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INTRODUCTION

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. This section describes how standards are set out in a uniform manner and also describes a uniform reference system for Codex documents and working papers. It 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 Seventeenth Edition of the Procedural Manual was prepared by the Secretariat following the Thirtieth Session of the Codex Alimentarius Commission, Rome, 2007. 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 2007. 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. They were amended in 2007. 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.

STATUTES OF THE CODEX ALIMENTARIUS COMMISSION

ARTICLE 1

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

(a) protecting the health of the consumers and ensuring fair practices in the food trade;

(b) promoting coordination of all food standards work undertaken by international governmental and non governmental organizations;

(c) determining priorities and initiating and guiding the preparation of draft standards through and with the aid of appropriate organizations;

(d) finalizing standards elaborated under (c) above and publishing them in a Codex Alimentarius either as regional or worldwide 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 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.

RULES OF PROCEDURE OF THE CODEX ALIMENTARIUS COMMISSION

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, [1] shall take into account only the intervention of the party which has the right to vote.[2]

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

[2] 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 appoint the Chairperson of the Coordinating Committee where such committee has been set up under Rule XI.1(b)(ii) for the region or group of countries concerned;

(ii) 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;

(iii) 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. Members elected on a geographic basis are expected to act within the Executive Committee in the interest of the Commission as a whole.

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 there from. 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 worldwide 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) 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 worldwide 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.

PROCEDURES FOR THE ELABORATION OF CODEX STANDARDS AND RELATED TEXTS

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 authorize, 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 of 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

- 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[3], the General Standard on Contaminants and Toxins in Foods[4], 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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3 including related methods of analysis and sampling plans

4 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[5]. 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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[5] 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.[6] 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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[6] 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 AMENDMENT AND REVISION OF CODEX STANDARDS AND RELATED TEXTS

1. 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. This Guide provides more detailed guidance on the existing procedure for the amendment and revision of Codex standards and related text.

2. When the Commission has decided to amend or revise a standard, the unrevised standard will remain the applicable Codex standard until the amendment to the standard or the revised standard has been adopted by the Commission.

3. For the purpose of this Guide:

Amendment means any addition, change or deletion of text or numerical values in a Codex standard or related text, may be editorial or substantive, and concerns one or a limited number of articles in the Codex text. In particular, amendments of an editorial nature may include but are not limited to:

- correction of an error;
- insertion of an explanatory footnote; and
- updating of references consequential to the adoption, amendment or revision of Codex standards and other texts of general applicability, including the provisions in the Procedural Manual.

Finalization or updating of methods of analysis and sampling as well as alignment of provisions, for consistency, to those in similar standards or related texts adopted by the Commission may be handled by the Commission in the same manner as amendments of an editorial nature, as far as the procedure described in this Guide is concerned.

Revision means any changes to a Codex standard or related text other than those covered under "amendment" as defined above.

The Commission has the final authority to determine whether a proposal made constitutes an amendment or a revision, and whether an amendment proposed is of an editorial or substantive nature.

4. Proposals for the amendment or revision of Codex standards and related texts should be submitted to the Commission by the subsidiary body concerned, by the Secretariat, or a member of the Commission where the subsidiary body concerned is not in existence or has been adjourned *sine die*. In the latter case, proposals should be received by the Secretariat in good time (not less than three months) before the session of the Commission at which they are to be considered. The proposal should be accompanied by a project document (see Part 2 of the Elaboration Procedures) unless the Executive Committee or the Commission decides otherwise. However, if the amendment proposed is of an editorial nature, the preparation of a project document is not required.

5. Taking into account the outcome of the on-going critical review conducted by the Executive Committee, the Commission decides whether the amendment or revision of a standard is necessary. If the Commission decides in the affirmative, one of the following courses of action will be taken:

(i) In the case of an amendment of an editorial nature, it will be open to the Commission to adopt the amendment at Step 8 of the Uniform Procedure (see Part 3 of the Elaboration Procedures).

(ii) In the case of an amendment proposed and agreed upon by a subsidiary body, it will also be open to the Commission to adopt the amendment at Step 5 of the Uniform Procedure (see Part 3 of the Elaboration Procedures).

(iii) In other cases, the Commission will approve the proposal as new work and the approved new work will be referred for consideration to the appropriate subsidiary body, if such body is still in existence. If such body is not in existence, the Commission will determine how best to deal with the new work.

6. Where Codex subsidiary bodies have been abolished or dissolved, or Codex committees have been adjourned *sine die*, the Secretariat keeps under review all Codex standards and related texts elaborated by these bodies and determines the need for any amendments, in particular those arising from decisions of the Commission If the need for amendments of an editorial nature is identified then the Secretariat should prepare proposed amendments for consideration and adoption by the Commission. If the need for amendments of a substantive nature is identified, the Secretariat, in cooperation with the national secretariat of the adjourned Committee if applicable, should prepare a working paper containing the reasons for proposing amendments and the wording of such amendments as appropriate, and request comments from members of the Commission: (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 members of the Commission 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 for consideration and adoption. 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.

GENERAL PRINCIPLES OF THE CODEX ALIMENTARIUS

PURPOSE OF THE CODEX ALIMENTARIUS

1. The Codex Alimentarius is a collection of internationally adopted food standards and related texts [7] presented in a uniform manner. These food standards and related texts aim at protecting consumers' health and ensuring fair practices in the food trade. 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, residues of pesticides and veterinary drugs, contaminants, labelling and presentation, methods of analysis and sampling, and import and export inspection and certification.

NATURE OF CODEX STANDARDS

3. Codex standards and related texts are not a substitute for, or alternative to national legislation. Every country's laws and administrative procedures contain provisions with which it is essential to comply.

4. Codex standards and related texts contain requirements for food aimed at ensuring for the consumer a safe, 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 sections listed therein.

REVISION OF CODEX STANDARDS

5. 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 in accordance with the Procedures for the Elaboration of Codex Standards and Related Texts. Each member of the Codex Alimentarius

[7] These include codes of practice, guidelines and other recommendations.

Commission is responsible for identifying, and presenting to the appropriate committee, any new scientific and other relevant information which may warrant revision of any existing Codex standards or related texts.

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

SCOPE AND APPLICATION

1) These guidelines establish the modalities of cooperation between the Codex Alimentarius Commission and International Intergovernmental Organizations when elaborating food standards or related texts.

2) These guidelines should be read in conjunction with the "Uniform Procedure for the Elaboration of Codex Standards and Related Texts".

TYPES OF COOPERATION

3) The Codex Alimentarius Commission may undertake the elaboration of any standard or related text in cooperation with another 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[8] that form the basis for membership in the Codex Alimentarius Commission and equivalent principles of standards-setting[9].

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[8] "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.

[9] "Equivalent principles of standards-setting" refers to the General Decisions of the Commission set out in the Appendix to the Procedural Manual.

COOPERATION AT THE INITIAL DRAFTING STAGES OF A CODEX STANDARD OR RELATED TEXT[10]

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".

[10] 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.

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

1. PURPOSE

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

2. TYPES OF RELATIONSHIP

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

3. ORGANIZATIONS ELIGIBLE FOR "OBSERVER STATUS"

The following shall be eligible for Observer Status:

(i) International Non-Governmental Organizations in consultative status, specialized consultative status or liaison status with FAO;

(ii) International Non-Governmental Organizations having official relations with WHO; and

(iii) 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[11] 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

[11] 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[12];

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

(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 in sections 3 and 4 above , or for reasons of exceptional nature, in accordance with the procedures set out in this section.

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

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

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

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

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

(a) Official name of the organization in different languages (with initials).

(b) Full postal address, Telephone, Facsimile and Email, as well as Telex and website addresses as appropriate.

(c) Aims and subject fields (mandate) of organization, and methods of operation. (Enclose charter, constitution, by-laws, rules of procedures, etc.). Date of establishment.

(d) Member organizations (name and address of each national affiliate, method of affiliation, giving number of members where possible, and names of principal officers. If the organization has individual members, please indicate approximate number in each country. If the organization is of a federal nature and has International Non-Governmental Organizations as members, please indicate whether any of those members already enjoy observer status with the Codex Alimentarius Commission).

(e) Structure (assembly or conference; council or other form of governing body; type of general secretariat; commissions on special topics, if any; etc.).

(f) Indication of source of funding (e.g. membership contributions, direct funding, external contributions, or grants).

(g) Meetings (indicate frequency and average attendance; send report of previous meeting, including any resolutions passed) that are concerned with matters covering all or part of the Commission's field of activity.

(h) Relations with other international organizations:

- UN and its organs (indicate consultative status or other relationship, if any).
- Other international organizations (document substantive activities).

(i) Expected contribution to the Joint FAO/WHO Food Standards Programme.

(j) Past activities on behalf of, or in relation to, the Codex Alimentarius Commission and the Joint FAO/WHO Food Standards Programme (indicate any relationship by national affiliates with the Regional Coordinating Committees and/or the National Codex Contact Points or Committees for at least the last three years preceding the application).

(k) Area of activity in which participation as an observer is requested (Commission and/or Subsidiary Bodies). If more than one organization with similar interests is requesting observer status in any field of activity, such organizations will be encouraged to form themselves into a federation or association for the purpose of participation. If the formation of such a single organization is not feasible, the application should explain why this is so.

(l) Previous applications for observer status with the Codex Alimentarius Commission, including those made by a member organization of the applicant organization. If successful, please indicate why and when observer status was terminated. If unsuccessful, please indicate the reasons you were given.

(m) Languages (English, French or Spanish) in which documentation should be sent to the International Non-Governmental Organization.

(n) Name, Function and address of the person providing the information.

(o) Signature and date.

DEFINITIONS FOR THE PURPOSES OF THE CODEX ALIMENTARIUS

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.

Good Manufacturing Practice in the Use of Food Additives means that:

- the quantity of the additive added to food does not exceed the amount reasonably required to accomplish its intended physical nutritional or other technical effect in food;
- the quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technological effect in the food itself, is reduced to the extent reasonably possible;
- the additive is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient. Food grade quality is achieved by compliance with the specifications as a whole and not merely with individual criteria in terms of safety.

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.

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.

