and that participation is open to all interest delegations and observers in order to preserve transparency;
 - Redefining, where possible, the scope of the subject matter being considered for the elaboration of standards in order to cut out issues on which consensus could not be reached;
 - Providing that matters are not progressed from step to step until all relevant concerns are taken into account and adequate compromises worked out;
 - Emphasizing to Committees and their Chairpersons that matters should not be passed on to the Commission until such time as consensus has been achieved at the technical level;
 - Facilitating the increased involvement and participation of developing countries.
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APPENDIX V**PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL
TERMS OF REFERENCE OF CODEX COMMITTEES AND TASK FORCES**

Amend the name and terms of reference of the Codex Committee on Meat and poultry Hygiene to read as follows:

CODEX COMMITTEE ON MEAT HYGIENE (CX-723)

To elaborate world-wide standards and/or codes of practice as appropriate for meat hygiene.