

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 4

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

*Twenty-eighth Session, FAO Headquarters, Rome, Italy
4 – 9 July 2005*

AMENDMENTS TO THE PROCEDURAL MANUAL

A. PROPOSED AMENDMENTS TO THE RULES OF PROCEDURE

1. The Commission is invited to consider and adopt the following proposals for amendment of the Rules of Procedure of the Codex Alimentarius Commission. A majority of the Members of the Commission constitutes a quorum for the purpose of adopting amendments of, or additions to, the Rules of Procedure (Rule V.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 and adopt the proposed 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.

Amendments to Rule VIII.5 - Observers

5. The Codex Alimentarius Commission, at its 26th 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

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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 and adopt the proposed amendments to 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.

Amendment to Rule V - Sessions

8. The Commission is invited to consider the amendments to the Rule V of the Rules of Procedure, forwarded by the 21st Session of the Codex Committee on General Principles, to include a new rule between current paragraphs 4 and 5 of the current Rule V, on the issue of the right to address the Chair (see ALINORM 04/27/33, paras 105-109).

9. The full text of the proposal is provided in Appendix IV.

B. PROPOSED AMENDMENT TO THE STATUTES

10. The Commission is invited to endorse the proposed amendment to Article 1 (d) and (e) of the Statutes of the Codex Alimentarius Commission, proposed by the 22nd Session of the Committee on General Principles, to abolish the Acceptance procedure (see ALINORM 05/28/33A, paras 77-89) and recommend its adoption by the FAO Conference and the World Health Assembly. A majority of the Members of the Commission constitutes a quorum for the purpose of making recommendations for amendments to the Statutes of the Commission (Rule V.6).

11. The full text of the proposal is provided in Appendix III. The related proposed amendments to other sections of the Procedural Manual are addressed in Section C below.

C. PROPOSALS TO AMEND OTHER SECTIONS OF THE PROCEDURAL MANUAL

12. The Commission is invited to consider and adopt 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, the General Principles of the Codex Alimentarius, the Guidelines for the Acceptance Procedure for Codex Standards, and the Terms of Reference of Subsidiary Bodies

13. The 22nd 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, the General Principles of the Codex Alimentarius, the Guidelines for the Acceptance Procedure for Codex Standards, and the Terms of Reference of FAO/WHO Coordinating Committees, in order to abolish the Acceptance procedure (see ALINORM 05/28/33A, paras. 77-89).

14. The full text of the proposal is provided in Appendix V. The Commission is invited to adopt these changes, on the understanding, however, that their entry into force is subject to the approval by the FAO Conference and the World Health Assembly of the proposed amendment to the Statutes of the Commission.

Draft Risk Analysis Principles Applied by the Committee on Food Additives and Contaminants and Draft CCFAC Policy for Exposure Assessment for Contaminants and Toxins in Foods and Foods Groups

15. The 26th Session of the Commission requested that relevant Codex Committees develop or complete specific guidelines on risk analysis in their respective areas, for inclusion in the Procedural Manual. The Commission noted that these texts would be submitted to the Committee on General Principles in order to ensure coordination of work and consistency with the overarching Working Principles (ALINORM 03/41 para. 147).

16. The 36th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) agreed to forward, through the Codex Committee on General Principles, the Draft Risk Analysis Principles Applied by the Committee on Food Additives and Contaminants and the Draft CCFAC Policy for Exposure Assessment for

Contaminants and Toxins in Foods and Foods Groups for adoption by the Commission and inclusion in the Procedural Manual (ALINORM 04/27/12, paras 39 and 129, Appendices II and XIV). The 21st Session of the Codex Committee on General Principles endorsed these texts with amendments (ALINORM 05/28/33, paras 11-25 and Appendices II and III).

17. The full texts of the proposals are provided in Appendices VI and VII.

Draft Revised Criteria for the Establishment of Work Priorities

18. The 21st Session of the Codex Committee on General Principles agreed to forward to the Commission, for adoption, the amendments to the Criteria for the Establishment of Work Priorities (see ALINORM 05/28/33, para. 36).

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

Draft Guidelines on Physical Working Groups and the Draft Guidelines on Electronic Working Groups

20. The 21st Session of the Codex Committee on General Principles agreed to forward to the Commission, for adoption, the Draft Guidelines on Physical Working Groups and the Draft Guidelines on Electronic Working Groups (see ALINORM 05/28/33, paras 47 and 54).

21. The full text of the proposal is provided in Appendices IX and X.

Draft Revised Principles concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission

22. The 21st Session of the Codex Committee on General Principles agreed to forward to the Commission, for adoption, the amendments to the Principles concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission (see ALINORM 05/28/33, para. 81).

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

Draft Guidelines for Cooperation with International Intergovernmental Organizations

24. The 21st Session of the Codex Committee on General Principles agreed to forward to the Commission, for adoption, the Draft Guidelines for Cooperation with International Intergovernmental Organizations (see ALINORM 05/28/33, para. 104).

25. The full text of the proposal is provided in Appendix XII.

26. The Commission's attention is drawn to the proceedings of the 21st Session of the Codex Committee on General Principles, where the representative of the FAO Legal Counsel informed the Committee that further consideration should be given to the use of the term "equivalent" principles of membership before adopting the text, and the Committee agreed to place this term in square brackets pending further advice (see ALINORM 05/28/33, para. 87).

27. Subsequently, in light of further review and consultations on the matter by the Legal Counsels of FAO and WHO, the proposal has been made to reinstate the earlier wording whereby the cooperating organization should have the same principles of membership as the Codex Alimentarius Commission. The proposed guidelines in Appendix XII reflect this position¹.

¹ Reference is made to Para. 6) of the Draft Guidelines and the corresponding footnote 16.

APPENDIX I

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

(New text and numbering appear in bold)

RULE III. OFFICERS

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:

- (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 14th 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 14th Edition of the Procedural Manual.

⁴ Rule XII.1 in the 14th 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 14th Edition of the Procedural Manual.

⁶ Rule X.1(a) and X.1 (b) in the 14th Edition of the Procedural Manual.

⁷ Rule VIII in the 14th 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 AMENDMENT TO THE STATUTES OF THE CODEX ALIMENTARIUS COMMISSION****ARTICLE 1**

The Codex Alimentarius Commission shall, subject to Article 5 below, be responsible for making proposals to, and shall be consulted by, the Directors-General of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) on all matters pertaining to the implementation of the Joint FAO/WHO Food Standards Programme, the purpose of which is:

- (a) protecting the health of the consumers and ensuring fair practices in the food trade;
- (b) promoting coordination of all food standards work undertaken by international governmental and non governmental organizations;
- (c) determining priorities and initiating and guiding the preparation of draft standards through and with the aid of appropriate organizations;
- (d) finalizing standards elaborated under (c) above and, ~~after acceptance by governments~~, publishing them in a Codex Alimentarius either as regional or world wide standards, together with international standards already finalized by other bodies under (b) above, wherever this is practicable;
- (e) amending published standards, ~~as after~~ appropriate, ~~survey~~ in the light of developments.

APPENDIX IV

PROPOSED AMENDMENT TO THE RULES OF PROCEDURE OF THE CODEX ALIMENTARIUS COMMISSION**RULE V. SESSIONS****NEW PARAGRAPH 5**

In plenary meetings of the Commission, the representative of a Member may designate an alternate who shall have the right to speak and vote in the name of his or her delegation on any question. Moreover, upon the request of the representative or any alternate so designated, the Chairperson may allow an adviser to speak on any particular point.

(Current paragraphs 5 and 6 shall be renumbered accordingly)

APPENDIX V

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

<p>Note: These procedures apply to the elaboration of Codex standards and related texts (e.g, codes of practice, guidelines, etc.) adopted by the Codex Alimentarius Commission as recommendations for governments</p>

INTRODUCTION

Paragraphs 1 to 8 : Unchanged

9. Codex standards and related texts are published and are sent to governments as well as to international organizations to which competence in the matter has been transferred by their Member States (see Part 5 of this document).

PART 1 to 4 : Unchanged

PART 5. SUBSEQUENT PROCEDURE CONCERNING PUBLICATION AND ACCEPTANCE OF CODEX STANDARDS

The Codex standard **or related text** is published and issued to all Member States and Associate Members of FAO and/or WHO and to the international organizations concerned. ~~Members of the Commission and international organizations to which competence in the matter has been transferred by their Member States notify the Secretariat of the status or use of the Codex standard in accordance with the notification acceptance procedure set out in paragraph 4, paragraph 5 or paragraph 6 of the General Principles of the Codex Alimentarius, whichever is appropriate. Member States and Associate Members of FAO and/or WHO that are not Members of the Commission are also invited to notify the Secretariat if they wish to accept the Codex standard.~~

~~The Secretariat publishes periodically details of notifications received from governments and from international organizations to which competence in the matter has been transferred by their Member States with respect to the acceptance or otherwise of Codex standards and in addition to this information an appendix for each Codex standard (a) listing the countries in which products conforming with such standard may be freely distributed, and (b) where applicable, stating in detail all specified deviations which may have been declared in respect to acceptance.~~

The above mentioned publications will constitute the *Codex Alimentarius*.