Codex maximum level for a contaminant in a food or feed commodity is the maximum concentration of that substance recommended by the Codex Alimentarius Commission to be legally permitted in that commodity.

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

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.

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.

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.

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.

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 the Establishment of Subsidiary Bodies
- Criteria for the Establishment of Work Priorities
- Guidelines for the Inclusion of Specific Provisions in Codex Standards and Related Texts
- Uniform Reference System for Codex Documents
- Format for Codex Commodity Standards
- Relations between Commodity and General 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. This section also describes the criteria for establishing new subsidiary bodies and for the establishment of work priorities.

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 located in Codex members.

GUIDELINES FOR CODEX COMMITTEES AND *AD HOC* INTERGOVERNMENTAL TASK FORCES

GUIDELINES TO HOST GOVERNMENTS OF CODEX COMMITTEES AND AD HOC INTERGOVERNMENTAL TASK FORCES

INTRODUCTION

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

COMPOSITION OF CODEX COMMITTEES

MEMBERSHIP

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

OBSERVERS

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

attend in an observer capacity sessions of those Codex Committees which are of interest to them.

ORGANIZATION AND DUTIES

CHAIRPERSON

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

SECRETARIAT

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

DUTIES AND TERMS OF REFERENCE

The duties of a Codex Committee shall include:

(a) the drawing up of a list of priorities as appropriate, among the subjects and products within its terms of reference,

(b) consideration of the types of safety and quality elements (or recommendations) to be covered, whether in standards for general application or in reference to specific food products,

(c) consideration of the types of product to be covered by standards, e.g., whether materials for further processing into food should be covered,

(d) preparation of draft Codex standards within its terms of reference,

(e) reporting to each session of the Commission on the progress of its work and, where necessary, on any difficulties caused by its terms of reference, together with suggestions for their amendment, and

(f) the review and, as necessary, revision of existing standards and related texts on a scheduled, periodic basis to ensure that the standards and related texts within its terms of reference are consistent with current scientific knowledge and other relevant information.

SESSIONS

DATE AND PLACE

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

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

INVITATIONS AND PROVISIONAL AGENDA

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

Invitations should include the following:

(a) title of the Codex Committee,

(b) time and date of opening and date of closing of the session,

(c) place of the session,

(d) languages to be used and arrangements for interpretation, i.e. whether simultaneous or not,

(e) if appropriate, information on hotel accommodation,

(f) request for the names of the chief delegate and other members of the delegation, and for information on whether the chief delegate of a government will be attending as a representative or in the capacity of an observer.

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

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

(a) adoption of the agenda,

(b) if considered necessary, election of rapporteurs,

(c) items relating to subject matter to be discussed, including, where appropriate, the step in the Commission's Procedure for the Elaboration of Standards at which the item is being dealt with at the session. There should also be reference to the Committee papers relevant to the item,

(d) any other business,

(e) consideration of date and place of next session,

(f) adoption of draft report.

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

ORGANIZATION OF WORK

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

Ad hoc working groups established to accomplish specific tasks shall be

disbanded once the tasks have been accomplished as determined by the Committee.

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

PREPARATION AND DISTRIBUTION OF PAPERS

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

(i) all Codex Contact Points,

(ii) chief delegates of member countries, of observer countries and of international organizations, and

(iii) other participants on the basis of replies received. Twenty copies of all papers in each of the languages used in the Committee concerned should be sent to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Rome.

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

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

Codex Contact Points will be responsible for ensuring that papers [13] are circulated to those concerned within their own country and for ensuring that all necessary action is taken by the date specified.

Consecutive reference numbers in suitable series should be assigned to all documents of Codex Committees. The reference number should appear at the top right-hand corner of the first page together with a statement of the language in which the document was prepared and the date of its preparation. A clear statement should be made of the provenance (origin or author country) of the

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[13] See *Uniform System of References for Codex Documents*.

paper immediately under the title. The text should be divided into numbered paragraphs. At the end of these guidelines is a series of references for Codex documents adopted by the Codex Alimentarius Commission for its own sessions and those of its subsidiary bodies.

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

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

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

INTRODUCTION

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

CONDUCT OF MEETINGS

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

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

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

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

Delegations and delegations from observer countries who wish their opposition to a decision of the Committee to be recorded may do so, whether the decision has been taken by a vote or not, by asking for a statement of their position to be contained in the report of the Committee. This statement should not merely use

a phrase such as: "The delegation of X reserved its position" but should make clear the extent of the delegation's opposition to a particular decision of the Committee and state whether they were simply opposed to the decision or wished for a further opportunity to consider the question.

REPORTS

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

(a) decisions should be clearly stated; action taken in regard to economic impact statements should be fully recorded; all decisions on draft standards should be accompanied by an indication of the step in the Procedure that the standards have reached;

(b) if action has to be taken before the next meeting of the Committee, the nature of the action, who is to take it and when the action must be completed should be clearly stated;

(c) where matters require attention by other Codex Committees, this should be clearly stated;

(d) if the report is of any length, summaries of points agreed and the action to be taken should be included at the end of the report, and in any case, a section should be included at the end of the report showing clearly in summary form:

- standards considered at the session and the steps they have reached;
- standards at any step of the Procedure, the consideration of which has been postponed or which are held in abeyance and the steps which they have reached;
- new standards proposed for consideration, the probable time of their consideration at Step 2 and the responsibility for drawing up the first draft.

The following appendices should be attached to the report:

(a) list of participants with full postal addresses,

(b) draft standards with an indication of the step in the Procedure which has been reached.

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

Circular Letters should be attached to the report, as required, requesting comments on Proposed Draft or Draft Standards or Related Texts at Step 5, 8 or Step 5 (Accelerated), with the indication of the date by which comments or proposed amendments must be received in writing, so as to allow such comments to be considered by the Commission.

DRAWING UP OF CODEX STANDARDS

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

(a) the guidance given in the General Principles of the Codex Alimentarius;

(b) that all standards and related texts should have a preface containing the following information:

- the description of the standard or related text,
- a brief description of the scope and purpose(s) of the standard or related text,
- references including the step which the standard or related text has reached in the Commission's Procedures for the Elaboration of Standards, together with the date on which the draft was approved,
- matters in the draft standard or related text requiring endorsement or action by other Codex Committees.

(c) that for standards or any related text for a product which includes a number of sub-categories, the Committee should give preference to the development of a general standard or related text with specific provisions as necessary for sub-categories.

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

INTRODUCTION

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

DESIGNATION

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

CRITERIA FOR THE APPOINTMENT OF CHAIRPERSONS

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

The Member countries who shall be designated, under Rule XI.10, as responsible for appointing Chairpersons of subsidiary bodies established under Rule XI.1(b)(i) and Rule XI.1(b)(ii), shall retain the right to appoint a chairperson of their choice.

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

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

CONDUCT OF MEETINGS

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

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

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

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

Chairpersons should also ensure that the written comments, received in a timely manner, of members and observers not present at the session are considered by the Committee and that all issues are put clearly to the Committee. This can usually best be done by stating what appears to be the generally acceptable view and asking delegates whether they have any objection to its being adopted.

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

CONSENSUS[14]

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

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

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

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

(a) the need for timely progress in developing standards;

(b) the need to achieve consensus among the members as to the content of, and justification for, proposed standards;

(c) the importance of achieving consensus at all stages of the elaboration of standards and that draft standards should, as a matter of principle, be submitted to the Commission for adoption only where consensus has been achieved at the technical level.

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

[14] Reference is made to the *Measures to facilitate consensus* (see Appendix: General Decisions of the Codex Alimentarius Commission).

(a) ensuring that: *(i)* the scientific basis is well established on current data including, wherever possible, scientific data and intake and exposure information from the developing countries; *(ii)* where data from developing countries are not available, an explicit request for collecting and making available such data is made; and *(iii)* where necessary, further studies are carried out in order to clarify controversial issues;

(b) ensuring that issues are thoroughly discussed at meetings of the Committees concerned;

(c) organizing informal meetings of the parties concerned where disagreements arise, provided that the objectives of any such meetings are clearly defined by the Committee concerned and that participation is open to all interested delegations and observers in order to preserve transparency;

(d) requesting the Commission, where possible, for a redefinition of the scope of the subject matter being considered for the elaboration of standards in order to cut out issues on which consensus cannot be reached;

(e) ensuring that matters are not progressed from step to step until all relevant concerns are taken into account and adequate compromises worked out[15];

(f) facilitating increased involvement and participation of developing countries.

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

GUIDELINES ON PHYSICAL WORKING GROUPS

INTRODUCTION

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

The Rules of Procedure and the guidelines governing the work of a Codex Committee shall apply, *mutatis mutandis*, to the working groups this Committee establishes, unless stated otherwise in these Guidelines.[16]

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

COMPOSITION OF WORKING GROUPS

MEMBERSHIP

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

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

OBSERVERS

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

ORGANIZATION AND DUTIES

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

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[16] The provisions of the "Guidelines to Host Governments of Codex Committees and *ad hoc* Intergovernmental Task Forces", the "Guidelines on the Conduct of Meetings of Codex Committees and *ad hoc* Intergovernmental Task Forces" and the "Guidelines to Chairpersons of Codex Committees and *ad hoc* Intergovernmental Task Forces" are especially relevant in this matter.

CHAIRPERSON

The Host is responsible for appointing the chairperson of the working group. While selecting of the appointee, the Host may consider applying, where relevant, the *Codex Criteria for the Appointment of Chairpersons*[17].

SECRETARIAT

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

DUTIES AND TERMS OF REFERENCE

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

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

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

They shall not be binding on the Committee.

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

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

SESSIONS

DATE

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

When convened in-between two sessions of the Committee, the session of the working group should be scheduled as to allow the working group to report to the Committee well in advance of the next meeting so that countries and other

[17] Reference is made to the *Guidelines to Chairpersons of Codex Committees and ad hoc Intergovernmental Task Forces.*

interested parties, that were not members of the working group, can comment on the proposals that the working group might put to the Committee.

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

WORKING GROUP NOTIFICATION AND PROVISIONAL AGENDA

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

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

ORGANIZATION OF WORK

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

PREPARATION AND DISTRIBUTION OF PAPERS

The secretariat of the Host should circulate the papers at least two months before the opening of the session.

