

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 3

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

*Twenty-seventh Session, International Conference Centre, Geneva, Switzerland
28th June – 3rd July 2004*

AMENDMENTS TO THE PROCEDURAL MANUAL

A. PROPOSED AMENDMENTS TO THE RULES OF PROCEDURE

1. The Commission is invited to consider the following proposals for amendment to the Rules of Procedure of the Procedural Manual. 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).

Amendments concerning the enlargement of the Executive Committee, the functions of the Executive Committee and matters related to budget and expenses.

2. The Commission is invited to consider the amendments to the Rules of Procedure (Rules III. Officers, Rule IV. Executive Committee and Rule XIII. Budget and expenses), proposed by the 19th Session of the Committee on General Principles, to implement the decision the 26th Session of the Codex Alimentarius Commission as a result of the Joint FAO/WHO Evaluation of the Codex Alimentarius and other FAO and WHO Work on Food Standards (see ALINORM 04/27/33, paras. 7-33).

3. Consequential to the amendments proposed for Rule IV. Executive Committee, the Commission is also invited to adopt the deletion of obsolete phrases in Rule X.5 and Rule X.10.

4. The full text of the proposal is provided in Appendix I.

Proposed Amendments to Rule VIII.5 - Observers of the Rules of Procedure

5. The Codex Alimentarius Commission, at its Twenty-sixth Session, in connection with the consideration of the Joint FAO/WHO Evaluation of the Codex Alimentarius and other FAO and WHO Work on Food Standards, requested the "FAO and WHO Legal Counsels and the Secretariat to prepare a preliminary paper on Rule VIII.5 of the Rules of Procedure of the Commission, for consideration by the Committee on General Principles". The Commission requested further the Committee on General Principles to revise Rule VIII.5 on the basis of a paper to be presented by the Legal Counsels, and to submit its proposals to the Commission in 2004, if possible. The

proposed amendments to the Rules of Procedure of the Codex Alimentarius Commission were reviewed by the FAO Committee on Constitutional and Legal Matters, at its Seventy-sixth Session, held on 30 March 2004.

6. The Commission is invited to consider the amendments to the Rule VIII.5 of the Rules of Procedure forwarded by the 20th Session of the Codex Committee on General Principles (see ALINORM 04/27/33A, paras. 31-36).

7. The full text of the proposal is provided in Appendix II.

B. 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 to the procedures for the elaboration of Codex Standards and related texts

9. The 20th Session of the Codex Committee on General Principles agreed to forward to the Commission, for adoption, the amendments to the procedure for the elaboration of Codex standards and related texts, that allow the Executive Committee to carry out its standard management functions as per the decision by the 26th Session of the Codex Alimentarius Commission and as a result of the Joint FAO/WHO Evaluation of the Codex Alimentarius (see ALINORM 04/27/33, paras. 55-76).

10. The 20th Session of the Codex Committee on General Principles endorsed the amendment proposed to paragraph 4 of the Critical Review proposed by the 19th (Extraordinary) Session of the Committee to the effect that “methods of analysis and sampling plans” related to the General Standard for Food Additives and the General Standard for Contaminants and Toxins in Foods should be subject to the procedures established by the Committees concerned and endorsed by the Commission. (see ALINORM 04/27/33A, para. 30).

11. The full text of the proposal is provided in Appendix III.

Advice to Host countries: Draft criteria for the appointment of Chairpersons and Draft Guidelines to Host Governments of Codex Committees and *ad hoc* Intergovernmental Task Forces

12. The 19th Session of the Codex Committee on General Principles agreed to forward to the Commission, for adoption, the Draft Criteria for the appointment of chairpersons and the Draft Guidelines to Host Governments of Codex Committees and *ad hoc* Intergovernmental Task Forces developed at the request of the 26th Session of the Codex Alimentarius Commission, in connection with the consideration of the Joint FAO/WHO Evaluation of the Codex Alimentarius and other FAO and WHO Work on Food Standards (see ALINORM 04/27/33, paras. 84-91).

13. The full texts of the proposals are provided in Appendix IV and V.

Conduct of Meetings: Draft Guidelines on the Conduct of Meetings of Codex Committees and *ad hoc* Intergovernmental Task Forces and Draft Guidelines to Chairpersons of Codex Committees and *ad hoc* Intergovernmental Task Forces

14. The 19th Session of the Codex Committee on General Principles agreed to forward to the Commission, for adoption, the Draft Guidelines on the Conduct of Meetings of Codex Committees and *ad hoc* Intergovernmental Task Forces and Draft Guidelines to Chairpersons of Codex Committees and *ad hoc* Intergovernmental Task Forces developed at the request of the 26th Session of the Codex Alimentarius Commission, in connection with the consideration of the Joint FAO/WHO Evaluation of the Codex Alimentarius and other FAO and WHO Work on Food Standards (see ALINORM 04/27/33, paras. 92-103).

15. The full texts of the proposals are provided in Appendix VI and VII.

Amendments concerning Methods of Analysis and Sampling

Single laboratory validated methods of analysis.

16. The 24th session of the Codex Committee on Pesticide Residues had proposed criteria of a general nature for the selection of single-laboratory validated methods of analysis, to be included in the Procedural Manual after the General Criteria, in order to recognize that inter-laboratory validation of methods of analysis was not always available and applicable for multi-residue analysis purposes.

17. The Commission is invited to consider the proposed General Criteria for Selection of Single-Laboratory Validated Methods of Analysis endorsed by the 25th session of the Codex Committee on Methods of Analysis and Sampling and, subsequently, the 20th session of the Codex Committee on General Principles (see ALINORM 04/27/33A, paras 10-12).

18. The full text of the proposal is provided in Appendix VIII.

Analytical terminology.

19. The Commission is invited to consider the proposed Amendments to the Analytical Terminology for Codex Use of the Procedural Manual, forwarded by the 25th session of the Codex Committee on Methods of Analysis and Sampling and endorsed by the 20th session of the Codex Committee on General Principles (see ALINORM 04/27/33A, paras 13-14).

20. The full text of the proposal is provided in Appendix IX.

Definitions for Food Safety Objective, Performance Objective, and Performance Criterion

21. The Committee on Food Hygiene had developed definitions for Food Safety Objective, Performance Objective, and Performance Criterion while discussing the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management. The Committee had agreed to forward these definitions to the Committee on General Principles for endorsement and subsequent adoption by the Commission, and inclusion in the Procedural Manual in the section on Definitions of Risk Analysis Terms Related to Food Safety.

22. The 20th Session of the Codex Committee on General Principles agreed to forward the definitions for adoption on an interim basis to the 27th Session of the Commission (see ALINORM 04/27/33A, paras. 15-21).