~~The Secretariat examines deviations notified by governments and reports periodically to the Codex Alimentarius Commission concerning possible amendments to standards which might be considered by the Commission in accordance with the Procedure for the Revision and Amendment of Recommended Codex Standards.~~

Subsequent Procedure Concerning Publication, ~~Acceptance~~ and Possible Extension of Territorial Application of the Regional Standard

~~The Codex Regional Standard is published and issued to all Member States and Associate Members of FAO and/or WHO and to the international organizations concerned. Members of the region or group of countries concerned notify the Secretariat of the status and use the Codex Regional Standard in accordance with the notification procedure set out in Section 4 of the General Principles of the Codex Alimentarius. Other Members of the Commission may likewise notify the Secretariat of their use of the standard or of any other measures they propose to adopt with respect thereto, and also submit any observations as to its application. Member States and Associate Members of FAO and/or WHO that are not Members of the Commission are invited to notify the Secretariat of the status or use of the Codex standard.~~

It is open to the Commission to consider at any time the possible extension of the territorial application of a Codex Regional Standard or its conversion into a World-wide Codex Standard. ~~in the light of all notifications received.~~

Arrangements for the Amendment of Codex Standards Elaborated by Codex Committees which have Adjourned *sine die*

1. The need to consider amending or revising adopted Codex standards arises from time to time for a variety of reasons amongst which can be:

- (a) changes in the evaluation of food additives, pesticides and contaminants;
- (b) finalization of methods of analysis;
- (c) editorial amendments of guidelines or other texts adopted by the Commission and related to all or a group of Codex standards e.g. "Guidelines on Date Marking", "Guidelines on Labelling of Non-retail Containers", "Carry-over Principle";
- (d) consequential amendments to earlier Codex standards arising from Commission decisions on currently adopted standards of the same type of products;
- (e) consequential and other amendments arising from either revised or newly elaborated Codex standards and other texts of general applicability which have been referenced in other Codex standards (Revision of General Principles of Food Hygiene, Codex Standard for the Labelling of Prepackaged Foods);
- (f) technological developments or economic considerations e.g. provisions concerning styles, packaging media or other factors related to composition and essential quality criteria and consequential changes in labelling provisions;
- ~~(g) modifications of standards being proposed following an examination of government notifications of acceptances and specified deviations by the Secretariat as required in accordance with the Procedure for the Elaboration of Codex standards i.e. "Subsequent Procedure concerning Publication and Acceptance of Codex Standards", page 9.~~

2. The “Guide to the Procedure for the Revision and Amendment of Codex Standards” (see page 27) covers sufficiently amendments to Codex standards which have been elaborated by still active Codex Committees [and those mentioned] ~~under paragraph 1 (g) above~~. In the case of amendments proposed to Codex standards elaborated by Codex Committees which have adjourned *sine die*, the procedure places an obligation on the Commission to “determine how best to deal with the proposed amendment”. In order to facilitate consideration of such amendments, ~~in particular, those of the type mentioned in para. 1 (a), (b), (c), (d), (e) and (f)~~, the Commission has established more detailed guidance within the existing procedure for the amendment and revision of Codex standards.

3. In the case where Codex committees have adjourned *sine die*:

(a) the Secretariat keeps under review all Codex standards originating from Codex Committees adjourned *sine die* and to determine the need for any amendments arising from decisions of the Commission, in particular amendments of the type mentioned in para. 1(a), (b), (c), (d) and those of (e) if of an editorial nature. If a need to amend the standard appears appropriate then the Secretariat should prepare a text for adoption in the Commission;

(b) amendments of the type in para. (f) and those of (e) of a substantive nature, the Secretariat in cooperation with the national secretariat of the adjourned Committee and, if possible, the Chairperson of that Committee, should agree on the need for such an amendment and prepare a working paper containing the wording of a proposed amendment and the reasons for proposing such amendment, and request comments from Member Governments: (a) on the need to proceed with such an amendment and (b) on the proposed amendment itself. If the majority of the replies received from Member Governments is affirmative on both the need to amend the standard and the suitability of the proposed wording for the amendment or an alternative proposed wording, the proposal should be submitted to the Commission with a request to approve the amendment of the standard concerned. In cases where replies do not appear to offer an uncontroversial solution then the Commission should be informed accordingly and it would be for the Commission to determine how best to proceed.

PROPOSED AMENDMENTS TO THE GENERAL PRINCIPLES OF CODEX ALIMENTARIUS

Purpose of the Codex Alimentarius

1. The Codex Alimentarius is a collection of internationally adopted food standards presented in a uniform manner. These food standards aim at protecting consumers' health and ensuring fair practices in the food trade. The Codex Alimentarius also includes provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures intended to assist in achieving the purposes of the Codex Alimentarius. The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade.

Scope of the Codex Alimentarius

2. The Codex Alimentarius includes standards for all the principle foods, whether processed, semi-processed or raw, for distribution to the consumer. Materials for further processing into foods should be included to the extent necessary to achieve the purposes of the Codex Alimentarius as defined. The Codex Alimentarius includes provisions in respect of food hygiene, food additives, pesticide residues, contaminants, labelling and presentation, methods of analysis and sampling. It also includes provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures.

Nature of Codex Standards

3. Codex standards contain requirements for food aimed at ensuring for the consumer a sound, wholesome food product free from adulteration, correctly labelled and presented. A Codex standard for any food or foods should be drawn up in accordance with the Format for Codex Commodity Standards and contain, as appropriate, the criteria listed therein.

Acceptance of Codex Commodity Standards

4.A. — A Codex standard may be accepted by a country in accordance with its established legal and administrative procedures in respect of distribution of the product concerned, whether imported or home produced, within its territorial jurisdiction in the following ways:

(i) — Full acceptance

- (a) Full acceptance means that the country concerned will ensure that a product to which the standard applies will be permitted to be distributed freely, in accordance with (c) below, within its territorial jurisdiction under the name and description laid down in the standard, provided that it complies with all the relevant requirements of the standard.
- (b) The country will also ensure that products not complying with the standard will not be permitted to be distributed under the name and description laid down in the standard.
- (c) The distribution of any sound products conforming with the standard will not be hindered by any legal or administrative provisions in the country concerned relating to the health of the consumer or to other food standard matters except for considerations of human, plant or animal health which are not specifically dealt with in the standard.

(ii) — Acceptance with specified deviations

Acceptance with specified deviations means that the country concerned gives acceptance, as defined in paragraph 4.A(i), to the standard with the exception of such deviations as are specified in detail in its declaration of acceptance; it being understood that a product complying with the standard as qualified by these deviations will be permitted to be distributed freely within the territorial jurisdiction of the country concerned. The country concerned will further include in its declaration of acceptance a statement of the reasons for these deviations, and also indicate:

- (a) whether products fully conforming to the standard may be distributed freely within its territorial jurisdiction in accordance with paragraph 4.A(i);
- (b) whether it expects to be able to give full acceptance to the standard and, if so, when.

(iii) — Free distribution

A declaration of free distribution means that the country concerned undertakes that products conforming with a Codex commodity standard may be distributed freely within its territorial jurisdiction insofar as matters covered by the Codex commodity standard are concerned.

B. — A country which considers that it cannot accept the standard in any of the ways mentioned above should indicate:

- (i) whether products conforming to the standard may be distributed freely within its territorial jurisdiction;
- (ii) in what ways its present or proposed requirements differ from the standard, and, if possible the reasons for these differences.

C. (i) A country which accepts a Codex standard according to one of the provisions of 4.A is responsible for the uniform and impartial application of the provisions of the standard as accepted, in respect of all home-produced and imported products distributed within its territorial jurisdiction. In addition, the country should be prepared to offer advice and guidance to exporters and processors of products for export to promote understanding of and compliance with the requirements of importing countries which have accepted a Codex standard according to one of the provisions of 4.A.

— (ii) Where, in an importing country, a product claimed to be in compliance with a Codex standard is found not to be in compliance with that standard, whether in respect of the label accompanying the product or otherwise, the importing country should inform the competent authorities in the exporting country of all the relevant facts and in particular the details of the origin of the product in question (name and address of the exporter), if it is thought that a person in the exporting country is responsible for such non-compliance.

Acceptance of Codex General Standards

5.A. — A Codex general standard may be accepted by a country in accordance with its established legal and administrative procedures in respect of the distribution of products to which the general standard applies, whether imported or home produced, within its territorial jurisdiction in the following ways:

(i) — *Full acceptance*

Full acceptance of a general standard means that the country concerned will ensure, within its territorial jurisdiction, that a product to which the general standard applies will comply with all the relevant requirements of the general standard except as otherwise provided in a Codex commodity standard. It also means that the distribution of any sound products conforming with the standard will not be hindered by any legal or administrative provisions in the country concerned, which relate to the health of the consumer or to other food standard matters and which are covered by the requirements of the general standard.

(ii) — *Acceptance with specified deviations*

Acceptance with specified deviations means that the country concerned gives acceptance, as defined in paragraph 5.A(i), to the general standard with the exception of such deviations as are specified in detail in its declaration of acceptance. The country concerned will further include in its declaration of acceptance a statement of the reasons for these deviations, and also indicate whether it expects to be able to give full acceptance to the general standard and, if so, when.

(iii) — *Free distribution*

A declaration of free distribution means that the country concerned undertakes that products conforming with the relevant requirements of a Codex general standard may be distributed freely within its territorial jurisdiction insofar as matters covered by the Codex general standard are concerned.

