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## **INTRODUCTION**

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The Procedural Manual of the Codex Alimentarius Commission is intended to help Member governments participate effectively in the work of the Joint FAO/WHO Food Standards Programme. The Manual is particularly useful for national delegations attending Codex meetings and for international organizations attending as observers. It will also be useful for Member governments which wish to participate in Codex work by correspondence.

Section I sets out the Commission's Statutes, Rules of Procedure and the other internal procedures necessary to achieve the Commission's objectives. These include the procedures for the elaboration of Codex Standards and related texts, general principles and some basic definitions.

Section II is devoted to guidelines for the efficient operation of Codex Committees and Task Forces. These Committees and Task Forces are organized and operated by Member Governments designated by the Commission. It describes how standards are set out in a uniform manner, describes a uniform reference system for Codex documents and working papers, and provides a number of general principles for formulating key sections of Codex standards and outlines the core functions of national Codex Contact Points.

Section III contains policy documents on risk analysis for application by the Commission and its subsidiary bodies.

Section IV lists the Commission's subsidiary bodies with their Terms of Reference and the Membership of the Commission.

General decisions of the Commission are reproduced in the Appendix.

This Sixteenth Edition of the Procedural Manual was prepared by the Secretariat following the Twenty-ninth Session of the Codex Alimentarius Commission, Rome, 2006. Further information concerning the Codex Alimentarius Commission and its Subsidiary Bodies can be obtained from the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, 00153 Rome, Italy, and from the website at <http://www.codexalimentarius.net>.

## SECTION I

- Statutes
- Rules of Procedure
- Elaboration Procedures
- General Principles
- Guidelines on Cooperation between the Codex Alimentarius Commission and International Intergovernmental Organizations in the Elaboration of Standards and Related Texts
- Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission
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### CONTENTS OF THIS SECTION

The Statutes and Rules of Procedure of the Codex Alimentarius Commission were first established by FAO Conference and the World Health Assembly in 1961/63 when the Commission itself was established. The Statutes were revised in 1966 and in 2006. The Rules of Procedure have been amended on several occasions, the last time being in 2006. The Statutes form the legal basis of the Commission's work and provide its mandate or terms of reference. The Rules of Procedure describe the formal working procedures appropriate to an intergovernmental body.

The Procedure for the Elaboration of Codex Standards describes the way by which Codex standards are prepared and the various Steps in the process which ensure comprehensive review of draft standards by governments and other interested parties. It was comprehensively revised in 1993 to provide a uniform elaboration procedure for all Codex standards and related texts. The Procedure underwent a major revision in 2004 to introduce the strategic planning process and critical review.

The General Principles of the Codex Alimentarius define the scope and purpose of Codex Standards. This Section also contains Principles and Guidelines governing the relations between the Codex Alimentarius Commission and international observer organizations

This Section concludes with Definitions for the Purpose of the Codex Alimentarius which assist in the uniform interpretation of these texts.

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**STATUTES OF THE CODEX ALIMENTARIUS COMMISSION**

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***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 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 appropriate, in the light of developments.

***ARTICLE 2***

Membership of the Commission is open to all Member Nations and Associate Members of FAO and WHO which are interested in international food standards. Membership shall comprise such of these nations as have notified the Director-General of FAO or of WHO of their desire to be considered as Members.

***ARTICLE 3***

Any Member Nation or Associate Member of FAO or WHO which is not a Member of the Commission but has a special interest in the work of the Commission, may, upon request communicated to the Director-General of FAO or WHO, as appropriate, attend sessions of the Commission and of its subsidiary bodies and *ad hoc* meetings as observers.

***ARTICLE 4***

Nations which, while not Member Nations or Associate Members of FAO or WHO, are members of the United Nations, may be invited on their request to

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attend meetings of the Commission as observers in accordance with the provisions of FAO and WHO relating to the grant of observer status to nations.

### ***ARTICLE 5***

The Commission shall report and make recommendations to the Conference of FAO and the appropriate body of WHO through their respective Directors-General. Copies of reports, including any conclusions and recommendations, will be circulated to interested Member Nations and international organizations for their information as soon as they become available.

### ***ARTICLE 6***

The Commission shall establish an Executive Committee whose composition should ensure an adequate representation of the various geographical areas of the world to which the Members of the Commission belong. Between sessions, the Executive Committee shall act as the Executive organ of the Commission.

### ***ARTICLE 7***

The Commission may establish such other subsidiary bodies as it deems necessary for the accomplishment of its task, subject to the availability of the necessary funds.

### ***ARTICLE 8***

The Commission may adopt and amend its own Rules of Procedure which shall come into force upon approval by the Directors-General of FAO and WHO, subject to such confirmation as may be prescribed by the procedures of these Organizations.