23. The Committee also agreed to forward the definitions to the Committee on Pesticide Residues, the Committee on Food Additives and Contaminants, the Committee on Residues of Veterinary Drugs in Foods, the Committee on Meat Hygiene, and the Committee on Food Import and Export Inspection and Certification Systems, with the understanding that the Committee on General Principles would reconsider the definitions if required in the light of the advice of these Committees at its 23rd Session in 2006.

24. The full text of the proposal is provided in Appendix X.

Definition of traceability/product tracing

25. The Commission is invited to consider the proposed definition of Traceability / Product tracing forwarded by the 20th Session of the Codex Committee on General Principles for inclusion in the Procedural Manual (see ALINORM 04/27/33A, paras. 85-96).

26. The full text of the proposal is provided in Appendix XI.

APPENDIX I

PROPOSED AMENDMENT TO THE RULES OF PROCEDURE OF THE CODEX ALIMENTARIUS COMMISSION

(New text and numbering appear in bold)

RULE III. OFFICERS¹

1. The Commission shall elect a Chairperson and three Vice-Chairpersons from among the representatives, alternates and advisers (hereinafter referred to as “delegates”) of the Members of the Commission; it being understood that no delegate shall be eligible without the concurrence of the head of his delegation. They shall be elected at each session and shall hold office from the end of the session at which they were elected until the end of the following regular session. The Chairperson and Vice-Chairpersons may remain in office only with the continuing endorsement of the respective Member of the Commission of which they were a delegate at the time of election. The Directors-General of FAO and WHO shall declare a position vacant when advised by the Member of the Commission that such endorsement has ceased. The Chairperson and Vice-Chairpersons shall be eligible for re-election but after having served two consecutive terms shall be ineligible to hold such office for the next succeeding term.
2. The Chairperson, or in his absence a Vice-Chairperson, shall preside at meetings of the Commission and exercise such other function as may be required to facilitate the work of the Commission. A Vice-Chairperson acting as Chairperson shall have the same powers and duties as the Chairperson.
3. When neither the Chairperson nor the Vice-Chairperson are able to serve and, on the request of the outgoing Chairperson, during elections for the Chairperson, the Directors-General of FAO and WHO shall appoint a staff member to act as Chairperson, until either a temporary Chairperson or a new Chairperson has been elected. Any temporary Chairperson so elected shall hold office until the Chairperson or one of the Vice-Chairpersons is able to serve again.
4. The Commission may appoint one or more rapporteurs from among the delegates of the Members of the Commission.
5. The Directors-General of FAO and WHO shall be requested to appoint from the staffs of their organizations a Secretary of the Commission and such other officials, likewise responsible to them, as may be necessary to assist the officers and the Secretary in performing all duties that the work of the Commission may require.

RULE IV. COORDINATORS

1. The Commission may appoint a Coordinator from among the Members of the Commission for any of the geographic locations enumerated in **Rule V.1** (hereinafter referred to as “regions”) or for any group of countries specifically enumerated by the Commission (hereinafter referred to as ‘groups of countries’), whenever it may find, on the basis of a proposal of a majority of the Members of the Commission which constitute the region or group, that work for the Codex Alimentarius in the countries concerned so requires.
2. Appointment of Coordinators shall be made exclusively on the proposal of a majority of the Members of the Commission which constitute the region or group of countries concerned. Coordinators shall hold office from the end of the session of the Commission at which they were appointed until not later than the end of the third succeeding regular session, the precise term being determined by the Commission in each instance. After having served two consecutive terms, the Coordinators shall be ineligible to hold such office for the next succeeding term.
3. The functions of the Coordinators shall be:

¹ Reference is made to the 13th Edition of the Procedural Manual.

- (i) to assist and coordinate the work of the Codex Committees set up under **Rule XI.1(b)(i)**² in their region or group of countries in the preparation of draft standards, guidelines and other recommendations for submission to the Commission;
- (ii) to assist the Executive Committee and the Commission, as required, by advising them of the views of countries and recognized regional intergovernmental and non-government organizations in their respective regions on matters under discussion or of interest.

~~(d) In order to carry out their functions, Coordinators shall participate in the Executive Committee as Observers.~~

RULE V. EXECUTIVE COMMITTEE³

1. The Executive Committee shall consist of the Chairperson and the Vice-Chairpersons of the Commission, and the Coordinators appointed on the basis of Rule IV together with seven further Members elected by the Commission at regular sessions from among the Members of the Commission, one each coming from the following geographic locations: Africa, Asia, Europe, Latin America and the Caribbean, Near East, North America, South-West Pacific. Not more than one delegate from any one country shall be a member of the Executive Committee. Members elected on a geographic basis shall hold office from the end of the session of the Commission at which they were elected until the end of the second succeeding regular session and shall be eligible for re-election, but after having served two consecutive terms shall be ineligible to hold such office for the next succeeding term.
2. The Executive Committee shall, between sessions of the Commission, act on behalf of the Commission as its executive organ. In particular, the Executive Committee may make proposals to the Commission regarding general orientation, strategic planning, and programming of the work of the Commission, study special problems and shall assist in the management of the Commission's programme of standards development, namely by conducting a critical review of proposals to undertake work and monitoring the progress of standards development.
3. The Executive Committee shall consider specific matters referred to it by the Directors-General of FAO and WHO as well as the estimate of expenditure for the Commission's proposed programme of work as described in Rule XIII.1⁴.
4. The Executive Committee may establish such sub-committees from among its Members as it may deem necessary to enable it to exercise its functions as effectively as possible. Such sub-committees should be limited in numbers, carry out preparatory work and report to the Executive Committee. The Executive Committee shall appoint one of the Vice-Chairpersons of the Commission to serve as chairpersons of any such sub-committee. Consideration should be given to an appropriate geographical balance in the membership of sub-committees.
5. The Chairperson and Vice-Chairpersons of the Commission shall be respectively the Chairperson and Vice-Chairpersons of the Executive Committee.
6. Sessions of the Executive Committee may be convened as often as necessary by the Directors-General of FAO and WHO, in consultation with the Chairperson. The Executive Committee shall normally meet immediately prior to each session of the Commission.
7. The Executive Committee shall report to the Commission.

² Rule X.1 (b)(i) in the 13th Edition of the Procedural Manual. Changes in numbering are due to the presentation of the section on Coordinators as a separate Rule IV.

³ Rule IV in the 13th Edition of the Procedural Manual.