B. — A country which considers that it cannot accept the general standard in any of the ways mentioned above should indicate in what ways its present or proposed requirements differ from the general standard, and if possible, the reasons for these differences.

C. (i) A country which accepts a general standard according to one of the provisions of paragraph 5.A is responsible for the uniform and impartial application of the provisions of the standard as accepted, in respect of all home produced and imported products distributed within its territorial jurisdiction. In addition, the country should be prepared to offer advice and guidance to exporters and processors of products for export to promote understanding of and compliance with the requirements of importing countries which have accepted a general standard according to one of the provisions of paragraph 5.A.

— (ii) Where, in an importing country, a product claimed to be in compliance with a general standard is found not to be in compliance with that standard, whether in respect of the label accompanying the product or otherwise, the importing country should inform the competent authorities in the exporting country of all the relevant facts and in particular the details of the origin of the product in question (name and address of the exporter), if it is thought that a person in the exporting country is responsible for such non-compliance.

Acceptance of Codex Maximum Limits for Residues of Pesticides and Veterinary Drugs in Food

6.A. — A Codex maximum limit for residues of pesticides or veterinary drugs in food may be accepted by a country in accordance with its established legal and administrative procedures in respect of the distribution within its territorial jurisdiction of (a) home produced and imported food or (b) imported food only, to which the Codex maximum limit applies in the ways set forth below. In addition, where a Codex maximum limit applies to a group of foods not individually named, a country accepting such Codex maximum limit in respect of other than the group of foods, shall specify the foods in respect of which the Codex maximum limit is accepted.

(i) — *Full acceptance*

Full acceptance of a Codex maximum limit for residues of pesticides or veterinary drugs in food means that the country concerned will ensure, within its territorial jurisdiction, that a food, whether home produced or imported, to which the Codex maximum limit applies, will comply with that limit. It also means that the distribution of a

food conforming with the Codex maximum limit will not be hindered by any legal or administrative provisions in the country concerned which relate to matters covered by the Codex maximum limit.

(ii) — *Free distribution*

A declaration of free distribution means that the country concerned undertakes that products conforming with the Codex maximum limit for residues of pesticides or veterinary drugs in food may be distributed freely within its territorial jurisdiction insofar as matters covered by the Codex maximum limit are concerned.

B. — A country which considers that it cannot accept the Codex maximum limit for residues of pesticides or veterinary drugs in foods in any of the ways mentioned above should indicate in what ways its present or proposed requirements differ from the Codex maximum limit and, if possible, the reasons for these differences.

C. — A country which accepts a Codex maximum limit for residues of pesticides or veterinary drugs in food according to one of the provisions of paragraph 6.A should be prepared to offer advice and guidance to exporters and processors of food for export to promote understanding of and compliance with the requirements of importing countries which have accepted a Codex maximum limit according to one of the provisions of paragraph 6.A.

D. — Where, in an importing country, a food claimed to be in compliance with a Codex maximum limit is found not to be in compliance with the Codex maximum limit, the importing country should inform the competent authorities in the exporting country of all the relevant facts and, in particular, the details of the origin of the food in question (name and address of the exporter), if it is thought that a person in the exporting country is responsible for such non-compliance.

Withdrawal or Amendment of Acceptance

7. — The withdrawal or amendment of acceptance of a Codex standard or a Codex maximum limit for residues of pesticides or veterinary drugs in food by a country shall be notified in writing to the Codex Alimentarius Commission's Secretariat who will inform all Member States and Associate Members of FAO and WHO of the notification and its date of receipt. The country concerned should provide the information required under paragraphs 4.A(iii), 5.A(iii), 4.B, 5.B or 6.B above, whichever is appropriate. It should also give as long a notice of the withdrawal or amendment as is practicable.

Revision of Codex Standards

48. The Codex Alimentarius Commission and its subsidiary bodies are committed to revision as necessary of Codex standards and related texts to ensure that they are consistent with and reflect current scientific knowledge and other relevant information. When required, a standard or related text shall be revised or removed using the same procedures as followed for the elaboration of a new standard. Each member of the Codex Alimentarius Commission is responsible for identifying, and presenting to the appropriate committee, any new scientific and other relevant information which may warrant revision of any existing Codex standards or related texts.

GUIDELINES FOR THE ACCEPTANCE PROCEDURE FOR CODEX STANDARDS

The importance of a response to every notification

1. — The Codex Alimentarius is the record of Codex Standards and of acceptances or other notifications by Member Countries or international organizations to which competence in the matter has been transferred by their Member States. It is revised regularly to take account of the issue of new or amended standards and the receipt of notifications. It is important that governments respond to every issue of new or amended standards. Governments should aim at giving formal acceptance to the standards. If acceptance or free circulation cannot be given unconditionally, the deviations or conditions, and the reasons, can be included in the response. Early and regular responses will ensure that the Codex Alimentarius can be kept up to date so as to serve as an indispensable reference for governments and international traders.

2. Governments should ensure that the information in the Codex Alimentarius reflects the up to date position. When changing national laws or practices the need for a notification to the Codex Secretariat should always be kept in mind.

3. The Codex procedure for elaboration of standards enables governments to participate at all stages. Governments should be able to make an early response to the issue of a Codex standard and should do their utmost to be ready to do so.

The Codex Alimentarius: not a substitute for, or alternative to, referring to national legislation

4. Every country's laws and administrative procedures contain provisions which it is essential to understand and comply with. It is usually the practice to take steps to obtain copies of relevant legislation and/or to obtain professional advice about compliance. The Codex Alimentarius is a comparative record of the substantive similarities and differences between Codex Standards and corresponding national legislation. The Codex Standard will not normally deal with general matters of human, plant or animal health or with trade marks. The language which is required on labels will be a matter for national legislation and so will import licences and other administrative procedures.

5. The responses by governments should show clearly which provisions of the Codex Standard are identical to, similar to or different from, the related national requirements. General statements that national laws must be complied with should be avoided or accompanied by details of national provisions which require attention. Judgement will sometimes be required where the national law is in a different form or where it has different provisions.

Obligations under the Acceptance Procedure

6. The obligations which a country undertakes under the acceptance procedure are included in paragraph 4 of the General Principles. Paragraph 4.A(i)(a) provides for free distribution of conforming products, 4.A(i)(b) with the need to ensure that products which do not conform may not be distributed "under the name and description laid down". Paragraph 4.A(i)(c) is a general requirement not to hinder the distribution of sound products, except for matters relating to human, plant or animal health, not specifically dealt with in the standard. Similar provisions are included in Acceptance with Specified Deviations.

7. The essential difference between acceptances and notifications of free distribution is that a country which accepts, undertakes to enforce the Codex standard and to accept all the obligations set out in the General Principles subject to any specified deviations.

8. The Codex Committee on General Principles (CCGP) and the Commission (CAC) have reviewed the acceptance procedure and notifications by governments on a number of occasions. While recognizing that difficulties can arise from time to time in reconciling the obligations of the acceptance procedure with the laws and administrative procedures of a Member Country, the CCGP and the CAC have determined that the obligations are essential to the work and status of the CAC and that they should not be weakened in any way. The purpose of these guidelines therefore is to assist governments when they are considering how, in the light of the objectives of the acceptance procedure, to respond to Codex Standards.

The return of the response

9. The principal decision which is required is whether to notify an acceptance according to one of the methods prescribed, or non acceptance as provided for in 4.B. Free distribution (4.A(iii)) does not carry with it the obligation to prevent non conforming products from being circulated, and it may be useful in cases where there is no corresponding national standard and no intention to introduce one.

The need for an informed, responsible judgement when comparing the Codex Standard with national laws

10. There will be some occasions when the detail in the Codex Standard is identical with national laws. Difficulties will arise however when national laws are in a different form, contain different figures or no figures at all, or in cases where there may be no standard in the country which corresponds in substance to the Codex

Standard. The authority responsible for notifying the response to the CAC is urged to do its best to overcome any such difficulties by the exercise of its best endeavours and to respond, after such consultations as may be appropriate with the national organizations. The grounds on which the judgement has been based can be made clear in the notification. It may well be that they will not be such as to justify an acceptance, because of the obligations to stop the distribution of non conforming products, but a statement of free circulation should be possible on the basis of the facts and practices of each case. If there was a court decision or change in the law or practice subsequently, an amending response should be made.

Presumptive standards

11. A presumptive standard is one which is assumed to be the standard in the absence of any other. (A presumption in law is the assumption of the truth of anything until the contrary is proved.) Some countries have said that a Codex MRL is the presumptive limit for a pesticide residue. Countries may be able and willing to regard a Codex Standard as the presumptive standard in cases where there is no corresponding standard, code of practice or other accepted expression of the "nature, substance or quality" of the food. A country need not apply the presumption to all the provisions of the standard if the details of its additives, contaminants, hygiene or labelling rules are different from those in the standard. In such a case the provisions in the Codex Standard defining the description, essential composition and quality factors relating to the specified name and description could still be the presumptive standard for those matters.

12. The justification for regarding the Codex Standard as a presumptive standard is the fact that it is the minimum standard for a food elaborated in the CAC "so as to ensure a sound, wholesome product free from adulteration, correctly labelled and presented". (General Principles, Paragraph 3.) The word minimum does not have any pejorative connotations: it simply means the level of quality and soundness of a product judged by consensus to be appropriate for trade internationally and nationally.