Paper for the session prepared by the participants should be sent to the secretariat of the Host, in good time.

CONCLUSIONS

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

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

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

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

GUIDELINES ON ELECTRONIC WORKING GROUPS

INTRODUCTION

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

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

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

The Rules of Procedure and the guidelines governing the work of a Committee shall apply, *mutatis mutandis*, to the electronic working groups this Committee establishes, unless stated otherwise in these Guidelines.[18]

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

COMPOSITION OF ELECTRONIC WORKING GROUPS

MEMBERSHIP

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

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

OBSERVERS

Observers should notify the Chairperson of the Committee and the host country secretariat of the Committee, of their wish to participate in a working group.

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[18] The provisions of the "Guidelines to Host Governments of Codex Committees and *ad hoc* Intergovernmental Task Forces", the "Guidelines on the Conduct of Meetings of Codex Committees and *ad hoc* Intergovernmental Task Forces", the "Guidelines to Chairpersons of Codex Committees and *ad hoc* Intergovernmental Task Forces" and the "Guidelines on Physical Working Groups" are especially relevant in this matter.

Observers may participate in all the activities of an electronic working group, unless otherwise specified by Committee members.

ORGANIZATION AND DUTIES

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

MANAGEMENT

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

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

SECRETARIAT

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

DUTIES AND TERMS OF REFERENCE

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

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

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

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

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

ELECTRONIC WORKING GROUP NOTIFICATION AND PROGRAMME OF WORK

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

ORGANIZATION OF WORK

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

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

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

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

PREPARATION AND DISTRIBUTION OF MATERIALS

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

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

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

CONCLUSIONS

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

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

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

CRITERIA FOR THE ESTABLISHMENT OF SUBSIDIARY BODIES OF THE CODEX ALIMENTARIUS COMMISSION

When there is a proposal for the elaboration of a standard, code of practice or related text in an area not covered by the terms of reference of any existing subsidiary body[19], or the revision of standards, codes of practice or other texts elaborated by subsidiary bodies adjourned *sine die*, such a proposal should be accompanied by a written statement to the Commission explaining its justification in light of the Commission's Medium-Term Objectives and containing, as far as practicable, the information contained in the Criteria for the Establishment of Work Priorities.

Should the Commission decide to establish a Subsidiary Body for the purpose of elaborating an appropriate draft standard or related text or for the purpose of revising an existing standard(s) or related text(s), first consideration should be given to the establishment of an *ad hoc* Intergovernmental Task Force under Rule XI.1(b)(i) of the Commission's Rules of Procedure under the following conditions:

1. TERMS OF REFERENCE

- the terms of reference of the proposed *ad hoc* Intergovernmental Task Force shall be limited to the immediate task at hand and normally shall not be subsequently modified;
- the terms of reference shall clearly state the objective(s) to be achieved by the establishment of the *ad hoc* Intergovernmental Task Force;
- the terms of reference shall clearly state either (i) the number of sessions to be convened, or (ii) the date (year) by which the work is expected to be completed, which in any case shall not exceed five years.

2. REPORTING

The *ad hoc* Intergovernmental Task Force shall report to the Codex Alimentarius Commission and to the Executive Committee on the progress of its work. The reports of the *ad hoc* Intergovernmental Task Force shall be transmitted to all Members of the Commission and interested international organization.

[19] The Commission may wish to consider extending the Terms of Reference of an appropriate existing body to accommodate the proposal.

3. OPERATING EXPENSES

No provision shall be made concerning the operating expenditures of the *ad hoc* Intergovernmental Task Force in the estimate of expenditures of the Joint FAO/WHO Food Standards Programme, except insofar as costs involved in preparatory work are recognized as operating expenses of the Commission in accordance with Article 10 of its Statutes.

4. HOST GOVERNMENT ARRANGEMENTS

The Commission, at the time of the establishment of the *ad hoc* Intergovernmental Task Force, shall ascertain that there will be appropriate host government arrangements adequate to ensure the functioning of the Task Force for the duration of its assignment.[20]

5. WORKING PROCEDURES

Ad hoc Intergovernmental Task Forces shall be open to all Members of the Commission and the Rules of Procedure of the Codex Alimentarius Commission and the Uniform Procedure for the Elaboration of Codex Standards and Related Texts shall apply *mutatis mutandis* to *ad hoc* Intergovernmental Task Forces.

6. DISSOLUTION

The *ad hoc* Intergovernmental Task Force shall be dissolved after the specified work has been completed or when the number of sessions or the time limit allocated for the work has expired.

[20] This may involve Host Government arrangements with one or more Members of the Commission.

CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

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

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

CRITERIA

GENERAL CRITERION

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

CRITERIA APPLICABLE TO GENERAL SUBJECTS

(a) Diversification of national legislations and apparent resultant or potential impediments to international trade.

(b) Scope of work and establishment of priorities between the various sections of the work.

(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).

CRITERIA APPLICABLE TO COMMODITIES

(a) Volume of production and consumption in individual countries and volume and pattern of trade between countries.

(b) Diversification of national legislations and apparent resultant or potential impediments to international trade.

(c) International or regional market potential.

(d) Amenability of the commodity to standardisation.

(e) Coverage of the main consumer protection and trade issues by existing or proposed general standards.

(f) Number of commodities which would need separate standards indicating whether raw, semi-processed or processed.

(g) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).

CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR

1. GENERAL CRITERIA

1.1 Criteria for Inclusion of Compounds on the Priority List

Before a pesticide can be considered for the Priority List it:

i must be registered for use in a member country;

ii must be available for use as a commercial product;

iii must not have been already accepted for consideration; and

iv must give rise to residues in or on a food or feed commodity moving in international trade, the presence of which is (or may be) a matter of public health concern and thus create (or have the potential to create) problems in international trade.

1.2 Criteria for Selecting Food Commodities for which Codex MRLs or EMRLs Should Be Established

The commodity for which the establishment of a Codex MRL or EMRL is sought should be such that it may form a component in international trade. A higher priority will be given to commodities that represent a significant proportion of the diet.

> Note: *Before proposing a pesticide/commodity for prioritization, it is recommended that governments check if the pesticide is already in the Codex system. Pesticide/commodity combinations that are already included in the Codex system or under consideration are found in a working document prepared for and used as a basis of discussion at each Session of the Codex Committee on Pesticide Residues. Consult the document of the latest session to see whether or not a given pesticide has already been considered.*

2. CRITERIA FOR PRIORITISATION

2.1 New Chemicals

When prioritizing new chemicals for evaluation by the JMPR, the Committee will consider the following criteria:

1. If the chemical has a reduced acute and/or chronic toxicity risk to humans compared with other chemicals in its classification (insecticide, fungicide, herbicide);

2. The date when the chemical was nominated for evaluation;

3. Commitment by the sponsor of the compound to provide supporting data for review with a firm date for data submission;

4. The availability of regional/national reviews and risk assessments, and coordination with other regional/national lists; and

5. Allocating priorities to new chemicals, so that at least 50% of evaluations are for new chemicals, if possible.

> **Note:** *In order to satisfy the criterion that the proposed new chemical is a "safer" or "reduced risk" replacement chemical, the nominating country is required to provide:*
>
> *i the name(s) of the chemicals for which the proposed chemical is likely to be an alternative;*
>
> *ii a comparison of the acute and chronic toxicities of the proposed chemical with other chemicals in its classification (insecticide, fungicide, herbicide);*
>
> *iii a summary of acute and chronic dietary exposure calculations encompassing the range of diets considered by CCPR; and*
>
> *iv other relevant information to support classification of the proposed chemical as a safer alternative chemical.*

2.2 Periodic Re-Evaluation

When prioritizing chemicals for periodic re-evaluation by the JMPR, the Committee will consider the following criteria:

1. If the intake and/or toxicity profile indicate some level of public health concern;

2. Chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits for 15 years;

3. The year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation – Not Yet Scheduled;

4. The date that data will be submitted;

5. Whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;

6. If there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently; and

7. The availability of current labels arising from recent national re-evaluations.

2.3 Evaluations

When prioritizing proposed toxicological or residue evaluations by the JMPR the Committee will consider the following criteria:

1. The date the request was received;

2. Commitment by the sponsor to provide the required data for review with a firm date of submission;

3. Whether the data is submitted under the 4-year rule for evaluations; and

4. The nature of the data to be submitted, and the reason for its submission; for example, a request from CCPR.

Note: *Where a pesticide has already been evaluated by the JMPR and MRLs, EMRLs or GLs have been established, new evaluations may be initiated if one or more of the following situations arise:*

i *New toxicological data becomes available to indicate a significant change in the ADI or ARfD.*

ii *The JMPR may note a data deficiency in a Periodic Re-evaluation or New Chemical evaluation. In response, national governments or other interested parties may pledge to supply the information to the appropriate Joint Secretary of the JMPR with a copy for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data should be submitted subsequently to the appropriate Joint Secretary of the JMPR.*

iii *The CCPR may place a chemical under the four-year rule, in which case the government or industry should indicate support for the specific MRLs to the FAO Joint Secretary of the JMPR. Following scheduling in the JMPR tentative schedule, any data in support of maintenance of the MRL(s) would be submitted to the FAO Joint Secretary of the JMPR.*

iv *A government member may seek to expand the use of an existing Codex chemical: that is, obtain MRLs for one or more new commodities where some MRLs already exist for other commodities. Such requests should be directed to the FAO Joint Secretary of the JMPR and submitted for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.*

v *A government member may seek to review a MRL due to a change in GAP. For example a new GAP may necessitate a larger MRL. In this case the request should be made to the FAO Joint Secretary with a copy for consideration by the Committee. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.*

vi *The CCPR may request a clarification or reconsideration of a recommendation from the JMPR. In such cases the relevant Joint Secretary will schedule the request for the next JMPR.*

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

GUIDELINES ON THE ELABORATION AND/OR REVISION OF CODES OF HYGIENIC PRACTICE FOR SPECIFIC COMMODITIES

The establishment of additional food hygiene requirements for specific food items or food groups should be limited to the extent necessary to meet the defined objectives of individual codes.