⁴ Rule XII.1 in the 13th Edition of the Procedural Manual

RULE XIII. BUDGET AND EXPENSES⁵

1. The Directors-General of FAO and WHO shall prepare for consideration by the Commission at its regular sessions an estimate of expenditure based on the proposed programme of work of the Commission and its subsidiary bodies, together with information concerning expenditures for the previous financial period. This estimate, with such modifications as may be considered appropriate by the Directors-General in the light of recommendations made by the Commission, shall subsequently be incorporated in the Regular Budgets of the two Organizations for approval by the appropriate governing bodies.
2. The estimate of expenditure shall make provisions for the operating expenses of the Commission and the subsidiary bodies of the Commission established under **Rule XI.1(a) and XI.1(b)(ii)**⁶ and for the expenses relating to staff assigned to the Programme and other expenditures incurred in connection with the servicing of the latter.
3. **The estimate of expenditure shall make provision for the travel expenses (including a daily subsistence allowance) of members of the Executive Committee from developing countries for the purpose of participating in meetings of the Executive Committee.**
4. The operating costs of subsidiary bodies established under **Rule XI.1(b)(i)**⁶ (Codex Committees) shall be borne by each Member accepting the Chair of such a body. The estimate of expenditure may include a provision for such costs involved in preparatory work as may be recognized as operating expenses of the Commission in accordance with the provisions of Article 10 of the Statutes of the Commission.
5. **Except as provided for in Rule XIII. 3, the estimate of expenditure shall make no provision for expenses, including travel, incurred by delegations of the Members of the Commission or of observers referred to in Rule IX⁷, in connection with their attendance at sessions of the Commission or its subsidiary bodies.** Should experts be invited by the Directors-General of FAO or WHO to attend sessions of the Commission and its subsidiary bodies in their individual capacity, their expenses shall be borne out of the regular budgetary funds available for the work of the Commission.

Consequential Amendments to the Rules of Procedure

Rule X Subsidiary Bodies

[1. – 4.]

5. Subsidiary bodies may only be established by the Commission except where otherwise provided in these Rules. Their terms of reference and reporting procedures shall be determined by the Commission, ~~except where otherwise provided in these Rules.~~

[6. – 9.]

10. The Members who shall be responsible for appointing Chairpersons of subsidiary bodies established under Rule X.1(b)(i) and Rule X.1(b)(ii) shall be designated at each session by the Commission, ~~except where otherwise provided in these Rules,~~ and shall be eligible for re-designation. All other officers of subsidiary bodies shall be elected by the body concerned and shall be eligible for re-election.

[11.]

⁵ Rule XII in the 13th Edition of the Procedural Manual.

⁶ Rule X.1(a) and X.1 (b) in the 13th Edition of the Procedural Manual.

⁷ Rule VIII in the 13th Edition of the Procedural Manual.

APPENDIX II**PROPOSED AMENDMENT TO THE RULES OF PROCEDURE OF THE CODEX ALIMENTARIUS
COMMISSION****RULE VIII. OBSERVERS**

[1. – 4.]

5. Participation of intergovernmental organizations in the work of the Commission and the relations between the Commission and such organizations shall be governed by the relevant provisions of the Constitutions of FAO or WHO, as well as by the applicable regulations of FAO or WHO on relations with intergovernmental organizations; such relations shall be handled by the Director-General of FAO or WHO, as appropriate.

6. Participation of international non-governmental organizations in the work of the Commission and the relations between the Commission and such organizations shall be governed by the relevant provisions of the Constitution of FAO or WHO, as well as by applicable regulations of FAO or WHO on relations with international non-governmental organizations. Such relations shall be handled by the Director-General of FAO or WHO, as appropriate, on the advice of the Executive Committee. The Commission shall develop and keep under review principles and criteria concerning the participation of international non-governmental organizations in its work, consistent with the applicable regulations of FAO or WHO.

APPENDIX III

PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL
PROPOSED AMENDMENTS TO THE PROCEDURES FOR THE ELABORATION OF CODEX
STANDARDS AND RELATED TEXTS

Note: Throughout this text the word “Standard” is meant to include any of the recommendations of the Commission intended to be submitted to Governments for acceptance. Except for provisions relating to acceptance, the Procedures apply *mutatis mutandis* to codes of practice and other texts of an advisory nature.

INTRODUCTION

The full procedure for the elaboration of Codex standards is as follows.

- 1. The Commission shall implement a unified approach in the area of standards development by taking its decisions, based on a strategic planning process (“standards management”) (See Part 1 of this document).**
- 2. An on-going critical review shall ensure that proposals for new work and draft standards submitted to the Commission for adoption continue to meet the strategic priorities of the Commission and can be developed within a reasonable period of time, taking into account the requirements and availability of scientific expert advice (See Part 2 of this document).**
3. The Commission decides, taking into account the **outcome of the on-going critical review conducted by the Executive Committee**, that a standard should be elaborated and also which subsidiary body or other body should undertake the work. Decisions to elaborate standards may also be taken by subsidiary bodies of the Commission in accordance with the above-mentioned **outcome** subject to subsequent approval by the Commission at the earliest possible opportunity. The Secretariat arranges for the preparation of a “proposed draft standard” which is circulated to governments for comments and is then considered in the light of these by the subsidiary body concerned which may present the text to the Commission as a “draft standard”. If the Commission adopts the “draft standard” it is sent to governments for further comments and in the light of these and after further consideration by the subsidiary body concerned, the Commission reconsiders the draft and may adopt it as a “Codex standard”. The procedure is described in Part 3 of this document.
4. The Commission or any subsidiary body, subject to the confirmation of the Commission may decide that the urgency of elaborating a Codex standard is such that an accelerated elaboration procedure should be followed. While taking this decision, all appropriate matters shall be taken into consideration, including the likelihood of new scientific information becoming available in the immediate future. The accelerated elaboration procedure is described in Part 4 of this document.
5. The Commission or the subsidiary body or other body concerned may decide that the draft be returned for further work at any appropriate previous Step in the Procedure. The Commission may also decide that the draft be held at Step 8.
6. The Commission may authorise, on the basis of two-thirds majority of votes cast, the omission of Steps 6 and 7, where such an omission is recommended by the Codex Committee entrusted with the elaboration of the draft. Recommendations to omit steps shall be notified to Members and interested international organizations as soon as possible after the session of the Codex Committee concerned. When formulating recommendations to omit Steps 6 and 7, Codex Committees shall take all appropriate matters into consideration, including the need for urgency, and the likelihood of new scientific information becoming available in the immediate future.
7. The Commission may at any stage in the elaboration of a standard entrust any of the remaining Steps to a Codex Committee or other body different from that to which it was previously entrusted.
8. It will be for the Commission itself to keep under review the revision of “Codex standards”. The procedure for revision should, *mutatis mutandis*, be that laid down for the elaboration of Codex standards, except that the Commission may decide to omit any other step or steps of that Procedure where, in its opinion, an amendment

proposed by a Codex Committee is either of an editorial nature or of a substantive nature but consequential to provisions in similar standards adopted by the Commission at Step 8.