13. Whether a presumptive standard would merit an acceptance would depend on whether the country concerned could say that non conforming products could not be distributed under the same name and description laid down in the standard. However it would enable a declaration of free circulation to be made and countries are asked to give the idea serious consideration.

Format and Content of Codex Standards

Scope

14. This section, together with the name of the standard and the name and description laid down in the labelling section, should be examined in order to assess whether the obligations of the acceptance procedure can properly be accepted.

Description, essential composition and quality factors

15. These sections will define the minimum standard for the food. They will be the most difficult to address unless by chance the details are virtually identical (i.e. ignoring significant matters of editorial expression or format). However, a country which has taken part in the elaboration of the standard either by attending the meetings or by sending comments under the Step Procedure has, no doubt, consulted national organizations on the extent to which the draft provisions in the standard would be acceptable nationally. This factual information needs to be turned into a formal response when the standard is sent out for acceptance. Countries are asked to do their best to exercise an informal judgement on lines discussed in Paragraph 7 above. Some of the quality criteria e.g. allowances for defects may represent good manufacturing practice or be left to trade contracts. This will have to be taken into account. A free distribution response ought to be possible in most cases.

Food Additives

16. The food additives included in the standard have been assessed and cleared by JECFA. The Commodity Committee and the CCFAC have assessed technological need and safety in use. If national laws are different, all the detailed differences should be reported. It should be borne in mind, however, that the aim of international food standardization work is to harmonize policies and attitudes as much as possible. Therefore every effort should be made to keep deviations to the minimum.

Contaminants

17. ~~If national limits apply they should be quoted if not the same as those laid down in the Codex Standard. Where general laws about safety, health or nature of the food apply, the limits quoted in the standard could properly be regarded as representing those which are unavoidable in practice and within safety limits.~~

Hygiene and Weights and Measures

18. ~~If national requirements are different they should be reported.~~

Labelling

19. ~~The General Standard for the Labelling of Prepackaged Foods represents the international consensus on information to be included on the labels of all foods.~~

20. ~~Governments are exhorted to use the General Standard as a basis for their national legislation and to keep differences to an absolute minimum especially those of detail or minutiae. Governments should observe the footnote to the Scope section and should ensure that all compulsory provisions relating to presentation of information which are additional to, and different from, those in the standard should be notified. Any other compulsory provisions in national legislation should also be notified if they are not provided for in the Codex standard. The labelling provisions in Codex standards include sections of the revised General Standard by reference. When accepting a Codex commodity standard, a country which has already accepted and responded to the General Standard can then refer to the terms of that acceptance in any subsequent responses. As much specific information as is relevant and helpful should be given. In particular, this should include the name and description relating to the food, the interpretation of any special requirements relating to the law or custom of the country, any additional details about presentation of the mandatory information and detailed differences if any in the labelling requirements e.g. in relation to class names, declaration of added water, declaration of origin. It will be assumed that the language(s) in which the particulars should be given will be as indicated by national legislation or custom.~~

Methods of Analysis and Sampling

21. ~~The obligations which a country assumes in accepting the following Codex Defining Methods of Analysis included in Codex standards are as follows⁸:~~

~~(a) Codex Defining Methods of Analysis (Type I) are subject to acceptance by governments just as are the provisions which they define and which form part of Codex standards.~~

~~—“Full acceptance” of a Codex Defining Method means the acceptance that the value provided for in a Codex standard is defined by means of the Codex method. In determining compliance with the value in the Codex standard, governments undertake to use the Codex Defining Method, especially in cases of disputes involving the results of analysis.~~

~~—“Non acceptance” of Codex Defining Method or acceptance of Codex standards with substantive deviations in the Codex Defining Methods means acceptance of the Codex standard with specified deviation.~~

~~(b) The “acceptance” of Codex standards containing Codex Reference Methods of Analysis (Type II) means the recognition that Codex Reference Methods are methods the reliability of which has been demonstrated on the basis of internationally acceptable criteria. They are, therefore, obligatory for use, i.e. subject to acceptance by governments, in disputes involving the results of analysis. “Non acceptance” of the Codex Reference Method or acceptance of Codex standards with substantive~~

⁸ The Committee on General Principles, when elaborating these Guidelines, noted that the Classification of Methods was under review by the Codex Committee on Methods of Analysis and Sampling and that the application of Part (b) particularly could be unnecessarily restrictive.

~~deviations in the Codex Reference Methods for use in disputes involving methods of analysis, should be taken to mean acceptance of the Codex standard with specified deviation.~~

- ~~(e) The “acceptance” of Codex standards containing Codex Alternative Approved Methods of Analysis (Type III) means the recognition that Codex Alternative Approved Methods are methods the reliability of which has been demonstrated in terms of internationally acceptable criteria. They are recommended for use in food control, inspection or for regulatory purposes.~~

~~—“Non acceptance” of a Codex Alternative Approved Method does not constitute a deviation from the Codex standard.~~

- ~~(d) Since the reliability of the Tentative Methods (Type IV) has not yet been endorsed by the Codex Committee on Methods of Analysis and Sampling on the basis of the internationally accepted criteria, it follows that they cannot be regarded as final Codex methods. Type IV methods may, eventually become Type I, II or III methods with the resultant implications regarding the acceptance of Codex methods. Type IV methods are, therefore, not recommended as Codex methods until their reliability has been recognized by the CCMAS. They may be included in draft Codex standards or in Codex standards provided their non approved status is clearly indicated.~~

Summary

~~22. — Governments are urged to respond to every issue of Codex standards. The inclusion of responses in the Codex Alimentarius will enable the CAC and Member Governments to address the question of closer approximation of international and national requirements. Governments are urged to take the Codex standard fully into consideration when changing their national laws. The Codex Alimentarius will always be an invaluable reference for governments and for international traders although national legislation must always be consulted and complied with.~~

PROPOSED AMENDMENTS TO THE TERMS OF REFERENCE OF SUBSIDIARY BODIES

FAO/WHO Coordinating Committees

[(a) – (g)] Unchanged

(h) promotes the ~~use~~acceptance of Codex standards and ~~related texts~~maximum limits for residues by member countries.

APPENDIX VI

**DRAFT RISK ANALYSIS PRINCIPLES
APPLIED BY THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS****1. SCOPE**

- a) This document addresses the respective applications of risk analysis principles by the Codex Committee on Food Additives and Contaminants (CCFAC) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). For matters which cannot be addressed by JECFA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies.
- b) This document should be read in conjunction with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.

2. CCFAC and JECFA

- c) CCFAC and JECFA recognize that communication between risk assessors and risk managers is critical to the success of their risk analysis activities.
- d) CCFAC and JECFA should continue to develop procedures to enhance communication between the two committees.
- e) CCFAC and JECFA should ensure that their contributions to the risk analysis process involve all interested parties and are fully transparent and thoroughly documented. While respecting legitimate concerns to preserve confidentiality, documentation should be made available, upon request, in a timely manner to all interested parties.
- f) JECFA, in consultation with CCFAC, should continue to explore developing minimum quality criteria for data requirements necessary for JECFA to perform risk assessments. These criteria are used by CCFAC in preparing its Priority List for JECFA. The JECFA Secretariat should consider whether these minimum quality criteria for data have been met when preparing the provisional agenda for meetings of JECFA.

3. CCFAC

- g) CCFAC is primarily responsible for recommending risk management proposals for adoption by the CAC.
- h) CCFAC shall base its risk management recommendations to the CAC on JECFA's risk assessments, including safety assessments⁹, of food additives, naturally occurring toxicants, and contaminants in food.
- i) In cases where JECFA has performed a safety assessment and CCFAC or the CAC determines that additional scientific guidance is necessary, CCFAC or CAC may make a more specific request to JECFA to obtain the scientific guidance necessary for a risk management decision.
- j) CCFAC's risk management recommendations to the CAC with respect to food additives shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Food Additives.
- k) CCFAC's risk management recommendations to the CAC with respect to contaminants and naturally occurring toxicants shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Contaminants and Naturally Occurring Toxins in Food.
- l) CCFAC's risk management recommendations to the CAC that involve health and safety aspects of food standards shall be based on JECFA's risk assessments and other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*.

⁹ A Safety Assessment is defined as a scientifically-based process consisting of: 1) the determination of a NOEL (No Observed Effect Level) for a chemical, biological, or physical agent from animal feeding studies and other scientific considerations; 2) the subsequent application of safety factors to establish an ADI or tolerable intake; and 3) comparison of the ADI or tolerable intake with probable exposure to the agent (Temporary definition to be modified when JECFA definition will be available).