Codex Codes of Hygienic Practice should serve the primary purpose of providing advice to governments on the application of food hygiene provisions within the framework of national and international requirements.

The Revised Recommended International Code of Practice - General Principles of Food Hygiene (including the Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) System) and the Revised Principles for the Establishment and Application of Microbiological Criteria for Foods are the base documents in the field of food hygiene.

All Codex Codes of Hygienic Practice applicable to specific food items or food groups shall refer to the General Principles of Food Hygiene and shall only contain material additional to the General Principles which is necessary to take into account the particular requirements of the specific food item or food group.

Provisions in Codex Codes of Hygienic Practice should be drafted in a sufficiently clear and transparent manner such that extended explanatory material is not required for their interpretation.

The above considerations should also apply to Codex Codes of Practice which contain provisions relating to food hygiene.

PRINCIPLES FOR THE ESTABLISHMENT OF CODEX METHODS OF ANALYSIS

PURPOSE OF CODEX METHODS OF ANALYSIS

The methods are primarily intended as international methods for the verification of provisions in Codex standards. They should be used for reference, in calibration of methods in use or introduced for routine examination and control purposes.

METHODS OF ANALYSIS

Definition of types of methods of analysis

(a) Defining Methods (Type I)

Definition: A method which determines a value that can only be arrived at in terms of the method per se and serves by definition as the only method for establishing the accepted value of the item measured.

Examples: Howard Mould Count, Reichert-Meissl value, loss on drying, salt in brine by density.

(b) Reference Methods (Type II)

Definition: A Type II method is the one designated Reference Method where Type I methods do not apply. It should be selected from Type III methods (as defined below). It should be recommended for use in cases of dispute and for calibration purposes.

Example: Potentiometric method for halides.

(c) Alternative Approved Methods (Type III)

Definition: A Type III Method is one which meets the criteria required by the Codex Committee on Methods of Analysis and Sampling for methods that may be used for control, inspection or regulatory purposes.

Example: Volhard Method or Mohr Method for chlorides

(d) Tentative Method (Type IV)

Definition: A Type IV Method is a method which has been used traditionally or else has been recently introduced but for which the criteria required for acceptance by the Codex Committee on Methods of Analysis and Sampling have not yet been determined.

Examples: chlorine by X-ray fluorescence, estimation of synthetic colours in foods.

General Criteria for the Selection of Methods of Analysis

(a) Official methods of analysis elaborated by international organizations occupying themselves with a food or group of foods should be preferred.

(b) Preference should be given to methods of analysis the reliability of which have been established in respect of the following criteria, selected as appropriate:

  (i) specificity

  (ii) accuracy

(iii) precision; repeatability intra-laboratory (within laboratory), reproducibility inter-laboratory (within laboratory and between laboratories)

(iv) limit of detection

(v) sensitivity

(vi) practicability and applicability under normal laboratory conditions

(vii) other criteria which may be selected as required.

(c) The method selected should be chosen on the basis of practicability and preference should be given to methods which have applicability for routine use.

(d) All proposed methods of analysis must have direct pertinence to the Codex Standard to which they are directed.

(e) Methods of analysis which are applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities.

General Criteria for the Selection of Methods of Analysis using the Criteria Approach

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

General Criteria for the Selection of Single-Laboratory Validated Methods of Analysis

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

i. the method is validated according to an internationally recognized protocol (e.g. those referenced in the harmonized IUPAC Guidelines for Single-Laboratory Validation of Methods of Analysis)

ii. the use of the method is embedded in a quality system in compliance with the ISO/IEC 17025: 1999 Standard or Principles of Good Laboratory Practice;

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

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

WORKING INSTRUCTIONS FOR THE IMPLEMENTATION OF THE CRITERIA APPROACH IN CODEX

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

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

The minimum "approved" Codex analytical characteristics will include the following numeric criteria as well as the general criteria for methods laid down in the *Analytical Terminology for Codex Use*:

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

- linearity

CCMAS will generate the data corresponding to the above criteria.

CONVERSION OF SPECIFIC METHODS OF ANALYSIS TO METHOD CRITERIA BY THE CCMAS

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

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

These terms are defined in the Analytical Terminology for Codex Use, as are other terms of importance.

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

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

ASSESSMENT OF THE ACCEPTABILITY OF THE PRECISION CHARACTERISTICS OF A METHOD OF ANALYSIS

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

ANALYTICAL TERMINOLOGY FOR CODEX USE

Result: The final value reported for a measured or computed quantity, after performing a measuring procedure including all sub-procedures and evaluations.

Notes:

When a result is given, it should be made clear whether it refers to:

- the indication [signal];
- the uncorrected result;
- the corrected result; and
- whether several values were averaged.

A complete statement of the result of a measurement includes information about the uncertainty of measurement.

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

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

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

Note:

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

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

Notes:

1 The measure of trueness is usually expressed in terms of bias.

2 Trueness has been referred to as "accuracy of the mean". This usage is not recommended.

***Bias*:** The difference between the expectation of the test results and an accepted reference value.

Notes:

Bias is the total systematic error as contrasted to random error. There may be one or more systematic error components contributing to bias. A larger systematic difference from the accepted reference value is reflected by a larger bias value.

When the systematic error component(s) must be arrived at by a process that includes random error, the random error component is increased by propagation of error considerations and reduced by replication.

***Precision*:** The closeness of agreement between independent test results obtained under stipulated conditions.

Notes:

Precision depends only on the distribution of random errors and does not relate to the true value or to the specified value.

The measure of precision is usually expressed in terms of imprecision and computed as a standard deviation of the test results. Less precision is reflected by a larger standard deviation.

"Independent test results" means results obtained in a manner not influenced by any previous result on the same or similar test object. Quantitative measures of precision depend critically on the stipulated conditions. Repeatability and reproducibility conditions are particular sets of extreme conditions.

Repeatability [Reproducibility]: Precision under repeatability [reproducibility] conditions.

Repeatability conditions: Conditions where independent test results are obtained with the same method on identical test items in the same laboratory by the same operator using the same equipment within short intervals of time.

***Reproducibility conditions*:** Conditions where test results are obtained with the same method on identical test items in different laboratories with different operators using different equipment.

Notes:

When different methods give test results that do not differ significantly, or when different methods are permitted by the design of the experiment, as in a proficiency study or a material-certification study for the establishment of a consensus value of a reference material, the term "reproducibility" may be applied to the resulting parameters. The conditions must be explicitly stated.

Repeatability [Reproducibility] standard deviation: The standard deviation of test results obtained under repeatability [reproducibility] conditions.

Notes:

Repeatability [Reproducibility] standard deviation is a measure of the dispersion of the distribution of test results under repeatability [reproducibility] conditions.

Similarly "repeatability [reproducibility] variance" and "repeatability [reproducibility] coefficient of variation" could be defined and used as measures of the dispersion of test results under repeatability [reproducibility] conditions.

Repeatability [Reproducibility] limit: The value less than or equal to which the absolute difference between two test results obtained under repeatability [reproducibility] conditions may be expected to be with a probability of 95%.

Notes:

The symbol used is r [R].

When examining two single test results obtained under repeatability [reproducibility] conditions, the comparison should be made with the repeatability [reproducibility] limit r [R] = 2.8 sr[sR].

When groups of measurements are used as the basis for the calculation of the repeatability [reproducibility] limits (now called the critical difference), more complicated formulae are required that are given in ISO 5725-6:1994, 4.2.1 and 4.2.2.

Interlaboratory Study: A study in which several laboratories measure a quantity in one or more "identical" portions of homogeneous, stable materials under documented conditions, the results of which are compiled into a single document.

Notes:

The larger the number of participating laboratories, the greater the confidence that can be placed in the resulting estimates of the statistical parameters. The

IUPAC-1987 protocol (Pure & Appl. Chem., **66**, 1903-1911(1994)) requires a minimum of eight laboratories for method-performance studies.

Method-Performance Study: An interlaboratory study in which all laboratories follow the same written protocol and use the same test method to measure a quantity in sets of identical test samples. The reported results are used to estimate the performance characteristics of the method. Usually these characteristics are within-laboratory and among-laboratories precision, and when necessary and possible, other pertinent characteristics such as systematic error, recovery, internal quality control parameters, sensitivity, limit of determination, and applicability.

Notes:

The materials used in such a study of analytical quantities are usually representative of materials to be analyzed in actual practice with respect to matrices, amount of test component (concentration), and interfering components and effects. Usually the analyst is not aware of the actual composition of the test samples but is aware of the matrix.

The number of laboratories, number of test samples, number of determinations, and other details of the study are specified in the study protocol. Part of the study protocol is the procedure which provides the written directions for performing the analysis.

The main distinguishing feature of this type of study is the necessity to follow the same written protocol and test method exactly.

Several methods may be compared using the same test materials. If all laboratories use the same set of directions for each method and if the statistical analysis is conducted separately for each method, the study is a set of method-performance studies. Such a study may also be designated as a method-comparison study.

Laboratory-Performance (Proficiency) Study: An interlaboratory study that consists of one or more measurements by a group of laboratories on one or more homogeneous, stable, test samples by the method selected or used by each laboratory. The reported results are compared with those from other laboratories or with the known or assigned reference value, usually with the objective of improving laboratory performance.

Notes:

Laboratory-performance studies can be used to support accreditation of laboratories or to audit performance. If a study is conducted by an organization with some type of management control over the participating laboratories - organizational, accreditation, regulatory, or contractual - the method may be specified or the selection may be limited to a list of approved or equivalent

methods. In such situations, a single test sample is insufficient to judge performance.

A laboratory-performance study may be used to select a method of analysis that will be used in a method-performance study. If all laboratories, or a sufficiently large subgroup of laboratories, use the same method, the study may also be interpreted as a method-performance study, provided that the test samples cover the range of concentration of the analyte.

Laboratories of a single organization with independent facilities, instruments, and calibration materials, are treated as different laboratories.

Material-Certification Study: An interlaboratory study that assigns a reference value ("true value") to a quantity (concentration or property) in the test material, usually with a stated uncertainty.