### ***ARTICLE 9***

The operating expenses of the Commission and of its subsidiary bodies, other than those for which a Member has accepted the Chair, shall be borne by the budget of the Joint FAO/WHO Food Standards Programme which shall be administered by FAO on behalf of the two Organizations in accordance with the financial regulations of FAO. The Directors-General of FAO and WHO shall jointly determine the respective portion of the costs of the Programme to be borne by each Organization and prepare the corresponding annual expenditure estimates for inclusion in the Regular Budgets of the two Organizations for approval by the appropriate governing bodies.

### ***ARTICLE 10***

All expenses (including those relating to meetings, documents and interpretation) involved in preparatory work on draft standards undertaken by Members of the Commission, either independently or upon recommendation of the Commission, shall be defrayed by the government concerned. Within the

approved budgetary estimates, the Commission may, however, recommend that a specified part of the costs of the preparatory work undertaken by the government on behalf of the Commission be recognized as operating expenses of the Commission.

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**RULES OF PROCEDURE OF THE  
CODEX ALIMENTARIUS COMMISSION**

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***RULE I MEMBERSHIP***

1. Membership of the Joint FAO/WHO Codex Alimentarius Commission, hereinafter referred to as “the Commission”, is open to all Member Nations and Associate Members of FAO and/or WHO.
2. Membership shall comprise such eligible nations as have notified the Director-General of FAO or of WHO of their desire to be considered Members of the Commission.
3. Membership shall also comprise regional economic integration organizations members of either FAO or WHO that notify the Director-General of FAO or WHO of their desire to be considered Members of the Commission.
4. Each Member of the Commission shall communicate to the Director-General of FAO or of WHO the names of its representative and where possible other members of its delegation before the opening of each session of the Commission.

***RULE II - MEMBER ORGANIZATIONS***

1. A Member Organization shall exercise membership rights on an alternative basis with its Member States that are Members of the Commission in the areas of their respective competence.
2. A Member Organization shall have the right to participate in matters within its competence in any meetings of the Commission or its subsidiary bodies in which any of its Member States is entitled to participate. This is without prejudice to the possibility for the Member States to develop or support the position of the Member Organization in areas within its competence.
3. A Member Organization may exercise on matters within its competence, in any meetings of the Commission or any subsidiary body of the Commission in which it is entitled to participate in accordance with paragraph 2, a number of votes equal to the number of its Member States which are entitled to vote in such meetings and present at the time the vote is taken. Whenever a Member Organization exercises its right to vote, its Member States shall not exercise theirs, and conversely.
4. A Member Organization shall not be eligible for election or designation, nor to hold office in the Commission or any subsidiary body. A Member Organization shall not participate in voting for any elective places in the Commission and its subsidiary bodies.

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

6. Any Member of the Commission may request a Member Organization or its Member States to provide information as to which, as between the Member Organization and its Member States, has competence in respect of any specific question. The Member Organization or the Member States concerned shall provide this information on such request.

7. In cases where an agenda item covers both matters in respect of which competence has been transferred to the Member Organization and matters which lie within the competence of its Member States, both the Member Organization and its Member States may participate in the discussions. In such cases the meeting, in arriving at its decisions,<sup>1</sup> shall take into account only the intervention of the party which has the right to vote.<sup>2</sup>

8. For the purpose of determining a quorum, as specified in paragraph 7 of Rule VI, the delegation of a Member Organization shall be counted for a number equal to the number of its Member States which are entitled to participate in the meeting and are present at the time the quorum is sought, to the extent that it is entitled to vote under the relevant agenda item.

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<sup>1</sup> The word 'decisions' should be understood to mean both voting and situations where a decision is taken by consensus.

<sup>2</sup> The above is without prejudice to the question of whether or not the views of the party not having the right to vote shall be reflected in the report of the meeting. Where the views of the party not having the right to vote are reflected in the report, the fact that they are the views of the party not having the right to vote shall also be reflected in the report.

***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 twice, provided that by the end of their second term of office they have not served for a period of more than two years.
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. In principle, they shall be nominated at each session of the relevant Coordinating Committee established under Rule XI.1(b)(ii), and appointed at the following regular session of the Commission. They shall hold office from the end of this session. Coordinators may be reappointed for a second term. The Commission shall make such arrangements as may be necessary in order to ensure continuity in the functions of the Coordinators.

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) 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.

#### ***RULE V EXECUTIVE COMMITTEE***

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 if they have not served for more than two years in their current term, 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.1.

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.

#### ***RULE VI SESSIONS***

1. The Commission shall in principle hold one regular session each year at the Headquarters of either FAO or WHO. Additional sessions shall be held as considered necessary by the Directors-General of FAO and WHO after consultation with the Chairperson of the Executive Committee.

2. Sessions of the Commission shall be convened and the place of the meeting shall be determined by the Directors-General of FAO and WHO after consultation where appropriate, with the authorities of the host country.

3. Notice of the date and place of each session of the Commission shall be communicated to all Members of the Commission at least two months before the session.

4. Each Member of the Commission shall have one representative, who may be accompanied by one or more alternates and advisers.