9. Codex standards are published and governments are invited to notify the Commission's Secretariat of the status or use of the Codex standard in accordance with their established legal and administrative procedures. They are also sent to international organizations to which competence in the matter has been transferred by their Member States (See Part 5 of this document). Details of notifications are published periodically by the Commission's Secretariat.

PART 1. STRATEGIC PLANNING PROCESS

1. Taking into account the “*Criteria for the Establishment of Work Priorities*”, the strategic plan shall state broad priorities against which individual proposals for standards (and revision of standards) can be evaluated during the critical review process.

2. The strategic plan shall cover a six-year period and shall be renewed every two years on a rolling basis.

PART 2. CRITICAL REVIEW

Proposals to Undertake New Work or to Revise a Standard

1. Prior to approval for development, each proposal for new work or revision of a standard, shall be accompanied by a project document, prepared by the Committee or Member proposing new work or revision of a standard, detailing :

- the purposes and the scope of the standard ;
- its relevance and timeliness ;
- the main aspects to be covered ;
- an assessment against the *Criteria for the establishment of work priorities* ;
- relevance to the Codex strategic objectives ;
- information on the relation between the proposal and other existing Codex documents;
- identification of any requirement for and availability of expert scientific advice ;
- identification of any need for technical input to the standard from external bodies so that this can be planned for;
- the proposed time-line for completion the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission ; the time frame for developing a standard should not normally exceed five years.

2. The decision to undertake new work or to revise standards shall be taken by the Commission on the basis a critical review conducted by the Executive Committee.

3. The critical review includes:

- examination of proposals for development/revision of standards, taking into account the “*Criteria for the Establishment of Work Priorities*”, the strategic plan of the Commission and the required supporting work of independent risk assessment;
- identifying the standard setting needs of developing countries;
- advice on establishment and dissolution of committees and task forces, including *ad hoc* cross-committee task forces (in areas where work falls within several committee mandates); and

- preliminary assessment of the need for expert scientific advice and the availability of such advice from FAO, WHO or other relevant expert bodies, and the prioritisation of that advice.

4. The decision to undertake new work or revision of individual maximum residue limits for pesticides or veterinary drugs, or the maintenance of the General Standard on Food Additives⁸, the General Standard on contaminants and toxins in foods⁹, the Food categorization system and the International numbering System, shall follow the procedures established by the Committees concerned and endorsed by the Commission.

Monitoring Progress of Standards Development

5. The Executive Committee shall review the status of development of draft standards against the time frame agreed by the Commission and shall report its findings to the Commission.

6. The Executive Committee may propose an extension of the time frame; cancellation of work; or propose that the work be undertaken by a Committee other than the one to which it was originally entrusted, including the establishment of a limited number of ad hoc subsidiary bodies, if appropriate.

7. The critical review process shall ensure that progress in the development of standards is consistent with the envisaged time frame, that draft standards submitted to the Commission for adoption have been fully considered at Committee level, and that they are technically and legally sound.

8. Monitoring shall take place against the time line deemed necessary and revisions in the coverage of the standard shall need to be specifically endorsed by the Commission.

This shall therefore include:

- monitoring of progress in developing standards and advising what corrective action should be taken;
- examining proposed standards from Codex committees, before they are submitted to the Commission for adoption :
 - for consistency with the mandate of Codex, the decisions of the Commission, and existing Codex texts;
 - to ensure that the requirements of the endorsement procedure have been fulfilled, where appropriate,
 - for format and presentation, and
 - for linguistic consistency.

PART 3: UNIFORM PROCEDURE FOR THE ELABORATION OF CODEX STANDARDS AND RELATED TEXTS

Steps 1, 2 and 3

(1) The Commission decides, taking into account the **outcome of the critical review conducted by the Executive Committee**, to elaborate a World-wide Codex Standard and also decides which subsidiary body or other body should undertake the work. A decision to elaborate a World-wide Codex Standard may also be taken by subsidiary bodies of the Commission in accordance with the above mentioned **outcome**, subject to subsequent approval by the Commission at the earliest possible opportunity. In the case of Codex Regional Standards, the Commission shall base its decision on the proposal of the majority of Members belonging to a

⁸ including related methods of analysis and sampling plans

⁹ including related methods of analysis and sampling plans

given region or group of countries submitted at a session of the Codex Alimentarius Commission.

- (2) The Secretariat arranges for the preparation of a proposed draft standard. In the case of Maximum Limits for Residues of Pesticides or Veterinary Drugs, the Secretariat distributes the recommendations for maximum limits, when available from the Joint Meetings of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues (JMPR), or the Joint FAO/WHO Expert Committee on Food Additives (JECFA). **Any other relevant information regarding risk assessment work conducted by FAO and WHO should also be made available.** In the cases of milk and milk products or individual standards for cheeses, the Secretariat distributes the recommendations of the International Dairy Federation (IDF).
- (3) The proposed draft standard is sent to Members of the Commission and interested international organizations for comment on all aspects including possible implications of the proposed draft standard for their economic interests.

Step 4

The comments received are sent by the Secretariat to the subsidiary body or other body concerned which has the power to consider such comments and to amend the proposed draft standard.

Step 5

The proposed draft standard is submitted through the Secretariat **to the Executive Committee for critical review and to the Commission** with a view to its adoption as a draft standard¹⁰. In taking any decision at this step, the Commission will give due consideration to **the outcome of the critical review and** to any comments that may be submitted by any of its Members regarding the implications which the proposed draft standard or any provisions thereof may have for their economic interests. In the case of Regional Standards, all Members of the Commission may present their comments, take part in the debate and propose amendments, but only the majority of the Members of the region or group of countries concerned attending the session can decide to amend or adopt the draft. In taking any decisions at this step, the Members of the region or group of countries concerned will give due consideration to any comments that may be submitted by any of the Members of the Commission regarding the implications which the proposed draft standard or any provisions thereof may have for their economic interests.

Step 6

The draft standard is sent by the Secretariat to all Members and interested international organizations for comment on all aspects, including possible implications of the draft standard for their economic interests.

Step 7

The comments received are sent by the Secretariat to the subsidiary body or other body concerned, which has the power to consider such comments and amend the draft standard.