Note:

A material-certification study often utilizes selected reference laboratories to analyze a candidate reference material by a method(s) judged most likely to provide the least-biased estimates of concentration (or of a characteristic property) and the smallest associated uncertainty.

Applicability: The analytes, matrices, and concentrations for which a method of analysis may be used satisfactorily to determine compliance with a Codex standard.

Note:

In addition to a statement of the range of capability of satisfactory performance for each factor, the statement of applicability (scope) may also include warnings as to known interference by other analytes, or inapplicability to certain matrices and situations.

Sensitivity: Change in the response divided by the corresponding change in the concentration of a standard (calibration) curve; i.e. the slope, s_i, of the analytical calibration curve.

Note:

This term has been used for several other analytical applications, often referring to capability of detection, to the concentration giving 1% absorption in atomic absorption spectroscopy, and to ratio of found positives to known, true positives in immunological and microbiological tests. Such applications to analytical chemistry should be discouraged.

A method is said to be sensitive if a small change in concentration, c, or quantity, q, causes a large change in the measure, x; that is, when the derivative dx/dc or dx/dq is large.

Although the signal may vary with the magnitude of c_i or q_i, the slope, s_i, is usually constant over a reasonable range of concentrations. s_i may also be a function of the c or q of other analytes present in the sample.

***Ruggedness*:** The ability of a chemical measurement process to resist changes in results when subjected to minor changes in environmental and procedural variables, laboratories, personnel, etc.

TERMS TO BE USED IN THE CRITERIA APPROACH

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

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

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

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

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

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

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

Linearity: The ability of a method of analysis, within a certain range, to provide an instrumental response or results proportional to the quality of analyte to be determined in the laboratory sample. This proportionality is expressed by an a priori defined mathematical expression. The linearity limits are the experimental limits of concentrations between which a linear calibration model

can be applied with a known confidence level (generally taken to be equal to 1%).

PRINCIPLES FOR THE ESTABLISHMENT OR SELECTION OF CODEX SAMPLING PROCEDURES

PURPOSE OF CODEX METHODS OF SAMPLING

Codex Methods of Sampling are designed to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard. The sampling methods are intended for use as international methods designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to sampling and by diverging interpretation of results of analysis in relation to lots or consignments of foods, in the light of the relevant provision(s) of the applicable Codex standard.

METHODS OF SAMPLING

Types of Sampling Plans and Procedures

(a) Sampling Plans for Commodity Defects:

Such plans are normally applied to visual defects (e.g. loss of colour, misgrading for size, etc.) and extraneous matter. They are normally attributes plans, and plans such as those included in Section 3.1 and 4.2 of the *General Guidelines on Sampling (CAC/GL 50-2004)* (hereinafter referred to as "General Guidelines") may be applied.

(b) Sampling Plans for Net Contents:

Such plans are those which apply to pre-packaged foods generally and are intended to serve to check compliance of lots or consignments with provisions for net contents. Plans such as those included in Section 3.3 and 4.4 of the General Guidelines may be applied.

(c) Sampling Plans for Compositional Criteria:

Such plans are normally applied to analytically determined compositional criteria (e.g., loss on drying in white sugar, etc.). They are predominantly based on variable procedures with unknown standard deviation. Plans such as those included in Section 4.3 of the General Guidelines may be applied.

(d) Specific Sampling Plans for Health-related Properties:

Such plans are normally applied to heterogeneous conditions, e.g. in the assessment of microbiological spoilage, microbial by-products or sporadically occurring chemical contaminants.

General Instructions for the Selection of Methods of Sampling

(a) Sampling methods described in the General Guidelines or official methods of sampling elaborated by international organizations occupying themselves with a food or a group of foods are preferred. Such official methods may be written using the General Guidelines when attracted to Codex standards.

(b) When selecting appropriate sampling plans, Table 1 in the General Guidelines may be utilized.

(c) The appropriate Codex Commodity Committee should indicate, before it elaborates any sampling plan, or before any plan is endorsed by the Codex Committee on Methods of Analysis and Sampling, the following:

(i) the basis on which the criteria in the Codex Commodity standards have been drawn up (e.g. whether on the basis that every item in a lot, or a specified high proportion, shall comply with the provision in the standard or whether the average of a set of samples extracted from a lot must comply and, if so, whether a minimum or maximum tolerance, as appropriate, is to be given);

(ii) whether there is to be any differentiation in the relative importance of the criteria in the standards and, if so, what is the appropriate statistical parameter each criterion should attract, and hence, the basis for judgement when a lot is in conformity with a standard.

(d) Instructions on the procedure for the taking of samples should indicate the following:

(i) the measures necessary in order to ensure that the sample taken is representative of the consignment or of the lot;

(ii) the size and the number of individual items forming the sample taken from the lot or consignment;

(iii) the administrative measures for taking and handling the sample.

(e) The sampling protocol may include the following information:

(i) the statistical criteria to be used for acceptance or rejection of the lot on the basis of the sample;

(ii) the procedures to be adopted in cases of dispute.

GENERAL CONSIDERATIONS

(a) The Codex Committee on Methods of Analysis and Sampling should maintain closest possible relations with all interested organizations working on methods of analysis and sampling.

(b) The Codex Committee on Methods of Analysis and Sampling should organize its work in such a manner as to keep under constant review all methods of analysis and sampling published in the Codex Alimentarius.

(c) In the Codex methods of analysis, provision should be made for variations in reagent concentrations and specifications from country to country.

(d) Codex methods of analysis which have been derived from scientific journals, theses, or publications, either not readily available or available in languages other than the official languages of FAO and WHO, or which for other reasons should be printed in the Codex Alimentarius *in extenso*, should follow the standard layout for methods of analysis as adopted by the Codex Committee on Methods of Analysis and Sampling.

(e) Methods of analysis which have already been printed as official methods of analysis in other available publications and which are adopted as Codex methods need only be quoted by reference in the Codex Alimentarius.

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

ISSUES INVOLVED

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

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

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

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

RECOMMENDATIONS

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

1. Sampling Plans

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

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

2. Measurement Uncertainty

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

3. Recovery

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

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

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

4. Significant Figures

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

PROCEDURES FOR CONSIDERATION OF THE ENTRY AND REVIEW OF FOOD ADDITIVE PROVISIONS IN THE GENERAL STANDARD FOR FOOD ADDITIVES

SCOPE

The Codex General Standard for Food Additives is intended to include food additive provisions for standardised and non-standardised foods in the Codex Alimentarius.

The following text describes the data and information that should be submitted to the Codex Committee on Food Additives when requesting the Committee to initiate work to add or revise food additive provisions in the Codex General Standard for Food Additives. The decisions required to establish acceptance or rejection of new proposals are also elaborated.

Provisions for the use of processing aids (e.g. most enzyme preparations, clarifying and filtering aids, extraction solvents) are not included in the General Standard for Food Additives.

INITIATION OF WORK

Revision

The food additive provisions of the General Standard for Food Additives may be revised by the Committee on Food Additives after requests submitted by Codex Committees, Codex members, or the Codex Alimentarius Commission. Information to support amendment of the General Standard for Food Additives shall be provided by the proposing body. Supporting information provided to the Committee on Food Additives should include, as appropriate:

- Specifications for the food additive;
- A summary of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) safety evaluation of the food additive;
- The food categories or sub-categories in which the additive is intended to be used;
- An indication of the technological need / justification for the additive, referencing one or more of the General Principles for the Use of Food Additives of the GSFA (Section 3);
- Maximum use levels for the food additive in the specified food categories:

- For additives with a numerical Acceptable Daily Intake (ADI), a numerical maximum use level for each specified use although for certain cases, a level of GMP may be appropriate;
- For additives with an ADI Not Specified or Not Limited, a recommendation to list the additive in Table 3 accompanied by additional proposals for inclusion in Tables 1 and 2 for use in the food categories listed in the Annex to Table 3, as appropriate;
- For additives with an " acceptable" ADI, either a numerical maximum use level for the acceptable level of treatment of a food or a level of GMP, consistent with the JECFA evaluation.

- A justification of the maximum use levels from a technological point-of-view; and an indication, by means of the procedure indicated in Annex A of the General Standard for Food Additives or an exposure assessment, that this level meets the safety requirements enumerated in Section 3.1 of the General Standard for Food Additives.
- A reasoned statement that consumers will not be misled by the use of the additive.

The Committee on Food Additives shall consider all amendments to the General Standard for Food Additives proposed by Codex Committees, Codex members, or the Codex Alimentarius Commission.

Review

The food additive provisions for the General Standard for Food Additives shall be reviewed by the Committee on Food Additives on a regular basis and revised as necessary in light of revisions of the risk assessment by JECFA or of changing technological need and justification for use.

- If JECFA changes an ADI to a Temporary ADI, the food additive provisions of the General Standard for Food Additives may remain unchanged until the ADI has been withdrawn or the full status has been restored by JECFA.
- If JECFA withdraws an ADI the food additive provisions of the General Standard for Food Additives shall be amended by removing all provision for the use of the additive.

The following additional guidance is provided regarding the information to be submitted:

- Identity of the food additive
  - Food additives shall have been evaluated by JECFA and either assigned a full numerical or non-numerical ("not specified" or "not limited") ADI, or deemed to be acceptable for a particular use.
  - Food additives shall have been assigned an International Numbering System number.
- Functional effect of the food additive
  - The functional class list used in *Class Names and the International Numbering System* (CAC/GL 36-1989) should be used.
- Proposed use of the food additive
  - The appropriate food categories from the food category system (Annex B of the General Standard for Food Additives) and maximum use levels should be specified.
  - With regard to the acceptable maximum use level:
    - A numerical use level should be provided for a food additive assigned a numerical ADI. However, in some cases, reporting the use level as good manufacturing practice ("GMP") may be appropriate.
    - For a food additive assigned a non-numerical ("not specified" or " not limited") ADI that is listed in Table 3 of the General Standard for Food Additives, a numerical or good manufacturing practice ("GMP") use level should be provided for any request to list the additive in a food category in the Annex to Table 3.
    - For some food additives, the ADI has been reported on a specific basis (e.g. "as phosphorus" for phosphates; "as benzoic acid" for benzoates). For consistency, the maximum use level for these additives should be reported on the same basis as the ADI.
- Justification for the use and technological need of the food additive
  - Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives should be included.