- m) CCFAC's risk management recommendations to the CAC shall take into account the relevant uncertainties and safety factors described by JECFA.
- n) CCFAC shall endorse maximum use levels only for those additives for which 1) JECFA has established specifications of identity and purity and 2) JECFA has completed a safety assessment or has performed a quantitative risk assessment.
- o) CCFAC shall endorse maximum levels only for those contaminants for which 1) JECFA has completed a safety assessment or has performed a quantitative risk assessment and 2) the level of the contaminant in food can be determined through appropriate sampling plans and analysis methods, as adopted by Codex. CCFAC should take into consideration the analytical capabilities of developing countries unless public health considerations require otherwise.
- p) CCFAC shall take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending maximum use levels for additives or maximum levels for contaminants and naturally occurring toxicants in food.
- q) Before finalising proposals for maximum levels for contaminants and naturally occurring toxicants, CCFAC shall seek the scientific advice of JECFA about the validity of the analysis and sampling aspects, about the distribution of concentrations of contaminants and naturally occurring toxicants in foods and about other relevant technical and scientific aspects, including dietary exposure, as necessary to provide for a suitable scientific basis for its advice to CCFAC.
- r) When establishing its standards, codes of practice, and guidelines, CCFAC shall clearly state when it applies any other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*, in addition to JECFA's risk assessment, and specify its reasons for doing so.
- s) CCFAC's risk communication with JECFA includes prioritising substances for JECFA review with the view towards obtaining the best available risk assessment for purposes of elaborating safe conditions of use for food additives and elaborating safe maximum levels or codes of practice for contaminants and naturally occurring toxicants in food.
- t) CCFAC shall consider the following when preparing its priority list of substances for JECFA review:
- Consumer protection from the point of view of health and prevention of unfair trade practices;
 - CCFAC's Terms of Reference;
 - JECFA's Terms of Reference;
 - The Codex Alimentarius Commission's Strategic Plan , its relevant plans of work and *Criteria for the Establishment of Work Priorities*;
 - The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;
 - The prospect of completing the work in a reasonable period of time;
 - The diversity of national legislation and any apparent impediments to international trade;
 - The impact on international trade (i.e., magnitude of the problem in international trade);
 - The needs and concerns of developing countries; and,
 - Work already undertaken by other international organizations;
- u) When referring substances to JECFA, CCFAC shall provide background information and clearly explain the reasons for the request when chemicals are nominated for evaluation;
- v) CCFAC may also refer a range of risk management options, with a view toward obtaining JECFA's guidance on the attendant risks and the likely risk reductions associated with each option.
- w) CCFAC requests JECFA to review any methods and guidelines being considered by CCFAC for assessing maximum use levels for additives or maximum levels for contaminants and naturally occurring toxicants. CCFAC makes any such request with a view toward obtaining JECFA's guidance on the limitations, applicability, and appropriate means for implementation of a method or guideline for CCFAC's work.

4. JECFA

- x) JECFA is primarily responsible for performing the risk assessments upon which CCFAC and ultimately the CAC base their risk management decisions.
- y) JECFA's scientific experts should be selected on the basis of their competence and independence, taking into account geographical representation to ensure that all regions are represented.
- z) JECFA should strive to provide CCFAC with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCFAC's risk-management discussions. For contaminants and naturally occurring toxicants, JECFA should determine to the extent possible the risks associated with various levels of intake. Because of the lack of appropriate information, including data in humans, however, this may be possible in only a few cases for the foreseeable future. For additives, JECFA should continue to use its safety assessment process for establishing ADIs.
- aa) JECFA should strive to provide CCFAC with science-based quantitative risk assessments and safety assessments for food additives, contaminants, and naturally occurring toxicants in a transparent manner.
- bb) JECFA should provide CCFAC with information on the applicability and any constraints of the risk assessment to the general population to particular sub-populations and should as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g., children, women of child-bearing age, the elderly).
- cc) JECFA should also strive to provide CCFAC with specifications of identity and purity essential to assessing risk associated with the use of additives.
- dd) JECFA should strive to base its risk assessments on global data, including data from developing countries. These data should include epidemiological surveillance data and exposure studies.
- ee) JECFA is responsible for evaluating exposure to additives, contaminants, and naturally occurring toxicants.
- ff) When evaluating intake of additives or contaminants and naturally occurring toxicants during its risk assessment, JECFA should take into account regional differences in food consumption patterns.
- gg) JECFA should provide to CCFAC its scientific views on the validity and the distribution aspects of the available data regarding contaminants and naturally occurring toxicants in foods which have been used for exposure assessments, and should give details on the magnitude of the contribution to the exposure from specific foods as may be relevant for risk management actions or options of CCFAC.
- hh) JECFA should communicate to CCFAC the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA should provide CCFAC with a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment.
- ii) JECFA should communicate to CCFAC the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.
- jj) JECFA's risk assessment output to CCFAC is limited to presenting its deliberations and the conclusions of its risk assessments and safety assessments in a complete and transparent manner. JECFA's communication of its risk assessments should not include the consequences of its analyses on trade or other non-public health consequence. Should JECFA include risk assessments of alternative risk management options, JECFA should ensure that these are consistent with the Working Principles for Risk Analysis for the Application in the Framework of the Codex Alimentarius and Risk Analysis Principles applied by the Codex Committee on Food Additives and Contaminants.
- kk) When establishing the agenda for a JECFA meeting, the JECFA Secretariat work closely with CCFAC to ensure that CCFAC's risk management priorities are addressed in a timely manner. With respect to food additives, the JECFA Secretariat should normally give first priority to compounds that have been assigned a temporary ADI, or equivalent. Second priority should normally be given to food additives or groups of additives that have previously been evaluated and for which an ADI, or equivalent, has been estimated, and for which new information is available. Third priority should normally be given to food additives that have not been previously evaluated. With respect to contaminants and naturally occurring toxicants, the JECFA Secretariat should give priority to substances that present both a significant risk to public health and are a known or expected problem in international trade.
- ll) When establishing the agenda for a JECFA meeting, the JECFA Secretariat should give priority to substances that are known or expected problems in international trade or that present an emergency or imminent public health risk.

APPENDIX VII**DRAFT CCFAC POLICY FOR EXPOSURE ASSESSMENT OF CONTAMINANTS AND TOXINS
IN FOODS OR FOOD GROUPS****INTRODUCTION**

1. Maximum Limits (MLs) do not need to be set for all foods that contain a contaminant or a toxin. The Preamble of the Codex General Standard for Contaminants and Toxins in Foods (GSCTF) states in Section 1.3.2 that “maximum levels (MLs) shall only be set for those foods in which the contaminant may be found in amounts that are significant for the total exposure of the consumer. They should be set in such a way that the consumer is adequately protected”. Setting standards for foods that contribute little to dietary exposure would mandate enforcement activities that do not contribute significantly to health outcomes.
2. Exposure assessment is one of the four components of risk assessment within the risk analysis framework adopted by Codex as the basis for all standard-setting processes. The estimated contribution of specific foods or food groups to the total dietary exposure to a contaminant as it relates to a quantitative health hazard endpoint (e.g., PMTDI, PTWI) provides further information needed for the setting of priorities for the risk management of specific foods/food groups. Exposure assessments must be guided by clearly articulated policies elaborated by Codex with the aim of increasing the transparency of risk management decisions.
3. The purpose of this Annex is to outline steps in contaminant data selection and analysis undertaken by JECFA when requested by CCFAC to conduct a dietary exposure assessment.
4. The following components highlight aspects of JECFA’s exposure assessment of contaminants and toxins that contribute to ensuring transparency and consistency of science-based risk assessments. Exposure assessments of contaminants and toxins in foods are performed by JECFA at the request of CCFAC. CCFAC will take this information into account when considering risk management options and making recommendations regarding contaminants and toxins in foods.

**1. ESTIMATION OF TOTAL DIETARY EXPOSURE TO A CONTAMINANT OR TOXIN FROM
FOODS/FOOD GROUPS**

5. JECFA uses available data from member countries and from GEMS/Food Operating Program for analytical laboratories system on contaminant levels in foods and the amount of foods consumed to estimate total dietary exposure to a contaminant or toxin. This is expressed as a percentage of the tolerable intake (e.g., PTDI, PTWI, or other appropriate toxicological reference point). For a carcinogen with no clear threshold, JECFA uses available data on intake combined with data on carcinogenic potency to estimate potential population risks.
6. Median/mean contaminant levels in foods are determined from available analytical data submitted by countries and from other sources. These data are combined with information available for the GEMS/Food Regional diets to generate dietary exposure estimates for regions in the world. JECFA provides an estimate as to which of the GEMS/Food Regional diets are likely to approach or exceed the tolerable intake.
7. In some cases, available national contaminant and/or individual food consumption data may be used by JECFA to provide more accurate estimates of total dietary exposure, particularly for vulnerable groups such as children.
8. JECFA performs exposure assessments if requested by CCFAC using the GEMS/Food Regional Diets and, if needed, available national consumption data to estimate the impact on dietary exposure of proposed alternative maximum levels to inform CCFAC about these risk management options.

**2. IDENTIFICATION OF FOODS/FOOD GROUPS THAT CONTRIBUTE SIGNIFICANTLY TO
TOTAL DIETARY EXPOSURE OF THE CONTAMINANT OR TOXIN**

9. From dietary exposure estimates JECFA identifies foods/food groups that contribute significantly to the exposure according to CCFAC’s criteria for selecting food groups that contribute to exposure.

10. The CCFAC determines criteria for selecting foods/food groups that contribute significantly to total dietary exposure of a contaminant or toxin. These criteria are based upon the percentage of the tolerable intake (or similar health hazard endpoint) that is contributed by a given food/food group and the number of geographic regions (as defined by the GEMS/Food Regional diets) for which dietary exposures exceed that percentage.
11. The criteria are as follows:
 - a) Foods or food groups for which exposure to the contaminant or toxin contributes approximately 10%¹⁰ or more of the tolerable intake (or similar health hazard endpoint) in one of the GEMS/Food Regional diets;
or,
 - b) Foods or food groups for which exposure to the contaminant or toxin contributes approximately 5%¹ or more of the tolerable intake (or similar health hazard endpoint) in two or more of the GEMS/Food Regional diets;
or,
 - c) Foods or food groups that may have a significant impact on exposure for specific groups of consumers, although exposure may not exceed 5% of the tolerable intake (or similar health hazard endpoint) in any of the GEMS/Food Regional diets. These would be considered on a case-by-case basis.