Step 8

The draft standard is submitted through the Secretariat **to the Executive Committee for critical review and to the Commission**, together with any written proposals received from Members and interested international organizations for amendments at Step 8, with a view to its adoption as a Codex standard. In the case of Regional standards, all Members and interested international organizations may present their comments, take part in the debate and propose amendments but only the majority of Members of the region or group of countries concerned

¹⁰ Without prejudice to **the outcome of the critical review conducted by the Executive Committee and/or** any decision that may be taken by the Commission at Step 5, the proposed draft standard may be sent by the Secretariat for government comments prior to its consideration at Step 5, when, in the opinion of the subsidiary body or other body concerned, the time between the relevant session of the Commission and the subsequent session of the subsidiary body or other body concerned requires such action in order to advance the work

attending the session can decide to amend and adopt the draft.

PART 4: UNIFORM ACCELERATED PROCEDURE FOR THE ELABORATION OF CODEX STANDARDS AND RELATED TEXTS

Steps 1, 2 and 3

- (1) The Commission, on the basis of a two-thirds majority of votes cast, taking into account the **outcome of the critical review conducted by the Executive Committee**, shall identify those standards which shall be the subject of an accelerated elaboration process.¹¹ The identification of such standards may also be made by subsidiary bodies of the Commission, on the basis of a two-thirds majority of votes cast, subject to confirmation at the earliest opportunity by the Commission.
- (2) The Secretariat arranges for the preparation of a proposed draft standard. In the case of Maximum Limits for Residues of Pesticides or Veterinary Drugs, the Secretariat distributes the recommendations for maximum limits, when available from the Joint Meetings of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues (JMPR), or the Joint FAO/WHO Expert Committee on Food Additives (JECFA). **Any other relevant information regarding risk assessment work conducted by FAO and WHO should also be made available.** In the cases of milk and milk products or individual standards for cheeses, the Secretariat distributes the recommendations of the International Dairy Federation (IDF).
- (3) The proposed draft standard is sent to Members of the Commission and interested international organizations for comment on all aspects including possible implications of the proposed draft standard for their economic interests. When standards are subject to an accelerated procedure, this fact shall be notified to the Members of the Commission and the interested international organizations.

Step 4

The comments received are sent by the Secretariat to the subsidiary body or other body concerned which has the power to consider such comments and to amend the proposed draft standard.

Step 5

In the case of standards identified as being subject to an accelerated elaboration procedure, the draft standard is submitted through the Secretariat **to the Executive Committee for critical review and to the Commission**, together with any written proposals received from Members and interested international organizations for amendments, with a view to its adoption as a Codex standard. In taking any decision at this step, the Commission will give due consideration to any comments that may be submitted by any of its Members regarding the implications which the proposed draft standard or any provisions thereof may have for their economic interests.

GUIDE TO THE PROCEDURE FOR THE REVISION AND AMENDMENT OF CODEX STANDARDS

1. Proposals for the amendment or revision of Codex standards should be submitted to the Commission's Secretariat in good time (not less than three months) before the session of the Commission at which they are to be considered. The proposer of an amendment should indicate the reasons for the proposed amendment and should also state whether the proposed amendment had been previously submitted to and considered by the Codex committee concerned and/or the Commission. If the proposed amendment has already been considered by the Codex committee and/or Commission, the outcome of the consideration of the proposed amendment should be stated.
2. Taking into account such information regarding the proposed amendment, as may be supplied in accordance with paragraph 1 above, **and the outcome of the on-going critical review conducted by the Executive**

¹¹ Relevant considerations could include, but need not be limited to, matters concerning new scientific information; new technology(ies); urgent problems related to trade or public health; or the revision or up-dating of existing standards.

Committee, the Commission will decide whether the amendment or revision of a standard is necessary. If the Commission decides in the affirmative, and the proposer of the amendment is other than a Codex committee, the proposed amendment will be referred for consideration to the appropriate Codex committee, if such committee is still in existence. If such committee is not in existence, the Commission will determine how best to deal with the proposed amendment. If the proposer of the amendment is a Codex committee, it would be open to the Commission to decide that the proposed amendment be circulated to governments for comments prior to further consideration by the sponsoring Codex Committee. In the case of an amendment proposed by a Codex Committee, it will also be open to the Commission to adopt the amendment at Step 5 or Step 8 as appropriate, where in its opinion the amendment is either of an editorial nature or of a substantive nature but consequential to provisions in similar standards adopted by it at Step 8.

3. The procedure for amending or revising a Codex standard would be as laid down in paragraphs **5** and **6** of the Introduction to the Procedure for the Elaboration of Codex Standards (see page .. above).
 4. When the Commission has decided to amend or revise a standard, the unrevised standard will remain the applicable Codex standard until the revised standard has been adopted by the Commission.
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APPENDIX IV**PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL****DRAFT CRITERIA FOR THE APPOINTMENT OF CHAIRPERSONS**

By virtue of Article 7 of its Statutes, the Commission may establish such subsidiary bodies as it deems necessary for the accomplishment of its task.

The Member countries who shall be designated, under Rule X.10¹², as responsible for appointing Chairpersons of subsidiary bodies established under Rule X.1(b)(i) and Rule X.1(b)(ii), shall retain the right to appoint a chairperson of their choice.

The following criteria may be considered during the selection of the appointee:

- to be a national of the member country responsible for appointing the chairperson of the Committee;
 - to have a general knowledge in the fields of the subsidiary body concerned and to be able to understand and analyse technical issues;
 - insofar as possible, to be able to serve in a continuing capacity;
 - to be familiar with the system of Codex and its rules, and to have experience in the work of relevant international, governmental or non-governmental organizations;
 - to be able to communicate clearly both orally and in writing in one of the working languages of the Commission;
 - to have demonstrated ability in chairing meetings with objectivity and impartiality, and in facilitating consensus building;
 - to exercise tact and sensitivity to issues of particular importance to members of the Commission;
 - not to engage and/or not to have engaged in activities which could give rise to a conflict of interest on any item on the agenda of the Committee.
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¹²

APPENDIX V

PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL**DRAFT GUIDELINES TO HOST GOVERNMENTS OF CODEX COMMITTEES AND AD HOC INTERGOVERNMENTAL TASK FORCES****INTRODUCTION**

By virtue of Article 7 of the Statutes of the Codex Alimentarius Commission and Rule X.1(b)¹³ of its Rules of Procedure, the Commission has established a number of Codex Committees and *ad hoc* Intergovernmental Task Forces to prepare standards in accordance with the Procedure for the Elaboration of Codex Standards and Coordinating Committees to exercise general coordination of its work in specific regions or groups of countries. The Rules of Procedure of the Commission shall apply, *mutatis mutandis*, to Codex Committees, Coordinating Committees and *ad hoc* Intergovernmental Task Forces. The Guidelines applying to Codex Committees, as described in this Section, apply also to Coordinating Committees and to Codex *ad hoc* Intergovernmental Task Forces.