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.
6. Meetings of the Commission shall be held in public, unless the Commission decides otherwise.
7. The majority of the Members of the Commission shall constitute a quorum for the purposes of making recommendations for amendments to the Statutes of the Commission and of adopting amendments of, or additions to, the present Rules in accordance with Rule XV.1. For all other purposes the majority of the Members of the Commission attending the session shall constitute a quorum, provided that such a majority shall be not less than 20 percent of the total membership of the Commission, nor less than 25 Members. In addition, in the case of amendment or adoption of a proposed standard for a given region or group of countries, the quorum of the Commission shall include one third of the Members belonging to the region or group of countries concerned.

#### ***RULE VII AGENDA***

1. The Directors-General of FAO and WHO, after consultation with the Chairperson of the Commission or with the Executive Committee, shall prepare a Provisional Agenda for each session of the Commission.
2. The first item on the Provisional Agenda shall be the adoption of the Agenda.
3. Any Member of the Commission may request the Directors-General of FAO or WHO to include specific items in the Provisional Agenda.
4. The Provisional Agenda shall be circulated by the Directors-General of FAO or WHO to all Members of the Commission at least two months before the opening of the session.
5. Any Member of the Commission, and the Directors-General of FAO and WHO, may, after the dispatch of the Provisional Agenda, propose the inclusion of specific items in the Agenda with respect to matters of an urgent nature. These items shall be placed on a supplementary list, which, if time permits before the opening of the session, shall be dispatched by the Directors-General of FAO and WHO to all Members of the Commission, failing which the supplementary list shall be communicated to the Chairperson for submission to the Commission.
6. No items included in the Agenda by the governing bodies or the Directors-General of FAO and WHO shall be deleted therefrom. After the Agenda has

been adopted, the Commission may, by a two-thirds majority of the votes cast, amend the Agenda by the deletion, addition or modification of any other item.

7. Documents to be submitted to the Commission at any session shall be furnished by the Directors-General of FAO and WHO to all Members of the Commission, to the other eligible Nations attending the session as observers and to the non-member nations and international organizations invited as observers thereto, in principle at least two months prior to the session at which they are to be discussed.

### ***RULE VIII VOTING AND PROCEDURES***

1. Subject to the provisions of paragraph 3 of this Rule, each Member of the Commission shall have one vote. An alternate or adviser shall not have the right to vote except where substituting for the representative.

2. Except as otherwise provided in these rules, decisions of the Commission shall be taken by a majority of the votes cast.

3. At the request of a majority of the Members of the Commission constituting a given region or a group of countries that a standard be elaborated, the standard concerned shall be elaborated as a standard primarily intended for that region or group of countries. When a vote is taken on the elaboration, amendment or adoption of a draft standard primarily intended for a region or group of countries, only Members belonging to that region or group of countries may take part in the voting. The adoption of the standard may, however, take place only after submission of the draft text to all Members of the Commission for comments. The provisions of this paragraph shall not prejudice the elaboration or adoption of a corresponding standard with a different territorial scope.

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

5. Elections shall be decided by secret ballot, except that, where the number of candidates does not exceed the number of vacancies, the Chairperson may submit to the Commission that the election be decided by clear general consent. Any other matter shall be decided by secret ballot if the Commission so determines.

6. Formal proposals relating to items of the Agenda and amendments thereto shall be introduced in writing and handed to the Chairperson, who shall circulate them to representatives of Members of the Commission.

7. The provisions of Rule XII of the General Rules of FAO shall apply *mutatis mutandis* to all matters which are not specifically dealt with under Rule VIII of the present Rules.

### ***RULE IX OBSERVERS***

1. Any Member Nation and any Associate Member of FAO or WHO which is not a Member of the Commission but has a special interest in the work of the Commission, may, upon request communicated to the Director-General of FAO or WHO, attend sessions of the Commission and of its subsidiary bodies as an observer. It may submit memoranda and participate without vote in the discussion.

2. Nations which, while not Member Nations or Associate Members of FAO or WHO, are Members of the United Nations, may, upon their request and subject to the provisions relating to the granting of observer status to nations adopted by the Conference of FAO and the World Health Assembly, be invited to attend in an observer capacity sessions of the Commission and of its subsidiary bodies. The status of nations invited to such sessions shall be governed by the relevant provisions adopted by the Conference of FAO.

3. Any Member of the Commission may attend as an observer the sessions of the subsidiary bodies and may submit memoranda and participate without vote in the discussions.

4. Subject to the provisions of paragraphs 5 and 6 of this Rule, the Directors-General of FAO or WHO may invite intergovernmental and international non-governmental organizations to attend as observers sessions of the Commission and of its subsidiary bodies.