- Safe use of the food additive
    - An intake assessment of the proposed use of the food additive, in accordance with Section 3.1 of the Preamble of the General Standard for Food Additives, should be included as appropriate.
- Justification that the use does not mislead the consumer
    - A reasoned statement that consumers will not be misled by the use of the additive should be provided.

DOES THE FOOD ADDITIVE USE MEET THE CRITERIA OF SECTION 3.2 OF THE PREAMBLE OF THE GENERAL STANDARD FOR FOOD ADDITIVES?

Section 3.2 of the Preamble of the General Standard for Food Additives establishes the criteria for justifying the use of a food additive. Adherence to these criteria is necessary for the inclusion of the food additive in the General Standard for Food Additives. If the use of the additive does not meet these criteria, it is not considered further and the work is discontinued. If the information provided to justify the use of the additive is inadequate for the Committee on Food Additives to reach a decision, further information on the use and technological justification and need for the food additive will be requested for consideration at the Committee's next session. If this information is not provided by the next session, work on the provision is discontinued.

IS THE FOOD ADDITIVE USED IN STANDARDIZED FOOD?

The Codex Committee on Food Additives, asks the relevant Codex commodity committee to consider the functional classes of additives, additives and their technological justification for the commodity and to refer back this information by the next available session. In light of this information, the Codex Committee on Food Additives recommends appropriate conditions of use based on proposals of the commodity committee.

In certain cases, however, it may be appropriate for the Codex commodity committee to develop a list of food additives with associated functional classes and acceptable maximum use levels that would be forwarded to the Committee on Food Additives for endorsement and, ultimately, incorporation into the General Standard for Food Additives. The development of such food additive lists should be consistent with the principles used in the development of the General Standard for Food Additives. However, the development of food additive lists in commodity standards should be restricted as much as possible. For example, an additive may be listed in a commodity standard if it is needed to achieve a technical effect that is not achievable by the use of other additives of the same functional class. Additives may also be listed in a commodity standard if there is a need, based on a safety assessment, to limit the use of the additive. Justification for such exceptions should be provided by the Codex commodity committees to the Committee on Food Additives for consideration.

If the Codex commodity committee has been adjourned, the Committee on Food Additives may revise the food additive provisions in commodity standards under the purview of the adjourned committee, as necessary.

The Committee on Food Additives would consider any proposed revision in light of the principles of technological justification for the use of additives as indicated in Section 3.2 of the Preamble of the General Standard for Food

Additives. These revisions, once adopted by the Commission, would be incorporated into the General Standard for Food Additives.

HAS A NON-NUMERICAL ("NOT SPECIFIED" OR "NOT LIMITED") ADI BEEN ASSIGNED?

Yes - Non-Numerical ("Not Specified" or "Not Limited") ADI:

Food additives assigned a non-numerical ADI are proposed for inclusion in Table 3 of the General Standard for Food Additives. Requests for the use of these additives in the food categories listed in the Annex to Table 3 are made by proposing provisions for inclusion in Tables 1 and 2 of the General Standard for Food Additives. These proposals are considered by the Codex Committee on Food Additives according to the criteria described under "**Consideration of Conditions of Use in the Specific Food Categories**", below.

No - Numerical ADI or Acceptable for Limited Use:

Food additives assigned a numerical ADI or evaluated to be acceptable for one or more particular uses are proposed for inclusion in Tables 1 and 2 of the General Standard for Food Additives. These proposals are considered by the Codex Committee on Food Additives according to the criteria described under "**Consideration of Conditions of Use in the Specific Food Categories**", below.

CONSIDERATION OF CONDITIONS OF USE IN THE SPECIFIC FOOD CATEGORIES

The Codex Committee on Food Additives identifies and recommends appropriate food categories and use levels for inclusion in Tables 1 and 2 of the General Standard for Food Additives. For this purpose, the Committee will consider the following general principles for the inclusion of a food additive provision in Tables 1 and 2 of the General Standard for Food Additives:

1. Food additives that share a numerical group ADI will be considered as a group without further restrictions on the use of individual additives in that group. However, in some cases, restrictions on the use of individual additives in that group could be appropriate (e.g. because of public health concerns).

2. Food additives that have multiple functional classes will be considered without further restrictions to their functional class.

3. In general, a numerical use level for a proposed use of a food additive in a food category is given preference over a use level reported as good manufacturing practice ("GMP"). However, exceptions, as noted under "**Initiation of Work**", shall also be taken into account by the Codex Committee on Food Additives on a case-by-case basis.

4. When establishing the acceptable maximum level of use for an additive in a specified food category, the Committee on Food Additives considers the technological justification for the proposed level and the exposure assessment in accordance with Sections 3.1 and 3.2 of the Preamble of the General Standard for Food Additives. If more than one maximum use level is proposed, and the Committee cannot reach consensus on the appropriate maximum use level, the delegations supporting and the delegations opposing the proposed maximum use level should provide additional justification for their proposed levels to address any specific concerns raised by the Committee, by the next available session, to the Committee on Food Additives, for consideration in its next session. Proposals lacking justification will no longer be considered, and the proposed level for which justification has been provided will be forwarded for adoption.

5. To resolve questions related to dietary exposure of food additives, the Committee on Food Additives may request JECFA to perform exposure assessments for the additives based on the acceptable maximum use levels under consideration by the Codex Committee on Food Additives.

6. Acceptable maximum use levels are established as described in the previous sections and the food additive provisions are entered in the General Standard for Food Additives. Each use level represents the highest acceptable maximum use level in the broadest food category for which the use is technologically justified. To the extent possible, the hierarchical structure of the food category system will be used to simplify the listing of the food additive provisions in Tables 1 and 2 of the General Standard of Food Additives. In this regard:

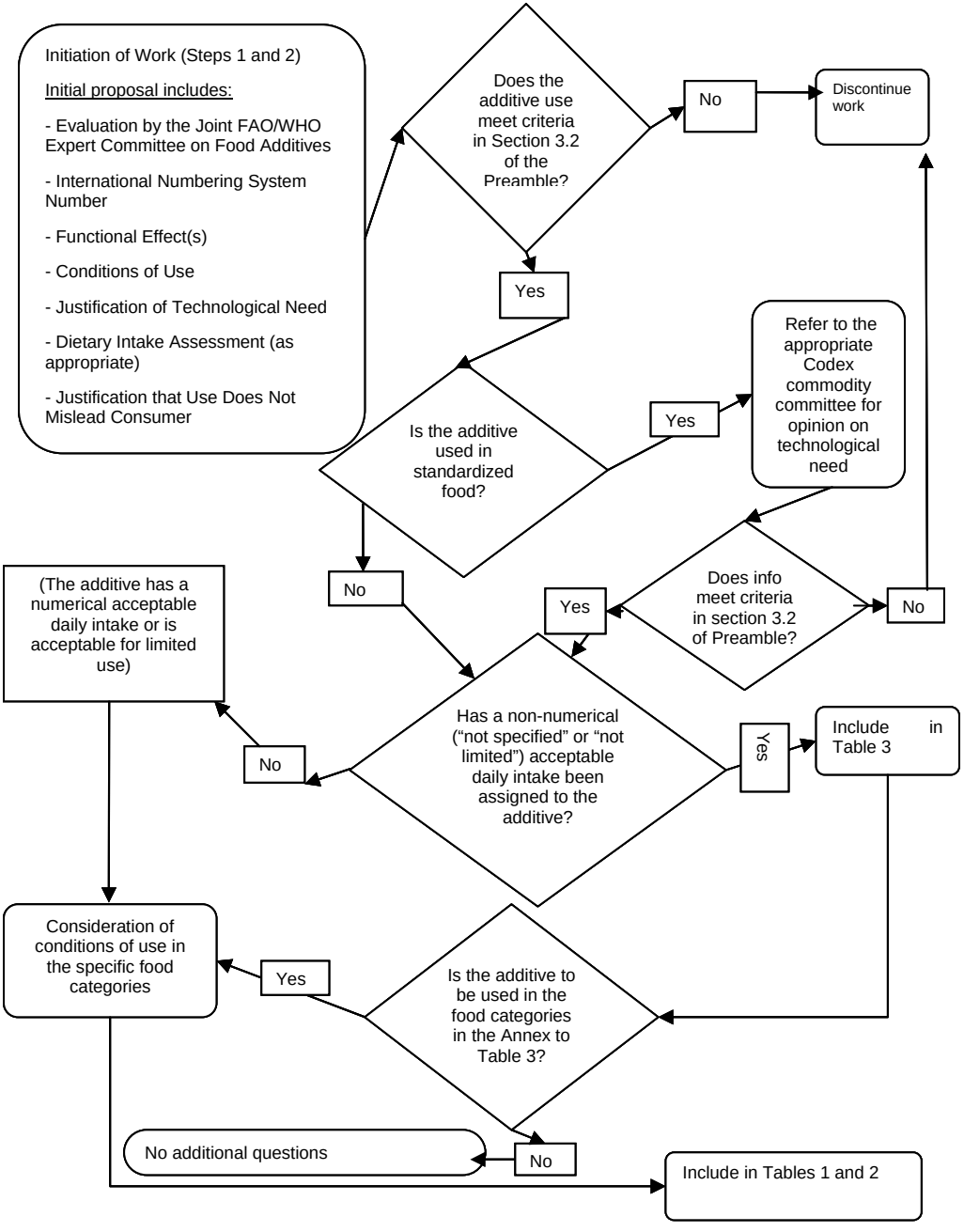
    - If the new use of a food additive is for a broader food category and at a maximum use level that is higher than or equal to those in the sub-categories of the broad food category that are already listed in the General Standard for Food Additives, then the new use in the broader food category supersedes the already-listed provisions. These provisions are discontinued (if proposed draft or draft provisions), or revoked upon adoption of the proposed use at Step 8 (if adopted provision at Step 8).