COMPOSITION OF CODEX COMMITTEES**MEMBERSHIP**

Membership of Codex Committees is open to Members of the Commission who have notified the Director-General of FAO or WHO of their desire to be considered as members thereof or to selected members designated by the Commission. Membership of Regional Coordinating Committees is open only to Members of the Commission belonging to the region or group of countries concerned.

OBSERVERS

Any other Member of the Commission or any Member or Associate Member of FAO or WHO which has not become a Member of the Commission may participate as an observer at any Codex Committee if it has notified the Director-General of FAO or WHO of its wish to do so. Such countries may participate fully in the discussions of the Committee and shall be provided with the same opportunities as other Members to express their point of view (including the submission of memoranda), but without the right to vote or to move motions either of substance or of procedure. International organizations which have formal relations with either FAO or WHO should also be invited to attend in an observer capacity sessions of those Codex Committees which are of interest to them.

ORGANIZATION AND DUTIES**CHAIRPERSON**

The Codex Alimentarius Commission will designate a member country of the Commission, which has indicated its willingness to accept financial and all other responsibility, as having responsibility for appointing a chairperson of the Committee. The member country concerned is responsible for appointing the chairperson of the Committee from among its own nationals. Should this person for any reason be unable to take the chair, the member country concerned shall designate another person to perform the functions of the chairperson for as long as the chairperson is unable to do so. A Committee may appoint at any session one or more rapporteurs from

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among the delegates present.

SECRETARIAT

A member country to which a Codex Committee has been assigned is responsible for providing all conference services including the secretariat. The secretariat should have adequate administrative support staff able to work easily in the languages used at the session and should have at its disposal adequate word processing and document reproducing equipment. Interpretation, preferably simultaneous, should be provided from and into all languages used at the session, and if the report of the session is to be adopted in more than one of the working languages of the Committee, then the services of a translator should be available. The Committee secretariat and the Joint FAO/WHO (Codex) Secretariat are charged with the preparation of the draft report in consultation with the rapporteurs, if any.

DUTIES AND TERMS OF REFERENCE

The duties of a Codex Committee shall include:

- (a) the drawing up of a list of priorities as appropriate, among the subjects and products within its terms of reference,
- (b) consideration of the types of safety and quality elements (or recommendations) to be covered, whether in standards for general application or in reference to specific food products,
- (c) consideration of the types of product to be covered by standards, e.g., whether materials for further processing into food should be covered,
- (d) preparation of draft Codex standards within its terms of reference,
- (e) reporting to each session of the Commission on the progress of its work and, where necessary, on any difficulties caused by its terms of reference, together with suggestions for their amendment.
- (f) the review and, as necessary, revision of existing standards and related texts on a scheduled, periodic basis to ensure that the standards and related texts within its terms of reference are consistent with current scientific knowledge and other relevant information.

SESSIONS

DATE AND PLACE

A member country to which a Codex Committee has been assigned is consulted by the Directors-general of FAO and WHO before they determine when and where a session of this Committee shall be convened.

The member country should consider arrangements for holding Codex sessions in developing countries.

INVITATIONS AND PROVISIONAL AGENDA

Sessions of Codex Committees and Coordinating Committees will be convened by the Directors-General of FAO and WHO in consultation with the chairperson of the respective Codex Committee. The letter of invitation and provisional agenda shall be prepared by the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Rome, in consultation with the chairperson of the Committee for issue by the Directors-General to all Members and Associate Members of FAO and WHO or, in the case of Coordinating Committees, to the countries of the region or group of countries concerned, Codex Contact Points and interested international organizations in accordance with the official mailing lists of FAO and WHO. Chairpersons should, before finalizing the drafts, inform and consult with the national Codex Contact Point where one has been established, and, if necessary, obtain clearance from the national authorities concerned (Ministry of Foreign Affairs, Ministry of Agriculture, Ministry of Health, or as the case may be). The invitation and Provisional Agenda will be translated and distributed by FAO/WHO in the working languages of the Commission at least four months before the date of the meeting.

Invitations should include the following:

- (a) title of the Codex Committee,
- (b) time and date of opening and date of closing of the session,
- (c) place of the session,
- (d) languages to be used and arrangements for interpretation, i.e., whether simultaneous or not,
- (e) if appropriate, information on hotel accommodation,
- (f) request for the names of the chief delegate and other members of the delegation, and for information on whether the chief delegate of a government will be attending as a representative or in the capacity of an observer.

Replies to invitations will normally be requested to be sent to reach the chairperson as early as possible and in any case not less than 30 days before the session. A copy should be sent also to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Rome. It is of the utmost importance that by the date requested a reply to invitations should be sent by all those governments and international organizations which intend to participate. The reply should specify the number of copies and the language of the documents required.

The Provisional Agenda should state the time, date and place of the meeting and should include the following items:

- (a) adoption of the agenda,
- (b) if considered necessary, election of rapporteurs,
- (c) items relating to subject matter to be discussed, including, where appropriate, the step in the Commission's Procedure for the Elaboration of Standards at which the item is being dealt with at the session. There should also be reference to the Committee papers relevant to the item,
- (d) any other business,
- (e) consideration of date and place of next session,
- (f) adoption of draft report.

The work of the Committee and the length of the meeting should be so arranged as to leave sufficient time at the end of the session for a report of the Committee's transactions to be agreed.

ORGANIZATION OF WORK

A Codex or Coordinating Committee may assign specific tasks to countries, groups of countries or to international organizations represented at meetings of the Committee and may ask member countries and international organizations for views on specific points.

Ad hoc working groups established to accomplish specific tasks shall be disbanded once the tasks have been accomplished as determined by the Committee.

A Codex or Coordinating Committee may not set up standing sub-committees, whether open to all Members of the Commission or not, without the specific approval of the Commission.

PREPARATION AND DISTRIBUTION OF PAPERS

Papers for a session should be sent by the chairperson of the Codex Committee concerned at least two months before the opening of the session to the following:

- (i) all Codex Contact Points,
- (ii) chief delegates of member countries, of observer countries and of international organizations, and
- (iii) other participants on the basis of replies received. Twenty copies of all papers in each of the languages used in the Committee concerned should be sent to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Rome.

Papers for a session prepared by participants must be drafted in one of the working languages of the Commission, which should, if possible, be one of the languages used in the Codex Committee concerned. These papers should be sent to the chairperson of the Committee, with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Rome, in good time to be included in the distribution of papers for the session.

Documents circulated at a session of a Codex Committee other than draft documents prepared at the session and ultimately issued in a final form, should subsequently receive the same distribution as other papers prepared for the Committee.