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

***RULE X RECORDS AND REPORTS***

1. At each session the Commission shall approve a report embodying its views, recommendations and conclusions, including when requested a statement of minority views. Such other records for its own use as the Commission may on occasion decide shall also be maintained.
2. The report of the Commission shall be transmitted to the Directors-General of FAO and WHO at the close of each session, who shall circulate it to the Members of the Commission, to other countries and to organizations that were represented at the session, for their information, and upon request to other Member Nations and Associate Members of FAO and WHO.
3. Recommendations of the Commission having policy, programme or financial implications for FAO and/or WHO shall be brought by the Directors-General to the attention of the governing bodies of FAO and/or WHO for appropriate action.
4. Subject to the provisions of the preceding paragraph, the Directors-General of FAO and WHO may request Members of the Commission to supply the Commission with information on action taken on the basis of recommendations made by the Commission.

***RULE XI SUBSIDIARY BODIES***

1. The Commission may establish the following types of subsidiary bodies:
  - (a) subsidiary bodies which it deems necessary for the accomplishment of its work in the finalization of draft standards;
  - (b) subsidiary bodies in the form of:
    - (i) Codex Committees for the preparation of draft standards for submission to the Commission, whether intended for world-wide use, for a given region or for a group of countries specifically enumerated by the Commission.
    - (ii) Coordinating Committees for regions or groups of countries which shall exercise general coordination in the preparation of standards relating to such regions or groups of countries and such other functions as may be entrusted to them.
2. Subject to paragraph 3 below, membership in these subsidiary bodies shall consist, as may be determined by the Commission, either of such Members of the Commission as have notified the Directors-General of FAO or WHO of their

desire to be considered as Members thereof, or of selected Members designated by the Commission.

3. Membership of subsidiary bodies established under Rule XI.1(b)(i) for the preparation of draft standards intended primarily for a region or group of countries, shall be open only to Members of the Commission belonging to such a region or group of countries.

4. Representatives of members of subsidiary bodies shall, insofar as possible, serve in a continuing capacity and shall be specialists active in the fields of the respective subsidiary bodies.

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.

6. Sessions of subsidiary bodies shall be convened by the Directors-General of FAO and WHO:

(a) in the case of bodies established under Rule XI.1(a), in consultation with the Chairperson of the Commission;

(b) in the case of bodies established under Rule XI.1(b)(i) (Codex Committees), in consultation with the chairperson of the respective Codex Committee and also, in the case of Codex Committees for the preparation of draft standards for a given region or group of countries, with the Coordinator, if a Coordinator has been appointed for the region or group of countries concerned;

(c) in the case of bodies established under Rule XI.1(b)(ii) (Coordinating Committees), in consultation with the Chairperson of the Coordinating Committee.

7. The Directors-General of FAO and WHO shall determine the place of meeting of bodies established under Rule XI.1(a) and Rule XI.1(b)(ii) after consultation, where appropriate, with the host country concerned and, in the case of bodies established under Rule XI.1(b)(ii), after consultation with the Coordinator for the region or group of countries concerned, if any.

8. Notice of the date and place of each session of bodies established under Rule XI.1(a) shall be communicated to all Members of the Commission at least two months before the session.

9. The establishment of subsidiary bodies under Rule XI.1(a) and Rule XI.1(b)(ii) shall be subject to the availability of the necessary funds, as shall the establishment of subsidiary bodies under Rule XI.1(b)(i) when any of their expenses are proposed to be recognized as operating expenses within the budget of the Commission in accordance with Article 10 of the Statutes of the

Commission. Before taking any decision involving expenditure in connection with the establishment of such subsidiary bodies, the Commission shall have before it a report from the Director-General of FAO and/or WHO, as appropriate, on the administrative and financial implications thereof.

10. The Members who shall be responsible for appointing Chairpersons of subsidiary bodies established under Rule XI.1(b)(i) and Rule XI.1(b)(ii) shall be designated at each session by the Commission 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. The Rules of Procedure of the Commission shall apply *mutatis mutandis* to its subsidiary bodies.

#### ***RULE XII ELABORATION AND ADOPTION OF STANDARDS***

1. Subject to the provisions of these Rules of Procedure, the Commission may establish the procedures for the elaboration of world-wide standards and of standards for a given region or group of countries, and, when necessary, amend such procedures.

2. The Commission shall make every effort to reach agreement on the adoption or amendment of standards by consensus. Decisions to adopt or amend standards may be taken by voting only if such efforts to reach consensus have failed.

#### ***RULE XIII BUDGET AND EXPENSES***

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) 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) (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 IX, 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.

#### ***RULE XIV LANGUAGES***

1. The languages of the Commission and of its subsidiary bodies set up under Rule XI.1(a) shall be not less than three of the working languages, as shall be determined by the Commission, which are working languages both of FAO and of the Health Assembly of WHO.

2. Notwithstanding the provisions of paragraph 1 above, other languages which are working languages either of FAO or of the Health Assembly of WHO may be added by the Commission if

(a) the Commission has before it a report from the Directors-General of FAO and WHO on the policy, financial and administrative implications of the addition of such languages; and

(b) the addition of such languages has the approval of the Directors-General of FAO and WHO.

3. Where a representative wishes to use a language other than a language of the Commission he shall himself provide the necessary interpretation and/or translation into one of the languages of the Commission.