3. GENERATION OF DISTRIBUTION CURVES FOR CONCENTRATIONS OF THE CONTAMINANT IN SPECIFIC FOODS/FOOD GROUPS (concurrent with section 2, or subsequent step)

12. If requested by CCFAC, JECFA uses available analytical data on contaminant or toxin levels in foods/food groups identified as significant contributors to dietary exposure to generate distribution curves of contaminant concentrations in individual foods. CCFAC will take this information into account when considering risk management options and, if appropriate, for proposing the lowest achievable levels for contaminants/toxins in food on a global basis.
13. Ideally, individual data from composite samples or aggregated analytical data would be used by JECFA to construct the distribution curves. When such data are not available, aggregated data would be used (for example mean and geometric standard deviation). However, methods to construct distribution curves using aggregated data would need to be validated by JECFA.
14. In presenting the distribution curves to CCFAC, JECFA should, to the extent possible, provide a comprehensive overview of the ranges of contamination of foods (i.e., both the maximum and outlier values) and of the proportion of foods/food groups that contain contaminants/toxins at those levels.

4. ASSESSMENT OF THE IMPACT OF AGRICULTURAL AND PRODUCTION PRACTICES ON CONTAMINANT LEVELS IN FOODS/FOOD GROUPS (concurrent with section 2, or subsequent step)

15. If requested by CCFAC, JECFA assesses the potential impact of different agricultural and production practices on contaminant levels in foods to the extent that scientific data are available to support such assessments. CCFAC takes this information into account when considering risk management options and for proposing Codes of Practice.
16. Taking this information into account, CCFAC proposes risk management decisions. To refine them, CCFAC may request JECFA to undertake a second assessment to consider specific exposure scenarios based on proposed risk management options. The methodology for assessing potential contaminant exposure in relation to proposed risk management options needs to be further developed by JECFA.

¹⁰ Rounded to the nearest 1/10th of a percent.

APPENDIX VIII**DRAFT CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES**

When a Codex Committee proposes to elaborate a standard, code of practice or related text within its terms of reference, it should first consider the priorities established by the Commission in the strategic plan, the relevant outcomes of the critical review conducted by the Executive Committee, and the prospect of completing the work within a reasonable period of time. It should also assess the proposal against the criteria set out below.

If the proposal falls in an area outside the Committee's terms of reference the proposal should be reported to the Commission in writing together with proposals for such amendments to the Committee's terms of reference as may be required.

CRITERIA***General criterion***

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

Criteria applicable to general subjects

- (a) Diversification of national legislations and apparent resultant or potential impediments to international trade.
- (b) Scope of work and establishment of priorities between the various sections of the work.
- (c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).

Criteria applicable to commodities

- (a) Volume of production and consumption in individual countries and volume and pattern of trade between countries.
- (b) Diversification of national legislations and apparent resultant or potential impediments to international trade.
- (c) International or regional market potential.
- (d) Amenability of the commodity to standardisation.
- (e) Coverage of the main consumer protection and trade issues by existing or proposed general standards.
- (f) Number of commodities which would need separate standards indicating whether raw, semi-processed or processed.
- (g) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).

APPENDIX IX**DRAFT GUIDELINES ON PHYSICAL WORKING GROUPS****INTRODUCTION**

Working groups should be *ad hoc*, open to all members, take into account the problems of developing country participation and only be established where there is consensus in the Committee to do so and other strategies have been considered.

The Rules of Procedure and the guidelines governing the work of a Codex Committee shall apply, *mutatis mutandis*, to the working groups this Committee establishes, unless stated otherwise in these Guidelines.¹¹

The Guidelines applying to physical working groups (hereinafter, "working groups") established by Codex Committees as described in these guidelines apply also to those established by Regional Coordinating Committees and by Codex ad hoc Intergovernmental Task Forces.

COMPOSITION OF WORKING GROUPS***Membership***

Membership of a working group is notified to the chairperson of the Codex Committee and to the host country secretariat of the Committee.

When establishing a working group, a Codex Committee should ensure, as far as possible, that the membership is representative of the membership of the Commission.

Observers

Observers should notify the Chairperson of the Codex Committee and to the host country secretariat of the Committee of their wish to participate in a working group. Observers may participate in all sessions and activities of a working group, unless otherwise specified by the Committee members.

ORGANIZATION AND DUTIES

A Codex Committee may decide that the working groups will be managed by the Host Government Secretariat, or by another member of the Commission, having volunteered to undertake this responsibility and having been accepted by the Committee (hereinafter "the Host").

Chairperson

The Host is responsible for appointing the chairperson of the working group. While selecting of the appointee, the Host may consider applying, where relevant, the *Codex Criteria for the Appointment of Chairpersons*¹².

Secretariat

The Host is responsible for providing all conference services, including the secretariat, for the working group and should meet all the requirements agreed upon by the Committee, when the working group was established.

Duties and Terms of Reference

The terms of reference of the working group shall be established by the Committee during its plenary session, shall be limited to the immediate task at hand and normally shall not be subsequently modified.

¹¹ The provisions of the "Guidelines to Host Governments of Codex Committees and Ad Hoc Intergovernmental Task Forces", the "Guidelines on the Conduct of Meetings of Codex Committees and Ad Hoc Intergovernmental Task Forces" and the "Guidelines to Chairpersons of Codex Committees and Ad Hoc Intergovernmental Task Forces" are especially relevant in this matter.

¹² Reference is made to the *Guidelines to Chairpersons of Codex Committees and Ad Hoc Intergovernmental Task Forces*.

The terms of reference shall clearly state the objective(s) to be achieved by the establishment of the working group and the language(s) to be used. Interpretation and translation services should be provided in all languages of the Committee, unless decided otherwise by the Committee.

The terms of reference shall clearly state the time frame by which the work is expected to be completed. The proposals/recommendations of a working group shall be presented to the Committee for consideration.

They shall not be binding on the Committee.

The working group shall be dissolved after the specified work has been completed or when the time limit allocated for the work has expired or at any other point in time, if the Codex Committee which has established it, so decides.

No decision on behalf of the Committee, nor vote, either on point of substance or of procedure, shall take place in working groups.

SESSIONS

Date

A session of a working group may be held at any time, in-between two sessions or in conjunction with the session of the Committee, which has established it.

When convened in-between two sessions of the Committee, the session of the working group should be scheduled as to allow the working group to report to the Committee well in advance of the next meeting so that countries and other interested parties, that were not members of the working group, can comment on the proposals that the working group might put to the Committee.

When convened during a session of a Committee, a working group should be scheduled so as to allow participation of all delegations present at the session.

Working Group Notification and Provisional Agenda

Sessions of a working group shall be convened by the Chairperson designated by the Host.

If the working group is scheduled in-between two sessions of the Committee, a notice of the working group meeting and provisional agenda shall be prepared, translated and distributed by the Host. It shall be issued to all Members and Observers who have expressed the willingness to attend the meeting. These documents should be distributed as far in advance of the meeting as possible.

Organization of Work

Written comments will be circulated to all concerned by the secretariat of the Host.

Preparation and Distribution of Papers

The secretariat of the Host should circulate the papers at least two months before the opening of the session. Paper for the session prepared by the participants should be sent to the secretariat of the Host, in good time.

CONCLUSIONS

The Secretariat of the Host should, as soon as possible after the end of the session of a working group, send a copy of the final conclusions, in the form of either a discussion paper or a working document, and the list of participants, to the Joint FAO/WHO Secretariat and to the host country secretariat of the Committee.

Conclusions of a working group shall be distributed to all Codex Contact Points and observers by the Joint FAO/WHO Secretariat in time to allow full consideration of the working group's recommendations.

The Joint FAO/WHO Secretariat should ensure that these conclusions are included in the distribution of papers for the next session of the Codex Committee.

The working group shall report, through its Chairperson, on the progress of its work at the next session of the Committee, which has established the working group.

APPENDIX X**DRAFT GUIDELINES ON ELECTRONIC WORKING GROUPS****INTRODUCTION**

The search for world-wide consensus and for greater acceptability of Codex Standards requires the involvement of all the Members of Codex and the active participation of developing countries.

Special efforts are needed to enhance the participation of developing countries in Codex Committees, by increased use of written communications, especially through remote participation via email, internet and other modern technologies, in the work done between sessions of Committees.

Codex Committees, when deciding to undertake work between sessions, should give the first priority to considering the establishment of electronic working groups.

The Rules of Procedure and the guidelines governing the work of a Committee shall apply, *mutatis mutandis*, to the electronic working groups this Committee establishes, unless stated otherwise in these Guidelines.¹³

The Guidelines applying to electronic working groups established by Codex Committees, as described in these Guidelines, apply also to those established by Regional Coordinating Committees and by Codex *ad hoc* Intergovernmental Task Forces.

COMPOSITION OF ELECTRONIC WORKING GROUPS***Membership***

Membership of an electronic working group is notified the chairperson of the Codex Committee and to the host country secretariat of the Committee.