    - If the new use of a food additive is for a broader food category and at a lower maximum use level than for the sub-categories of the broad food category that already exist in the General Standard for Food Additives, then the provisions listed in the General Standard for Food Additives are determined

according to the hierarchy of the food category system. The highest maximum use level in each food sub-category, whether from an existing provision or from the new use in the broader food category, is entered into the General Standard for Food Additives. Any existing provisions that are superseded by the new use are discontinued (if proposed draft or draft provisions), or revoked upon adoption of the proposed use at Step 8 (if adopted provision at Step 8).

- If the new use of a food additive, together with the already-listed provisions in the General Standard for Food Additives, represents use in all of the sub-categories of a broader food category at the same maximum use level, then the use in the broader food category will be listed in the General Standard for Food Additives. The already-listed provisions in the sub-categories are discontinued (if proposed draft or draft provisions), or revoked upon adoption of the provision in the broader food category at Step 8 (if adopted provision at Step 8).

Diagram of procedure for consideration of the entry and review of food additives in the Codex General Standard for Food Additives



UNIFORM SYSTEM OF REFERENCES FOR CODEX DOCUMENTS

In referencing Codex documents, the Document Reference given in the table below appear first, followed by the year in which the session will be held, the session number, and finally the consecutive number of the document.

For example, documents prepared for the 20th session of the Codex Committee on General Principles meeting in 2004, are identified by the series CX/GP 04/20/1, 2, 3 etc.

Prior to 2003, most documents are identified by the Document Reference, year, and series number only (except for the Executive Committee).

Statutory Bodies	**Document Reference**
Codex Alimentarius Commission	ALINORM
Executive Committee	CX/EXEC
Subsidiary Bodies	
Codex Committees	
General Principles	CX/GP
Food Additives	CX/FA
Contaminants	CX/CF
Food Hygiene	CX/FH
Food Labelling	CX/FL
Methods of Analysis and Sampling	CX/MAS
Pesticide Residues	CX/PR
Residues of Veterinary Drugs in Foods	CX/RVDF
Food Import and Export Inspection and Certification Systems	CX/FICS
Nutrition and Foods for Special Dietary Uses	CX/NFSDU
Cereals, Pulses and Legumes	CX/CPL

Cocoa Products and Chocolate	CX/CPC
Fats and Oils	CX/FO
Fish and Fishery Products	CX/FFP
Milk and Milk Products	CX/MMP
Meat Hygiene	CX/MH
Natural Mineral Waters	CX/NMW
Processed Fruits and Vegetables	CX/PFV
Sugars	CX/S
Vegetable Proteins	CX/VP
Fresh Fruits and Vegetables	CX/FFV
FAO/WHO Regional Coordinating Committees	
Africa	CX/AFRICA
Asia	CX/ASIA
Europe	CX/EURO
Latin America and the Caribbean	CX/LAC
Near East	CX/NEA
North America and the South West Pacific	CX/NASWP
***Ad hoc* Intergovernmental Task Forces**	
Foods derived from Biotechnology	CX/FBT
Antimicrobial Resistance	CX/AMR
Processing and Handling of Quick Frozen Foods	CX/QFF
Statutory Bodies Abolished, Dissolved or Renamed	
(for archival reference only)	
Codex Committee on Edible Ices	CX/IE
Codex Committee on Soups and Broths	CX/SB

Codex Committee on Processed Meat and Poultry Products	CX/PMPP
Codex Committee on Food Additives and Contaminants	CX/FAC
Ad hoc Intergovernmental Task Force on Animal Feeding	CX/AF
Ad hoc Intergovernmental Task Force on Fruit and Vegetable Juices	CX/FJ
Joint Codex/IOOC Meeting on the Standardization of Table Olives	CX/TO
Joint ECE/Codex Alimentarius Group of Experts on the Standardization of Fruit Juices	CX/FJ
Joint ECE/Codex Alimentarius Group of Experts on the Standardization of Quick Frozen Foods	CX/QFF

FORMAT FOR CODEX COMMODITY STANDARDS

INTRODUCTION

The Format is also intended for use as a guide by the subsidiary bodies of the Codex Alimentarius Commission in presenting their standards, with the object of achieving, as far as possible, a uniform presentation of commodity standards. The Format also indicates the statements which should be included in standards as appropriate under the relevant headings of the standard. The sections of the Format require to be completed in a standard only insofar as such provisions are appropriate to an international standard for the food in question.

NAME OF THE STANDARD

SCOPE

DESCRIPTION

ESSENTIAL COMPOSITION AND QUALITY FACTORS

FOOD ADDITIVES

CONTAMINANTS

HYGIENE

WEIGHTS AND MEASURES

LABELLING

METHODS OF ANALYSIS AND SAMPLING

NOTES ON THE HEADINGS

NAME OF THE STANDARD

The name of the standard should be clear and as concise as possible. It should usually be the common name by which the food covered by the standard is known or, if more than one food is dealt with in the standard, by a generic name covering them all. If a fully informative title should be inordinately long, a subtitle could be added.

SCOPE

This section should contain a clear, concise statement as to the food or foods to which the standard is applicable unless this is self-explanatory in the name of the standard. In the case of a general standard covering more than one specific product, it should be made clear as to which specific products the standard applies.

DESCRIPTION

This section should contain a definition of the product or products with an indication, where appropriate, of the raw materials from which it is derived and any necessary references to processes of manufacture. It may also include references to types and styles of product and to type of pack. There may also be additional definitions when these are required to clarify the meaning of the standard.

ESSENTIAL COMPOSITION AND QUALITY FACTORS

This section should contain all quantitative and other requirements as to composition including, where necessary, identity characteristics, provisions on packing media and requirements as to compulsory and optional ingredients. It should also include quality factors which are essential for the designation, definition or composition of the product concerned. Such factors could include the quality of the raw material, with the object of protecting the health of the consumer, provisions on taste, odour, colour and texture which may be apprehended by the senses, and basic quality criteria for the finished products, with the object of preventing fraud. This section may refer to tolerances for defects, such as blemishes or imperfect material, but this information should be contained in an appendix to the standard or in another advisory text.

FOOD ADDITIVES

This section should contain a general reference to the corresponding sections of the General Standard for Food Additives which should take the following form:

> *"[Food Additive functional class] used in accordance with Tables 1 and 2 of the Codex General Standard of Food Additives in food category x.x.x.x [food category name] or listed in Table 3 of the General Standard for Food Additives are acceptable for use in foods conforming to this standard."*

Exceptions from, or addition to, the General Standard for Food Additives that are necessary for its interpretation with respect to the product concerned should be justified fully, and should be restricted where possible. In cases where it is necessary to explicitly list food additives in a commodity standard, the names of the additives/functional classes permitted and, where appropriate, the maximum amount permitted in the food should be prepared in accordance with guidance given in the section on Food Additives in the *Relations between Commodity Committees and General Committees*, and may take the following form:

> *"The following provisions in respect of food additives and their specifications as contained in section ..... of the Codex Alimentarius are subject to endorsement [have been endorsed] by the Codex Committee on Food Additives."*

Then should follow a tabulation, viz:

> "INS number, *name of additive, maximum level (in percentage or mg/kg) grouped by functional classes.."*

In this section, provisions for flavourings and processing aids should also be included.

CONTAMINANTS

> *"The products covered by this Standard shall comply with the Maximum Levels of the Codex General Standard for Contaminants and Toxins in Foods (CODEX/STAN 193-1995) and the maximum residue limits for pesticides and veterinary drugs established by the CAC."*

HYGIENE

Any specific mandatory hygiene provisions considered necessary should be included in this section. They should be prepared in accordance with the guidance given in the section on Food Hygiene in the *Relations between Commodity Committees and General Committees*. Reference should also be made to applicable codes of hygienic practice. Any parts of such codes, including in particular any end-product specifications, should be set out in the standard, if it is considered necessary that they should be made mandatory. The following statement should also appear:

> "*The following provisions in respect of the food hygiene of this product are subject to endorsement [have been endorsed] by the Codex Committee on Food Hygiene."*

WEIGHTS AND MEASURES

This section should include all provisions, other than labelling provisions, relating to weights and measures, e.g. where appropriate, fill of container, weight, measure or count of units determined by an appropriate method of sampling and analysis. Weights and measures should be expressed in S.I. units. In the case of standards which include provisions for the sale of products in standardized amounts, e.g. multiples of 100 grams, S.I. units should be used, but this would not preclude additional statements in the standards of these standardized amounts in approximately similar amounts in other systems of weights and measures.

LABELLING

This section should include all the labelling provisions contained in the standard and should be prepared in accordance with the guidance given in the section on Food Labelling in the *Relations between Commodity Committees and General*

Committees. Provisions should be included by reference to the General Standard for the Labelling of Prepackaged Foods. The section may also contain provisions which are exemptions from, additions to, or which are necessary for the interpretation of the General Standard in respect of the product concerned provided that these can be justified fully. The following statement should also appear:

> *"The following provisions in respect of the labelling of this product are subject to endorsement [have been endorsed] by the Codex Committee on Food Labelling."*

METHODS OF ANALYSIS AND SAMPLING

This section should include, either specifically or by reference, all methods of analysis and sampling considered necessary and should be prepared in accordance with the guidance given in the section on Methods of Analysis and Sampling in the *Relations between Commodity Committees and General Committees*. If two or more methods have been proved to be equivalent by the Codex Committee on Methods of Analysis and Sampling, these could be regarded as alternatives and included in this section either specifically or by reference. The following statement should also appear:

> *"The methods of analysis and sampling described hereunder are to be endorsed [have been endorsed] by the Codex Committee on Methods of Analysis and Sampling."* [21]

[21] Methods of analysis should be indicated as being "defining", "reference", "alternative approved" or "tentative" methods, as appropriate.

RELATIONS BETWEEN COMMODITY COMMITTEES AND GENERAL COMMITTEES

Codex Committees may ask the advice and guidance of committees having responsibility for matters applicable to all foods on any points coming within their province.

The Committees on Food Labelling; Food Additives; Contaminants in Foods; Methods of Analysis and Sampling; Food Hygiene; Nutrition and Foods for Special Dietary Uses; and Food Import and Export Inspection and Certification Systems may establish general provisions on matters within their terms of reference. These provisions should only be incorporated into Codex Commodity Standards by reference unless there is a need for doing otherwise.