Codex Contact Points will be responsible for ensuring that papers¹⁴ are circulated to those concerned within their own country and for ensuring that all necessary action is taken by the date specified.

Consecutive reference numbers in suitable series should be assigned to all documents of Codex Committees. The reference number should appear at the top right-hand corner of the first page together with a statement of the language in which the document was prepared and the date of its preparation. A clear statement should be made of the provenance (origin or author country) of the paper immediately under the title. The text should be divided into numbered paragraphs. At the end of these guidelines is a series of references for Codex documents adopted by the Codex Alimentarius Commission for its own sessions and those of its subsidiary bodies.

Members of the Codex Committees should advise the Committee chairperson through their Codex Contact Point of the number of copies of documents normally required.

Working papers of Codex Committees may be circulated freely to all those assisting a delegation in preparing for the business of the Committee; they should not, however, be published. There is, however, no objection to the publication of reports of the meetings of Committees or of completed draft standards.

¹⁴

See Uniform System of References for Codex Documents – p. 86 of the Procedural Manual.

APPENDIX VI

PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL

DRAFT GUIDELINES ON THE CONDUCT OF MEETINGS OF CODEX COMMITTEES AND *AD HOC* INTERGOVERNMENTAL TASK FORCES

INTRODUCTION

By virtue of Article 7 of the Statutes of the Codex Alimentarius Commission and Rule X.1(b)¹⁵ of its Rules of Procedure, the Commission has established a number of Codex Committees and *ad hoc* Intergovernmental Task Forces to prepare standards in accordance with the Procedure for the Elaboration of Codex Standards and Coordinating Committees to exercise general coordination of its work in specific regions or groups of countries. The Rules of Procedure of the Commission shall apply, *mutatis mutandis*, to Codex Committees, Coordinating Committees and *ad hoc* Intergovernmental Task Forces. The Guidelines applying to the conduct of meetings of Codex Committees as described in this Section apply also to those of Coordinating Committees and to those of Codex *ad hoc* Intergovernmental Task Forces.

CONDUCT OF MEETINGS

Meetings of Codex and Coordinating Committees shall be held in public unless the Committee decides otherwise. Member countries responsible for Codex and Coordinating Committees shall decide who should open meetings on their behalf.

Meetings should be conducted in accordance with the Rules of Procedure of the *Codex Alimentarius* Commission.

Only the chief delegates of members, or of observer countries or of international organizations have the right to speak unless they authorize other members of their delegations to do so.

The representative of a regional economic integration organization shall provide the chairperson of the Committee, before the beginning of each session, with a written statement outlining where the competence lies between this organization and its members for each item, or subparts thereof, as appropriate, of the provisional agenda, pursuant to the Declaration of Competence submitted according to Rule II of the Rules of Procedure of the Codex Alimentarius Commission by this organization. In areas of shared ("mixed") competence between this organization and its members, this statement shall make clear which party has the voting right.

Delegations and delegations from observer countries who wish their opposition to a decision of the Committee to be recorded may do so, whether the decision has been taken by a vote or not, by asking for a statement of their position to be contained in the report of the Committee. This statement should not merely use a phrase such as: "The delegation of X reserved its position" but should make clear the extent of the delegation's opposition to a particular decision of the Committee and state whether they were simply opposed to the decision or wished for a further opportunity to consider the question.

(i) **REPORTS**

In preparing reports, the following points shall be borne in mind:

(a) decisions should be clearly stated; action taken in regard to economic impact statements should be fully

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recorded; all decisions on draft standards should be accompanied by an indication of the step in the Procedure that the standards have reached;

- (b) if action has to be taken before the next meeting of the Committee, the nature of the action, who is to take it and when the action must be completed should be clearly stated;
- (c) where matters require attention by other Codex Committees, this should be clearly stated;
- (d) if the report is of any length, summaries of points agreed and the action to be taken should be included at the end of the report, and in any case, a section should be included at the end of the report showing clearly in summary form:
 - standards considered at the session and the steps they have reached;
 - standards at any step of the Procedure, the consideration of which has been postponed or which are held in abeyance and the steps which they have reached;
 - new standards proposed for consideration, the probable time of their consideration at Step 2 and the responsibility for drawing up the first draft.

The following appendices should be attached to the report:

- (a) list of participants with full postal addresses,
- (b) draft standards with an indication of the step in the Procedure which has been reached.

The Joint FAO/WHO Secretariat should ensure that, as soon as possible and in any event not later than one month after the end of the session, copies of the final report, as adopted in the languages of the Committee, are sent to all participants, and all Codex Contact Points.

DRAWING UP OF CODEX STANDARDS

A Codex Committee, in drawing up standards and related texts, should bear in mind the following:

- (a) the guidance given in the General Principles of the Codex Alimentarius;
 - (b) that all standards and related texts should have a preface containing the following information:
 - the description of the standard or related text,
 - a brief description of the scope and purpose(s) of the standard or related text,
 - references including the step which the standard or related text has reached in the Commission's Procedures for the Elaboration of Standards, together with the date on which the draft was approved,
 - matters in the draft standard or related text requiring endorsement or action by other Codex Committees.
 - (c) that for standards or any related text for a product which includes a number of sub-categories, the Committee should give preference to the development of a general standard or related text with specific provisions as necessary for sub-categories.
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APPENDIX VII

PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL

DRAFT GUIDELINES TO CHAIRPERSONS OF CODEX COMMITTEES AND *AD HOC*
INTERGOVERNMENTAL TASK FORCES**INTRODUCTION**

By virtue of Article 7 of the Statutes of the Codex Alimentarius Commission and Rule X.1(b)¹⁶ of its Rules of Procedure, the Commission has established a number of Codex Committees and *ad hoc* Intergovernmental Task Forces to prepare standards in accordance with the Procedure for the Elaboration of Codex Standards and Coordinating Committees to exercise general coordination of its work in specific regions or groups of countries. The Rules of Procedure of the Commission shall apply, *mutatis mutandis*, to Codex Committees, Coordinating Committees and *ad hoc* Intergovernmental Task Forces. The Guidelines applying to the Chairpersons of Codex Committees as described in this Section apply also to those of Coordinating Committees and to those of Codex *ad hoc* Intergovernmental Task Forces.

DESIGNATION¹⁷

The Codex Alimentarius Commission will designate a member country of the Commission, which has indicated its willingness to accept financial and all other responsibility, as having responsibility for appointing a chairperson of the Committee. The member country concerned is responsible for appointing the chairperson of the Committee from among its own nationals. Should this person for any reason be unable to take the chair, the member country concerned shall designate another person to perform the functions of the chairperson for as long as the chairperson is unable to do so.