When establishing an electronic working group, a Codex Committee should ensure, as far as possible, that the membership is representative of the membership of the Commission.

Observers

Observers should notify the Chairperson of the Committee and to the host country secretariat of the Committee, of their wish to participate in a working group. Observers may participate in all the activities of an electronic working group, unless otherwise specified by Committee members.

ORGANIZATION AND DUTIES

Codex Committees may decide that the electronic working group will be managed by the Host Government Secretariat, or by another member of the Commission, having volunteered to undertake this responsibility and having been accepted by the Committee (hereinafter "the Host"). The Host should be notified of the participants in an electronic working group by Codex Members through their Codex Contact Points and by Observer organizations.

Management

The Host is responsible for the management of the electronic working group for which it has been appointed.

The business of an electronic working group is transacted exclusively by electronic means.

Secretariat

The Host is responsible for providing the secretariat of the electronic working group with all services needed for its functioning, including suitable Information Technology (IT) equipment, and should meet all the requirements agreed upon by the Committee.

¹³ The provisions of the "Guidelines to Host Governments of Codex Committees and Ad Hoc Intergovernmental Task Forces", the "Guidelines on the Conduct of Meetings of Codex Committees and Ad Hoc Intergovernmental Task Forces", the "Guidelines to Chairpersons of Codex Committees and Ad Hoc Intergovernmental Task Forces" and the "Guidelines on Physical Working Groups" are especially relevant in this matter.

Duties and Terms of Reference

The terms of reference of the electronic working group shall be established by the Committee during its plenary session, shall be limited to the immediate task at hand and normally shall not be subsequently modified.

The terms of reference shall clearly state the objective(s) to be achieved by the establishment of the electronic working group and the language(s) to be used. Interpretation and translation services should be provided in all languages of the Committee, unless decided otherwise by the Committee.

The terms of reference shall clearly state the time frame by which the work is expected to be completed.

The electronic working group shall be dissolved after the specified work has been completed or when the time limit allocated for the work has expired or at any other point in time, if the Codex Committee which has established it, so decides.

No decision on behalf of the Committee, nor vote, either on point of substance or of procedure, shall take place in electronic working groups.

Electronic Working Group Notification and Programme of Work

A notice indicating when the electronic working group starts to operate and a programme of work shall be prepared, translated and distributed by the Host to all Members and Observers who have expressed the willingness to contribute.

Organization of Work

Circulation of drafts and calls for comments shall include a request for the names, positions and e-mail addresses of all the persons willing to contribute to the business of the electronic working group.

Comments from participants should be submitted exclusively by electronic means. These submissions shall be circulated to all concerned by the Host.

Any participant should be made aware of the materials contributed by all others.

An update on the progress of its work shall be presented by the Host at each session of the Codex Committee which has established it, indicating the number of countries having sent contributions by mail. A compilation of these contributions should be made available.

Preparation and Distribution of Materials

Materials should be sent to the secretariat of the Host, in good time.

The Host is responsible for the distribution of all the materials submitted by a participant during the business of the electronic working group to all other participants of the electronic working group.

Attention should be given to constraints of a technical nature (file sizes and formats, limited band width, ...) and special care should be taken to ensure the widest distribution of all the available materials.

CONCLUSIONS

As soon as possible after the end of the business of an electronic working group, the secretariat of the Host should send a copy of the final conclusions, in the form of either a discussion paper or a working document and of the list of participants to the Joint FAO/WHO Secretariat and to the host country secretariat of the Committee.

The conclusions of an electronic working group and the list of participants shall be distributed to Codex Contact Points and observers by the Joint FAO/WHO Secretariat in time to allow full consideration of the electronic working group's recommendations.

The Joint FAO/WHO Secretariat should ensure that these conclusions are included in the distribution of papers for the next session of the Codex Committee, which has established the electronic working group.

APPENDIX XI**DRAFT REVISED PRINCIPLES CONCERNING THE PARTICIPATION OF INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS IN THE WORK OF THE CODEX ALIMENTARIUS COMMISSION****1. PURPOSE**

The purpose of collaboration with International Non-Governmental Organizations is to secure for the Codex Alimentarius Commission, expert information, advice and assistance from international non-governmental organizations and to enable organizations which represent important sections of public opinion and are authorities in their fields of professional and technical competence to express the views of their members and to play an appropriate role in ensuring the harmonizing of intersectoral interests among the various sectoral bodies concerned in a country, regional or global setting. Arrangements made with such organizations shall be designed to advance the purposes of the Codex Alimentarius Commission by securing maximum cooperation from International Non-Governmental Organizations in the execution of its programme.

2. TYPES OF RELATIONSHIP

Only one category of relationship shall be recognized, namely "Observer Status"; all other contacts, including working relations, shall be considered to be of an informal character.

3. ORGANIZATIONS ELIGIBLE FOR "OBSERVER STATUS"

1. The following shall be eligible for Observer Status:
 - International Non-Governmental Organizations in consultative status, specialized consultative status or liaison status with FAO;
 - International Non-Governmental Organizations having official relations with WHO; and
 - International Non-Governmental Organizations that:
 - (a) are international in structure and scope of activity, and representative of the specialized field of interest in which they operate;
 - (b) are concerned with matters covering a part or all of the Commission's field of activity;
 - (c) have aims and purposes in conformity with the Statutes of the Codex Alimentarius Commission;
 - (d) have a permanent directing body and Secretariat, authorized representatives and systematic procedures and machinery for communicating with its membership in various countries. Its members shall exercise voting rights in relation to its policies or action or shall have other appropriate mechanisms to express their views; and
 - (e) have been established at least three years before they apply for observer status.
2. For the purpose of paragraph (a), International Non-Governmental Organizations shall be considered "international in structure and scope of activity" if they have members and carry out activities in at least three countries. The Directors-General of FAO and WHO may, upon the advice of the Executive Committee, grant observer status to Organizations not meeting this requirement if it is clear from their application that they would make a significant contribution to advancing the purposes of the Codex Alimentarius Commission.

4. PROCEDURE FOR OBTAINING "OBSERVER STATUS"

4.1 INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS HAVING STATUS WITH FAO AND/OR OFFICIAL RELATIONS WITH WHO

“Observer status” shall be accorded to those International Non-Governmental Organizations in consultative status, specialized consultative status or liaison status with FAO or International Non-Governmental Organizations having official relations with WHO that inform the Secretary of the Codex Alimentarius Commission of their desire to participate in the work of the Commission and/or any or all of the Commission’s subsidiary bodies¹⁴ on a regular basis. They may also request invitations to participate at specific sessions of the Commission or its subsidiary bodies on an ad hoc basis.

4.2 INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS NEITHER HAVING STATUS WITH FAO NOR OFFICIAL RELATIONS WITH WHO

Before any form of formal relationship is established with a Non-Governmental Organization, such Organization shall supply the Secretary of the Commission with the information outlined in the Annex to these Procedures.

The Secretary of the Commission will verify the completeness of the information provided by the Organization, and will also perform an initial assessment of whether the Organization appears to meet the requirements indicated in Section 3 of these Principles. In case of doubts, he or she will consult with the Directors-General of FAO and WHO and may seek further information and clarifications from the Organization as appropriate.

Upon satisfactory completion of the verification and assessment referred to in the previous paragraph, the Secretary of the Commission will submit the application and all relevant information received from the applicant to the Executive Committee for its advice, pursuant to Rule VIII.6 of the Rules of Procedure of the Codex Alimentarius Commission.

The Secretary of the Commission will transmit the application, together with all relevant information received from the applicant and the advice of the Executive Committee, to the Directors-General who will decide whether an Organization is to be granted observer status. In case of rejection of an application, a re-application by the same Organization shall not normally be considered until two years have elapsed since the Directors-General's decision on the original application.

The Secretary of the Commission shall inform each Organization of the Directors-General's decision on its application, and shall provide a written explanation of the decision in case of rejection.

Observer Status at specific meetings will not normally be granted to individual organizations that are members of a larger organization authorized and that intends to represent them at these meetings.

5. PRIVILEGES AND OBLIGATIONS

International Non-governmental Organizations in Observer status shall have the following privileges and obligations:

5.1 PRIVILEGES OF INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS IN "OBSERVER STATUS"

An Organization in Observer Status:

(a) shall be entitled to send an observer (without the right to vote) to sessions of the Commission, who may be accompanied by advisers; to receive from the Secretary of the Commission, in advance of the session, all working documents and discussion papers; to circulate to the Commission its views in writing, without abridgement; and to participate in discussions when invited by the Chairperson¹⁵;

(b) shall be entitled to send an observer (without the right to vote) to sessions of specified Subsidiary Bodies, who may be accompanied by advisers; to receive from the Secretaries of the Subsidiary Bodies, in advance of

¹⁴ The term “subsidiary bodies” means any body established under Rule X of the Commission's Rules of Procedure.

¹⁵ An invitation to a Codex meeting and representation thereat by an observer shall not imply the granting to an international non-governmental organization of a status different from that which it already enjoys.

the session, all working documents and discussion papers; to circulate to these Bodies its views in writing, without abridgement; and to participate in discussions when invited by the Chairperson ¹⁵;

(c) may be invited by the Directors-General to participate in meetings or seminars on subjects organized under the Joint FAO/WHO Food Standards Programme which fall within its fields of interest, and if it does not so participate it may submit its views in writing to any such meeting or seminar;

(d) will receive documentation and information about meetings planned on subjects agreed upon with the Secretariat;

(e) may submit, under the authority of its governing body, written statements on matters before the Commission, in one of the languages of Commission, to the Secretary, who may communicate them to the Commission or the Executive Committee as appropriate.