4. Without prejudice to the provisions of paragraph 3 of this Rule, the languages of subsidiary bodies set up under Rule XI.1(b) shall include at least two of the languages of the Commission.

***RULE XV AMENDMENTS AND SUSPENSION OF RULES***

1. Amendments of or additions to these Rules may be adopted by a two thirds majority of the votes cast, provided that 24 hours' notice of the proposal for the amendment or addition has been given. Amendments of or additions to these Rules shall come into force upon approval by the Directors-General of FAO and WHO, subject to such confirmation as may be prescribed by the procedures of the two Organizations.

2. The Rules of the Commission, other than Rule I, Rule III.1, 2, 3 and 5, Rule V, Rule VI.2 and 7, Rule VII.1, 4 and 6, Rule VIII.1, 2 and 3, Rule IX, Rule X.3 and 4, Rule XI.5, 7 and 9, Rule XIII, Rule XV and Rule XVI, may be suspended by the Commission by a two thirds majority of the votes cast, provided that 24 hours' notice of the proposal for suspension has been given. Such notice may be waived if no representative of the Members of the Commission objects.

***RULE XVI ENTRY INTO FORCE***

1. In accordance with Article 8 of the Statutes of the Commission, these Rules of Procedure shall come into force upon approval by the Directors-General of FAO and WHO, subject to such confirmation as may be prescribed by the procedures of the two Organizations. Pending the coming into force of these Rules, they shall apply provisionally.

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## PROCEDURES FOR THE ELABORATION OF CODEX STANDARDS AND RELATED TEXTS

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

### *INTRODUCTION*

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

1. The Commission shall implement a unified approach in the area of standards development by taking its decisions, based on a strategic planning process (“standards management”) (See Part 1 of this document).
2. An on-going critical review shall ensure that proposals for new work and draft standards submitted to the Commission for adoption continue to meet the strategic priorities of the Commission and can be developed within a reasonable period of time, taking into account the requirements and availability of scientific expert advice (See Part 2 of this document).
3. The Commission decides, taking into account the outcome of the on-going critical review conducted by the Executive Committee, that a standard should be elaborated and also which subsidiary body or other body should undertake the work. Decisions to elaborate standards may also be taken by subsidiary bodies of the Commission in accordance with the above-mentioned outcome subject to subsequent approval by the Commission at the earliest possible opportunity. The Secretariat arranges for the preparation of a “proposed draft standard” which is circulated to governments for comments and is then considered in the light of these by the subsidiary body concerned which may present the text to the Commission as a “draft standard”. If the Commission adopts the “draft standard” it is sent to governments for further comments and in the light of these and after further consideration by the subsidiary body concerned, the Commission reconsiders the draft and may adopt it as a “Codex standard”. The procedure is described in Part 3 of this document.
4. The Commission or any subsidiary body, subject to the confirmation of the Commission may decide that the urgency of elaborating a Codex standard is such that an accelerated elaboration procedure should be followed. While taking this decision, all appropriate matters shall be taken into consideration, including the likelihood of new scientific information becoming available in the immediate future. The accelerated elaboration procedure is described in Part 4

of this document.

5. The Commission or the subsidiary body or other body concerned may decide that the draft be returned for further work at any appropriate previous Step in the Procedure. The Commission may also decide that the draft be held at Step 8.

6. The Commission may authorise, on the basis of two-thirds majority of votes cast, the omission of Steps 6 and 7, where such an omission is recommended by the Codex Committee entrusted with the elaboration of the draft. Recommendations to omit steps shall be notified to Members and interested international organizations as soon as possible after the session of the Codex Committee concerned. When formulating recommendations to omit Steps 6 and 7, Codex Committees shall take all appropriate matters into consideration, including the need for urgency, and the likelihood of new scientific information becoming available in the immediate future.

7. The Commission may at any stage in the elaboration of a standard entrust any of the remaining Steps to a Codex Committee or other body different from that to which it was previously entrusted.

8. It will be for the Commission itself to keep under review the revision of “Codex standards”. The procedure for revision should, *mutatis mutandis*, be that laid down for the elaboration of Codex standards, except that the Commission may decide to omit any other step or steps of that Procedure where, in its opinion, an amendment proposed by a Codex Committee is either of an editorial nature or of a substantive nature but consequential to provisions in similar standards adopted by the Commission at Step 8.

9. Codex standards 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. STRATEGIC PLANNING PROCESS***

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

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

## ***PART 2. CRITICAL REVIEW***

### ***Proposals to Undertake New Work or to Revise a Standard***

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

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

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

3. The critical review includes:

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

## *Elaboration procedures*

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

4. The decision to undertake new work or revision of individual maximum residue limits for pesticides or veterinary drugs, or the maintenance of the General Standard on Food Additives<sup>3</sup>, the General Standard on Contaminants and Toxins in Foods<sup>4</sup>, the Food Categorisation System and the International Numbering System, shall follow the procedures established by the Committees concerned and endorsed by the Commission.