CONDUCT OF MEETINGS

The chairperson should invite observations from members of the Committee concerning the Provisional Agenda and in the light of such observations formally request the Committee to adopt the Provisional Agenda or the amended agenda.

Meetings should be conducted in accordance with the Rules of Procedure of the Codex Alimentarius Commission. Attention is particularly drawn to Rule VII.7 which reads: "The provisions of Rule XII of the General Rules of FAO shall apply *mutatis mutandis* to all matters which are not specifically dealt with under Rule VII of the present Rules."

Rule XII of the General Rules of FAO, a copy of which will be supplied to all chairpersons of Codex and Coordinating Committees, gives full instructions on the procedures to be followed in dealing with voting, points of order, adjournment and suspension of meetings, adjournment and closure of discussions on a particular item, reconsideration of a subject already decided and the order in which amendments should be dealt with.

Chairpersons of Codex Committees should ensure that all questions are fully discussed, in particular statements concerning possible economic implications of standards under consideration at Steps 4 and 7.

Chairpersons should also ensure that the written comments, received in a timely manner, of members and observers not present at the session are considered by the Committee; that all issues are put clearly to the

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¹⁷ Should the CCGP agree on draft criteria for the selection of Chairpersons, the new text could be inserted in this section.

Committee. This can usually best be done by stating what appears to be the generally acceptable view and asking delegates whether they have any objection to its being adopted.

Chairpersons should use the statement submitted by the representatives of the regional economic integration organizations on the matters of respective competence between these organizations and their members in the conduct of meetings, including assessing of the situation with regard to the party which has the right to vote.

CONSENSUS¹⁸

The chairpersons should always try to arrive at a consensus and should not ask the Committee to proceed to voting if agreement on the Committee's decision can be secured by consensus.

The *Procedure for the Elaboration of Codex Standards and Related Texts* allows for full discussion and exchange of views on the issue under consideration, in order to ensure the transparency of the process and arrive at compromises that would facilitate consensus.

Much of the responsibility for facilitating the achievement of consensus would lie in the hands of the Chairpersons.

When working out the means of progressing the work of a Committee, the chairperson should consider:

- (a) the need for timely progress in developing standards ;
- (b) the need to achieve consensus among the members as to the content of, and justification for, proposed standards;
- (c) the importance of achieving consensus at all stages of the elaboration of standards and that draft standards should, as a matter of principle, be submitted to the Commission for adoption only where consensus has been achieved at the technical level.

The chairperson should also consider implementing the following measures in order to facilitate consensus building in the elaboration of standards at the Committee stage:

- (a) ensuring that: (i) the scientific basis is well established on current data including, wherever possible, scientific data and intake and exposure information from the developing countries; (ii) where data from developing countries are not available, an explicit request for collecting and making available such data is made; and (iii) where necessary, further studies are carried out in order to clarify controversial issues;
- (b) ensuring that issues are thoroughly discussed at meetings of the Committees concerned;
- (c) 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 interested delegations and observers in order to preserve transparency;
- (d) requesting the Commission, where possible, for a redefinition of the scope of the subject matter being considered for the elaboration of standards in order to cut out issues on which consensus cannot be reached;
- (e) ensuring that matters are not progressed from step to step until all relevant concerns are taken into account and adequate compromises worked out¹⁹;
- (f) facilitating increased involvement and participation of developing countries

¹⁸ Reference is made to the *Measures to facilitate consensus* (Decision of the 26th Session of the Codex Alimentarius Commission (2003), 13th Edition of the Procedural Manual).

¹⁹ This does not preclude square bracketing of parts of a text in the early stages of the elaboration of a standard, where there is consensus on the large majority of the text.

APPENDIX VIII**PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL
GUIDELINES FOR THE INCLUSION OF SPECIFIC PROVISIONS IN CODEX STANDARDS AND
RELATED TEXTS****PRINCIPLES FOR THE ESTABLISHMENT OF CODEX METHODS OF ANALYSIS****GENERAL CRITERIA FOR THE SELECTION OF SINGLE-LABORATORY VALIDATED METHODS OF ANALYSIS
(to be included after the General Criteria)**

Inter-laboratory validated methods are not always available or applicable, especially in the case of multi-analyte/multi substrate methods and new analytes. The criteria to be used to select a method are included in the General Criteria for the Selection of Methods of Analysis. In addition the single-laboratory validated methods must fulfill the following criteria:

- i. the method is validated according to an internationally recognized protocol (e.g. those referenced in the harmonized IUPAC Guidelines for Single-Laboratory Validation of Methods of Analysis)
- ii. the use of the method is embedded in a quality system in compliance with the ISO/IEC 17025: 1999 Standard or Principles of Good Laboratory Practice;

The method should be complemented with information on accuracy demonstrated for instance with:

- regular participation in proficiency schemes, where available;
 - calibration using certified reference materials, where applicable;
 - recovery studies performed at the expected concentration of the analytes;
 - verification of result with other validated method where available.
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APPENDIX IX

PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL

GUIDELINES FOR THE INCLUSION OF SPECIFIC PROVISIONS IN CODEX STANDARDS AND
RELATED TEXTS

PRINCIPLES FOR THE ESTABLISHMENT OF CODEX METHODS OF ANALYSIS

PROPOSED AMENDMENTS TO ANALYTICAL TERMINOLOGY FOR CODEX USE

Specificity: deleted

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

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.

Accuracy (as a concept) and Accuracy (as a statistic) to be replaced with the following definition:

Accuracy: The closeness of agreement between a test result and the accepted reference value.

Note:

The term accuracy, when applied to a set of test results, involves a combination of random components and a common systematic error or bias component.

Trueness: The closeness of agreement between the average value obtained from a series of test results and an accepted reference value.

Notes:

- 1 The measure of trueness is usually expressed in terms of bias.
- 2 Trueness has been referred to as “accuracy of the mean”. This usage is not recommended.

Terms to Be Used in the Criteria Approach

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

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.

APPENDIX X

PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL

DEFINITIONS FOR THE PURPOSE OF THE CODEX ALIMENTARIUS

DEFINITIONS OF RISK ANALYSIS TERMS RELATED TO FOOD SAFETY

Definitions to be added

Food Safety Objective (FSO): The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).

Performance Objective (PO): The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable.

Performance Criterion (PC): The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.

APPENDIX XI**PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL****DEFINITIONS FOR THE PURPOSE OF THE CODEX ALIMENTARIUS****DEFINITION OF TRACEABILITY / PRODUCT TRACING**

Definition to be added

Traceability / product tracing: the ability to follow the movement of a food through specified stage(s) of production, processing and distribution.