5.2 OBLIGATIONS OF INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS IN "OBSERVER STATUS"

An Organization in Observer Status shall undertake:

(a) to cooperate fully with the Codex Alimentarius Commission for the furtherance of the objectives of the Joint FAO/WHO Food Standards Programme;

(b) in cooperation with the Secretariat, to determine the ways and means of co-ordinating activities within the scope of the Joint FAO/WHO Food Standards Programme, with a view to avoiding duplication and overlapping;

(c) to contribute, as far as possible, and at the request of the Directors-General, to the promotion of a better knowledge and understanding of the Codex Alimentarius Commission and the Joint FAO/WHO Food Standards Programme through appropriate discussions or other forms of publicity;

(d) to send to the Secretary of the Commission on an exchange basis, its reports and publications concerned with matters covering all or part of the Commission's field of activity;

(e) to promptly report to the Secretary of the Commission changes in its structure and membership, important changes in its secretariat as well as any other important changes in the information provided in accordance with the Annex to the present Principles.

6. REVIEW OF "OBSERVER STATUS"

The Directors-General may terminate observer status if an Organization no longer meets the criteria that applied at the time it was granted observer status, or for reasons of exceptional nature, in accordance with the procedures set out in this section.

Without prejudice to the preceding paragraph, an international non-governmental organization in Observer Status which has neither attended any meetings nor provided any written comments during a period of four years shall be deemed not to have sufficient interest to warrant the continuance of such relationship.

If, in the view of the Directors-General, the conditions indicated in the previous paragraphs materialize, they shall inform the Organization concerned accordingly and invite it to submit its observations. The Directors-General will seek the advice of the Executive Committee and will submit any observation received from the Organization to it. The Directors-General, taking into account the advice of the Executive Committee and any observation submitted by the Organization, shall decide whether to terminate its observer status. A re-application from the same Organization shall not normally be considered until two years have elapsed since the Directors-General's decision to terminate its observer status.

The Secretary shall report to the Codex Alimentarius Commission on the relations between the Codex Alimentarius Commission and international nongovernmental organizations established in accordance with the present Procedures and shall provide a list of organizations granted Observer Status, with an indication of the membership that they represent. He or she shall also report to the Commission the termination of the observer status of any Organization.

The Commission shall periodically review these principles and procedures and shall consider, as necessary, any amendments which may seem desirable.

ANNEX: INFORMATION REQUIRED OF INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS REQUESTING “OBSERVER STATUS”

- (a) Official name of the organization in different languages (with initials)
- (b) Full postal address, Telephone, Facsimile and Email, as well as Telex and website addresses as appropriate
- (c) Aims and subject fields (mandate) of organization, and methods of operation. (Enclose charter, constitution, by-laws, rules of procedures, etc.). Date of establishment
- (d) Member organizations (name and address of each national affiliate, method of affiliation, giving number of members where possible, and names of principal officers. If the organization has individual members, please indicate approximate number in each country. If the organization is of a federal nature and has international non-governmental organizations as members, please indicate whether any of those members already enjoy observer status with the Codex Alimentarius Commission)
- (e) Structure (assembly or conference; council or other form of governing body; type of general secretariat; commissions on special topics, if any; etc.)
- (f) Indication of source of funding (e.g., membership contributions, direct funding, external contributions, or grants)
- (g) Meetings (indicate frequency and average attendance; send report of previous meeting, including any resolutions passed) that are concerned with matters covering all or part of the Commission’s field of activity
- (h) Relations with other international organizations:
- UN and its organs (indicate consultative status or other relationship, if any)
 - Other international organizations (document substantive activities)
- (i) Expected contribution to the Joint FAO/WHO Food Standards Programme
- (j) Past activities on behalf of, or in relation to, the Codex Alimentarius Commission and the Joint FAO/WHO Food Standards Programme (indicate any relationship by national affiliates with the Regional Coordinating Committees and/or the National Codex Contact Points or Committees for at least the last three years preceding the application)
- (k) Area of activity in which participation as an observer is requested (Commission and/or Subsidiary Bodies). If more than one organization with similar interests is requesting observer status in any field of activity, such organizations will be encouraged to form themselves into a federation or association for the purpose of participation. If the formation of such a single organization is not feasible, the application should explain why this is so.
- (l) Previous applications for observer status with the Codex Alimentarius Commission, including those made by a member organization of the applicant organization. If successful, please indicate why and when observer status was terminated. If unsuccessful, please indicate the reasons you were given.
- (m) Languages (English, French or Spanish) in which documentation should be sent to the international non-governmental organization
- (n) Name, Function and address of the person providing the information
- (o) Signature and date

APPENDIX XII**DRAFT GUIDELINES ON COOPERATION BETWEEN THE CODEX ALIMENTARIUS COMMISSION AND INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS IN THE ELABORATION OF STANDARDS AND RELATED TEXTS****SCOPE AND APPLICATION**

- 1) These guidelines establish the modalities of cooperation between the Codex Alimentarius Commission and international intergovernmental organizations when elaborating food standards or related texts.
- 2) These guidelines should be read in conjunction with the "Uniform Procedure for the Elaboration of Codex Standards and Related Texts".

TYPES OF COOPERATION

- 3) The Codex Alimentarius Commission may undertake the elaboration of any standard or related text in cooperation with another intergovernmental body or organization.
- 4) Such cooperation may consist of:
 - a) Cooperation at the initial drafting stages of a Codex standard or related text;
 - b) Cooperation through mutual exchange of information and participation in meetings.

COOPERATING ORGANIZATION

- 5) The cooperating organization shall have observer status with the Codex Alimentarius Commission.
- 6) The cooperating organization shall have the same principles of membership¹⁶ that form the basis for membership in the Codex Alimentarius Commission and equivalent principles of standards-setting¹⁷.

COOPERATION AT THE INITIAL DRAFTING STAGES OF A CODEX STANDARD OR RELATED TEXT¹⁸

- 7) The Commission, or a subsidiary body of the Commission subject to approval by the Commission and taking into account the Critical review conducted by the Executive Committee, as appropriate, may entrust the initial drafting of a proposed draft standard or related text to an international intergovernmental organisation with competence in the relevant field, in particular one of those referred to in Annex A of the WTO/SPS Agreement, on a case-by case basis, provided that the willingness of the cooperating organization to undertake such work has been ascertained. Such texts shall be circulated at Step 3 of the « Uniform Procedure for the Elaboration of Codex Standards and Related Texts ». When appropriate, the international intergovernmental organisations referred to Annex A of the WTO/SPS Agreement shall be associated in the drafting of standards or related texts at Step 2 of the Elaboration Procedure. The Commission shall entrust the remaining steps to the relevant Codex subsidiary body within the Codex Elaboration Procedure.
- 8) The Commission, or a subsidiary body of the Commission, may use, in whole or in part, an international standard or related text developed by an international intergovernmental organization with competence in the relevant field as a basis for preparing a proposed draft standard or related text at Step 2 of the Elaboration Procedure, subject to concurrence of the cooperating organization. The proposed draft standard or related

¹⁶ The same principles of membership” shall be taken to mean that the membership of the organization is open to all Members and Associate Members of FAO and of WHO.

¹⁷ “Equivalent principles of standards-setting” refers to the General Decisions of the Commission set out in the Appendix to the Procedural Manual.

¹⁸ See also Article 1 of the Statutes of the Codex Alimentarius Commission, Step 2 of the Uniform Procedure for the Elaboration of Codex Standards and Related Texts, and the Terms of reference of the Codex Committee on Fresh Fruits and Vegetables (*in* Procedural Manual of the Codex Alimentarius Commission, 14th Edition).

text shall be circulated at Step 3 of the "Uniform Procedure for the Elaboration of Codex Standards and Related Texts".

COOPERATION THROUGH MUTUAL EXCHANGE OF INFORMATION AND PARTICIPATION IN MEETINGS

- 9) The Commission or a subsidiary body of the Commission may identify an international intergovernmental organization having specific expertise of particular importance to the work of the Commission. Such organization may be encouraged to actively participate in the elaboration of standards by the Commission and its subsidiary bodies.
- 10) The Commission or a subsidiary body of the Commission may invite a cooperating organization having specific expertise of particular importance to the work of the Commission to report about its relevant work at their sessions on an *ad hoc* or regular basis.
- 11) The Commission or a subsidiary body of the Commission may recommend that the Chairperson of the Commission, the Chairperson of the subsidiary body, or, if they are not available, a Vice-chairperson or the Secretary of the Commission, as appropriate, participate in meetings of the cooperating organization, subject to the concurrence of the cooperating organization.
- 12) The Commission or a subsidiary body of the Commission may recommend that the Chairperson or the Secretary of the Commission forward comments, opinions or other relevant information of the Commission to the cooperating organization as regards international standard setting work in areas of mutual interest.
- 13) The Codex Alimentarius Commission may recommend to the Directors-General of FAO and WHO the conclusion of an appropriate arrangement with the executive head of the cooperating organization with a view to agreeing upon specific modalities to facilitate continuing cooperation between the Commission and the cooperating organization, as set out in the paragraphs above.