### ***Monitoring Progress of Standards Development***

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

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

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

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

This shall therefore include:

- monitoring of progress in developing standards and advising what corrective action should be taken;
- examining proposed standards from Codex committees, before they are submitted to the Commission for adoption :
  - for consistency with the mandate of Codex, the decisions of the Commission, and existing Codex texts,

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<sup>3</sup> including related methods of analysis and sampling plans

<sup>4</sup> including related methods of analysis and sampling plans

- to ensure that the requirements of the endorsement procedure have been fulfilled, where appropriate,
- for format and presentation, and
- for linguistic consistency.

### ***PART 3. UNIFORM PROCEDURE FOR THE ELABORATION OF CODEX STANDARDS AND RELATED TEXTS***

#### ***Steps 1, 2 and 3***

- (1) The Commission decides, taking into account the outcome of the critical review conducted by the Executive Committee, to elaborate a World-wide Codex Standard and also decides which subsidiary body or other body should undertake the work. A decision to elaborate a World-wide Codex Standard may also be taken by subsidiary bodies of the Commission in accordance with the above mentioned outcome, subject to subsequent approval by the Commission at the earliest possible opportunity. In the case of Codex Regional Standards, the Commission shall base its decision on the proposal of the majority of Members belonging to a given region or group of countries submitted at a session of the Codex Alimentarius Commission.
- (2) The Secretariat arranges for the preparation of a proposed draft standard. In the case of Maximum Limits for Residues of Pesticides or Veterinary Drugs, the Secretariat distributes the recommendations for maximum limits, when available from the Joint Meetings of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues (JMPR), or the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Any other relevant information regarding risk assessment work conducted by FAO and WHO should also be made available. In the cases of milk and milk products or individual standards for cheeses, the Secretariat distributes the recommendations of the International Dairy Federation (IDF).
- (3) The proposed draft standard is sent to Members of the Commission and interested international organizations for comment on all aspects including possible implications of the proposed draft standard for their economic interests.

#### ***Step 4***

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

***Step 5***

The proposed draft standard is submitted through the Secretariat to the Executive Committee for critical review and to the Commission with a view to its adoption as a draft standard<sup>5</sup>. In taking any decision at this step, the Commission will give due consideration to the outcome of the critical review and to any comments that may be submitted by any of its Members regarding the implications which the proposed draft standard or any provisions thereof may have for their economic interests. In the case of Regional Standards, all Members of the Commission may present their comments, take part in the debate and propose amendments, but only the majority of the Members of the region or group of countries concerned attending the session can decide to amend or adopt the draft. In taking any decisions at this step, the Members of the region or group of countries concerned will give due consideration to any comments that may be submitted by any of the Members of the Commission regarding the implications which the proposed draft standard or any provisions thereof may have for their economic interests.

***Step 6***

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

***Step 7***

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

***Step 8***

The draft standard is submitted through the Secretariat to the Executive Committee for critical review and to the Commission, together with any written proposals received from Members and interested international organizations for amendments at Step 8, with a view to its adoption as a Codex standard. In taking any decision at this step, the Commission will give due consideration to the outcome of the critical review and to any comments that may be submitted by

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



any of its Members regarding the implications which the draft standard or any provisions thereof may have for their economic interests. In the case of Regional standards, all Members and interested international organizations may present their comments, take part in the debate and propose amendments but only the majority of Members of the region or group of countries concerned attending the session can decide to amend and adopt the draft.

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

***Steps 1, 2 and 3***

- (1) The Commission, on the basis of a two-thirds majority of votes cast, taking into account the outcome of the critical review conducted by the Executive Committee, shall identify those standards which shall be the subject of an accelerated elaboration process.<sup>6</sup> The identification of such standards may also be made by subsidiary bodies of the Commission, on the basis of a two-thirds majority of votes cast, subject to confirmation at the earliest opportunity by the Commission.
- (2) The Secretariat arranges for the preparation of a proposed draft standard. In the case of Maximum Limits for Residues of Pesticides or Veterinary Drugs, the Secretariat distributes the recommendations for maximum limits, when available from the Joint Meetings of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues (JMPR), or the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Any other relevant information regarding risk assessment work conducted by FAO and WHO should also be made available. In the cases of milk and milk products or individual standards for cheeses, the Secretariat distributes the recommendations of the International Dairy Federation (IDF).
- (3) The proposed draft standard is sent to Members of the Commission and interested international organizations for comment on all aspects including possible implications of the proposed draft standard for their economic interests. When standards are subject to an accelerated procedure, this fact shall be notified to the Members of the Commission and the interested international organizations.

***Step 4***

The comments received are sent by the Secretariat to the subsidiary body or

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<sup>6</sup> Relevant considerations could include, but need not be limited to, matters concerning new scientific information; new technology(ies); urgent problems related to trade or public health; or the revision or up-dating of existing standards.

other body concerned which has the power to consider such comments and to amend the proposed draft standard.

***Step 5***

In the case of standards identified as being subject to an accelerated elaboration procedure, the proposed draft standard is submitted through the Secretariat to the Executive Committee for critical review and to the Commission, together with any written proposals received from Members and interested international organizations for amendments, with a view to its adoption as a Codex standard. In taking any decision at this step, the Commission will give due consideration to the outcome of the critical review and to any comments that may be submitted by any of its Members regarding the implications which the proposed draft standard or any provisions thereof may have for their economic interests. In the case of Regional standards, all Members and interested international organizations may present their comments, take part in the debate and propose amendments but only the majority of Members of the region or group of countries concerned attending the session can decide to amend and adopt the proposed draft.

***PART 5. SUBSEQUENT PROCEDURE CONCERNING  
PUBLICATION OF CODEX STANDARDS***

The Codex standard is published and issued to all Member States and Associate Members of FAO and/or WHO and to the international organizations concerned.

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

***SUBSEQUENT PROCEDURE CONCERNING PUBLICATION AND POSSIBLE  
EXTENSION OF TERRITORIAL APPLICATION OF THE 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.

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.

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

1. Proposals for the amendment or revision of Codex standards should be submitted to the Commission's Secretariat in good time (not less than three months) before the session of the Commission at which they are to be considered. The proposer of an amendment should indicate the reasons for the proposed amendment and should also state whether the proposed amendment had been previously submitted to and considered by the Codex committee

concerned and/or the Commission. If the proposed amendment has already been considered by the Codex committee and/or Commission, the outcome of the consideration of the proposed amendment should be stated.

2. Taking into account such information regarding the proposed amendment, as may be supplied in accordance with paragraph 1 above, and the outcome of the on-going critical review conducted by the Executive Committee, the Commission will decide whether the amendment or revision of a standard is necessary. If the Commission decides in the affirmative, and the proposer of the amendment is other than a Codex committee, the proposed amendment will be referred for consideration to the appropriate Codex committee, if such committee is still in existence. If such committee is not in existence, the Commission will determine how best to deal with the proposed amendment. If the proposer of the amendment is a Codex committee, it would be open to the Commission to decide that the proposed amendment be circulated to governments for comments prior to further consideration by the sponsoring Codex Committee. In the case of an amendment proposed by a Codex Committee, it will also be open to the Commission to adopt the amendment at Step 5 or Step 8 as appropriate, where in its opinion the amendment is either of an editorial nature or of a substantive nature but consequential to provisions in similar standards adopted by it at Step 8.
3. The procedure for amending or revising a Codex standard is laid down in paragraph 8 of the Introduction to the Procedure for the Elaboration of Codex Standards and Related Texts.
4. When the Commission has decided to amend or revise a standard, the unrevised standard will remain the applicable Codex standard until the revised standard has been adopted by the Commission.

***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;

2. The “Guide to the Procedure for the Revision and Amendment of Codex Standards” covers sufficiently amendments to Codex standards which have been elaborated by still active Codex Committees. 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, 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.

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## GENERAL PRINCIPLES OF THE CODEX ALIMENTARIUS

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### *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.

### *REVISION OF CODEX STANDARDS*

4. 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.

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**GUIDELINES ON COOPERATION BETWEEN THE CODEX  
ALIMENTARIUS COMMISSION AND INTERNATIONAL  
INTERGOVERNMENTAL ORGANIZATIONS IN THE ELABORATION OF  
STANDARDS AND RELATED TEXTS**

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**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 international 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 INTERNATIONAL INTERGOVERNMENTAL ORGANIZATION**

- 5) The cooperating international intergovernmental organization shall have observer status with the Codex Alimentarius Commission.
- 6) The cooperating international intergovernmental organization shall have the same principles of membership<sup>7</sup> that form the basis for membership in the

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<sup>7</sup> "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.

Codex Alimentarius Commission and equivalent principles of standards-setting<sup>8</sup>.

**COOPERATION AT THE INITIAL DRAFTING STAGES OF A CODEX STANDARD OR RELATED TEXT<sup>9</sup>**

- 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 World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (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 text shall be circulated at Step 3 of the "Uniform Procedure for the Elaboration of Codex Standards and Related Texts".

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<sup>8</sup> "Equivalent principles of standards-setting" refers to the General Decisions of the Commission set out in the Appendix to the Procedural Manual.

<sup>9</sup> 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.



## **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.

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**PRINCIPLES CONCERNING THE PARTICIPATION OF INTERNATIONAL  
NON-GOVERNMENTAL ORGANIZATIONS IN THE WORK OF THE  
CODEX ALIMENTARIUS COMMISSION**

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**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"**

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.

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 bodies<sup>10</sup> 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

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<sup>10</sup> The term "subsidiary bodies" means any body established under Rule XI of the Commission's Rules of Procedure.

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 IX.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 Chairperson<sup>11</sup>;

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<sup>11</sup> An invitation to a Codex meeting and representation thereof by an observer shall not imply the granting to an international non-governmental organization of a status different from that which it already enjoys.

(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 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;

(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.

*Principles concerning NGO Participation*

- (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



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**DEFINITIONS FOR THE PURPOSES OF THE CODEX ALIMENTARIUS**

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For the purposes of the Codex Alimentarius:

**Food** means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances used only as drugs.

**Food hygiene** comprises conditions and measures necessary for the production, processing, storage and distribution of food designed to ensure a safe, sound, wholesome product fit for human consumption.

**Food additive** means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include “contaminants” or substances added to food for maintaining or improving nutritional qualities.

**Contaminant** means any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter.

**Pesticide** means any substance intended for preventing, destroying, attracting, repelling, or controlling any pest including unwanted species of plants or animals during the production, storage, transport, distribution and processing of food, agricultural commodities, or animal feeds or which may be administered to animals for the control of ectoparasites. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant, fruit thinning agent, or sprouting inhibitor and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. The term normally excludes fertilizers, plant and animal nutrients, food additives, and animal drugs.

**Pesticide Residue** means any specified substance in food, agricultural commodities, or animal feed resulting from the use of a pesticide. The term

## Definitions

includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and impurities considered to be of toxicological significance.

**Good Agricultural Practice in the Use of Pesticides (GAP)** includes the nationally authorized safe uses of pesticides under actual conditions necessary for effective and reliable pest control. It encompasses a range of levels of pesticide applications up to the highest authorised use, applied in a manner which leaves a residue which is the smallest amount practicable.

Authorized safe uses are determined at the national level and include nationally registered or recommended uses, which take into account public and occupational health and environmental safety considerations.

Actual conditions include any stage in the production, storage, transport, distribution and processing of food commodities and animal feed.

**Codex maximum limit for pesticide residues (MRLP)** is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds. MRLs are based on GAP data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable.

Codex MRLs, which are primarily intended to apply in international trade, are derived from estimations made by the JMPR following:

- (a) toxicological assessment of the pesticide and its residue; and
- (b) review of residue data from supervised trials and supervised uses including those reflecting national good agricultural practices. Data from supervised trials conducted at the highest nationally recommended, authorized or registered uses are included in the review. In order to accommodate variations in national pest control requirements, Codex MRLs take into account the higher levels shown to arise in such supervised trials, which are considered to represent effective pest control practices.

Consideration of the various dietary residue intake estimates and determinations both at the national and international level in comparison with the ADI, should indicate that foods complying with Codex MRLs are safe for human consumption.

**Veterinary drug** means any substance applied or administered to any food producing animal, such as meat or milk producing animals, poultry, fish or bees, whether used for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behaviour.

**Residues of veterinary drugs** include the parent compounds and/or their metabolites in any edible portion of the animal product, and include residues of associated impurities of the veterinary drug concerned.

**Codex maximum limit for residues of veterinary drugs (MRLVD)** is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or µg/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food.

It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technological aspects.

When establishing an MRL, consideration is also given to residues that occur in food of plant origin and/or the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available.

**Good Practice in the Use of Veterinary Drugs (GPVD)** is the official recommended or authorized usage including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions.

**Processing aid** means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.

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

#### **DEFINITIONS OF RISK ANALYSIS TERMS RELATED TO FOOD SAFETY**

**Hazard:** A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

**Risk:** A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

**Risk Analysis:** A process consisting of three components : risk assessment, risk management and risk communication.

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**Risk Assessment:** A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

**Risk Management:** The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

**Risk Communication:** The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

**Risk Assessment Policy:** Documented guidelines on the choice of options and associated judgements for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained.

**Risk Profile:** The description of the food safety problem and its context.

**Risk Characterization:** The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

**Risk Estimate:** The quantitative estimation of risk resulting from risk characterization.

**Hazard Identification:** The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

**Hazard Characterization:** The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

**Dose-Response Assessment:** The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

**Exposure Assessment:** The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.

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

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

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

## SECTION II

- Guidelines for Codex Committees and Task Forces
- Criteria for Work Priorities and for Establishing Subsidiary Bodies
- Guidelines for the Inclusion of Specific Provisions in Codex Standards
- Reference System for Documents
- Format for Codex Commodity Standards
- Relations between Codex Committees
- Core Functions of Codex Contact Points

### **Contents of this section**

This Section of the Procedural Manual sets out the working procedures of the subsidiary bodies of the Codex Alimentarius Commission.

The Guidelines for Codex Committees and Task Forces describe the organization and conduct of meetings and the preparation and distribution of working papers and reports. A section describes the criteria for the establishment of work priorities and for establishing new subsidiary bodies.

The Format for Codex standards and an explanatory note on how Committees and Task Forces should draft Codex standards are described here.

To ensure that the appropriate sections of Codex commodity standards have been reviewed for food safety, nutrition, consumer protection and food analysis, a section on the Relations between Commodity Committees and General Committees is included for guidance to Codex Committees and Task Forces.

A section on Core Functions of Codex Contact Points lists the main tasks of Codex Contact Points at the national level.