Codex Commodity standards shall contain sections on hygiene, labelling and methods of analysis and sampling and these sections should contain all of the relevant provisions of the standard. Provisions of Codex General Standards, Codes or Guidelines shall only be incorporated into Codex Commodity Standards by reference unless there is a need for doing otherwise. Where Codex Committees are of the opinion that the general provisions are not applicable to one or more commodity standards, they may request the responsible Committees to endorse deviations from the general provisions of the Codex Alimentarius. Such requests should be fully justified and supported by available scientific evidence and other relevant information. Sections on hygiene, labelling, food additives and methods of analysis and sampling which contain specific provisions or provisions supplementing the Codex General Standards, Codes or Guidelines shall be referred to the responsible Codex Committees at the most suitable time during Steps 3, 4 and 5 of the Procedure for the Elaboration of Codex Standards and Related Texts, though such reference should not be allowed to delay the progress of the standard to the subsequent steps of the Procedure.

Subject and commodity Committees should refer to the principles and guidelines developed by the Codex Committee on Food Import and Export Inspection and Certification Systems when developing provisions and/or recommendations on inspection and certification and make any appropriate amendments to the standards, guidelines and codes within the responsibility of the individual committees at the earliest convenient time.

FOOD LABELLING

The provisions on food labelling should be included by reference to the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985). Exemptions from, or additions to, the General Standard which are

necessary for its interpretation in respect of the product concerned should be justified fully, and should be restricted as much as possible.

Information specified in each draft standard should normally be limited to the following:

- a statement that the product shall be labelled in accordance with the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985)
- the specified name of the food
- date marking and storage instructions (only if the exemption foreseen in Section 4.7.1 of the General Standard is applied)

Where the scope of the Codex Standard is not limited to prepackaged foods, a provision for labelling of non retail containers may be included.

In such cases the provision may specify that:

> *"Information on ...*[22] *shall be given either on the container or in accompanying documents, except that the name of the product, lot identification, and the name and address of the manufacturer or packer shall appear on the container.*[23]
>
> *However, lot identification, and the name and address of the manufacturer or packer may be replaced by an identification mark provided that such a mark is clearly identifiable with the accompanying documents."*

In respect of date marking (Section 4.7 of the General Standard), a Codex Committee may, in exceptional circumstances, determine another date or dates as defined in the General Standard, either to replace or to accompany the date of minimum durability, or alternatively decide that no date marking is necessary. In such cases, a full justification for the proposed action should be submitted to the Codex Committee on Food Labelling.

FOOD ADDITIVES

Codex commodity committees shall examine the General Standard for Food Additives with a view toward incorporating a reference to the General Standard. All proposals for additions or revisions to the General Standard in order to

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[22] Codex Committees should decide which provisions are to be included.

[23] Codex Committees may decide that further information is required on the container. In this regard, special attention should be given to the need for storage instructions to be included on the container.

establish a reference to the General Standard shall be referred to the Codex Committee on Food Additives. The Codex Committee on Food Additives shall consider such proposals for endorsement. Revisions of a substantive nature that are endorsed by the Food Additives Committee will be referred back to the commodity committee in order to achieve consensus between both committees at an early stage of the step procedure.

Should the Codex commodity committee consider that a general reference to the General Standard for Food Additives does not serve its purpose, a proposal should be prepared and forwarded to the Codex Committee on Food Additives for consideration and endorsement. The commodity committee shall provide a justification for why a general reference to the General Standard would not be appropriate in light of the criteria for the use of food additives established in the Preamble of the General Standard, in particular Section 3.

All provisions in respect of food additives (including processing aids) contained in Codex commodity standards should be referred to the Codex Committee on Food Additives, preferably before the Standards have been advanced to Step 5 of the Procedure for the Elaboration of Codex Standards or before they are considered by the Commodity Committee concerned at Step 7, though such referral should not be allowed to delay the progress of the Standard to the subsequent Steps of the Procedure.

All provisions in respect of food additives contained in commodity standards will require endorsement by the Codex Committee on Food Additives , on the basis of technological justification submitted by the commodity committees and on the recommendations of the Joint FAO/WHO Expert Committee on Food Additives concerning the safety-in-use (acceptable daily intake (ADI) and other restrictions) and an estimate of the potential and, where possible, the actual intake of the food additives, ensuring conformity with the Preamble of General Principles for the Use of Food Additives.

When forwarding a food additive section of a commodity standard for endorsement by the Codex Committee on Food Additives, the Secretariat should prepare a report to the Committee that includes the International System (INS) number, the Acceptable Daily Intake (ADI) assigned by the Joint FAO/WHO Expert Committee on Food Additives,, technological justification, proposed level, and whether the additive was previously endorsed by the Codex Committee on Food Additives.

When commodity standards are sent to governments for comment at Step 3, they should contain a statement that the provisions “in respect of food additives are subject to endorsement by the Codex Committees on Food Additives and to incorporation into the General Standard for Food Additives.”

When an active commodity committee exists, proposals for the use of additives in any commodity standard under consideration should be prepared by the committee concerned, and forwarded to the Codex Committee on Food Additives for endorsement and inclusion in the General Standard for Food Additives. When the Codex Committee on Food Additives decides not to endorse specific additives provisions, the reason should be clearly stated. The section under consideration should be referred back to the commodity committee concerned if further information is needed, or for information if the Codex Committee on Food Additives decides to amend the provision.

When no active commodity committee exists, proposals for new additive provisions or amendment of existing provisions for inclusion in the General Standard for Food Additives should be forwarded directly by Codex members to the Codex Committee on Food Additives .

CONTAMINANTS

Provisions concerning contaminants are presently under development by the Codex Committee for Contaminants in Foods.

FOOD HYGIENE

Commodity Committees should use in the commodity standards the following text:

> *"It is recommended that the products covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4-2003), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice."*
>
> *"The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997)."*

METHODS OF ANALYSIS AND SAMPLING

NORMAL PRACTICE

Except for methods of analysis and sampling associated with microbiological criteria, when Codex committees have included provisions on methods of analysis or sampling in a Codex commodity standard, these should be referred to the Codex Committee on Methods of Analysis and Sampling at Step 4, to ensure Government comments at the earliest possible stage in the development of the standard. A Codex Committee should, whenever possible, provide information to the Codex Committee on Methods of Analysis and Sampling for each individual analytical method proposed, relating to specificity, accuracy,

precision (repeatability, reproducibility) limit of detection, sensitivity, applicability and practicability, as appropriate. Similarly a Codex Committee should, whenever possible, provide information to the Codex Committee on Methods of Analysis and Sampling for each sampling plan relating to the scope or field of application, the type of sampling (e.g. bulk or unit), sample sizes, decision rules, details of plans (e.g. "Operating characteristic" curves), inferences to be made to lots or processes, levels of risk to be accepted and pertinent supportive data.

Other criteria may be selected as required. Methods of analysis should be proposed by the Commodity Committees in consultation if necessary with an expert body.

At Step 4 Codex Commodity Committees should discuss and report to the Codex Committee on Methods of Analysis and Sampling on matters connected with:

- Provisions in Codex standards which require analytical or statistical procedure;
- Provisions for which elaboration of specific methods of analysis or sampling are required;
- Provisions which are defined by the use of Defining Methods (Type I);
- All proposals to the extent possible should be supported by appropriate documentation; especially for Tentative Methods (Type IV);
- Any request for advice or assistance.

The Committee on Methods of Analysis and Sampling should undertake a coordinating role in matters relating to the elaboration of Codex methods of analysis and sampling. The originating committee is, however, responsible for carrying out the Steps of the Procedure.

When it is necessary, the Committee on Methods of Analysis and Sampling should try to ensure elaboration and collaborative testing of methods by other recognized bodies with expertise in the field of analysis.

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

In addition, the Committee on Methods of Analysis and Sampling will identify numeric values for the criteria for which it would wish such methods to comply.

METHODS OF ANALYSIS AND SAMPLING OF GENERAL APPLICATION TO FOODS

When the Committee on Methods of Analysis and Sampling itself elaborates methods of analysis and sampling which are of general application to foods, it is responsible for carrying out the steps of the Procedure.

METHODS OF ANALYSIS OF FOOD ADDITIVES AS SUCH

Methods of analysis included in Codex Advisory Food Additives Specifications, for the purpose of verifying the criteria of purity and identity of the food additive, need not be referred to the Committee on Methods of Analysis and Sampling for endorsement. The Committee on Food Additives is responsible for carrying out the steps of the Procedure.

METHODS OF ANALYSIS OF PESTICIDE RESIDUES IN FOOD

The methods for determining the levels of pesticide residues in food need not be referred to the Committee on Methods of Analysis and Sampling for endorsement. The Committee on Pesticide Residues is responsible for carrying out the steps of the Procedure.

MICROBIOLOGICAL METHODS OF ANALYSIS AND SAMPLING

When Codex committees have included provisions on microbiological methods of analysis and sampling for the purpose of verifying hygiene provisions, they should be referred to the Committee on Food Hygiene at the most suitable time during Steps 3, 4 and 5 of the Procedure for the Elaboration of Codex Standards, which will ensure that government comments on the methods of analysis and sampling are available to the Committee on Food Hygiene. The procedure to be followed will be as in the normal practice described above, substituting the Committee on Food Hygiene for the Committee on Methods of Analysis and Sampling. Microbiological methods of analysis and sampling elaborated by the Committee on Food Hygiene for inclusion in Codex commodity standards for the purpose of verifying hygiene provisions need not be referred to the Committee on Methods of Analysis and Sampling for endorsement.

CORE FUNCTIONS OF CODEX CONTACT POINTS

The operation of Codex Contact Points will differ in each country depending on national legislation, government structures and practices.

CODEX CONTACT POINTS:

1. Act as the link between the Codex Secretariat and Member countries;

2. Coordinate all relevant Codex activities within their own countries;

3. Receive all Codex final texts (standards, codes of practice, guidelines and other advisory texts) and working documents of Codex sessions and ensure that they are circulated to those concerned within their own countries;

4. Send comments on Codex documents or proposals to the Codex Alimentarius Commission or its subsidiary bodies and/or the Codex Secretariat;

5. Work in close cooperation with the national Codex committee, where such a committee has been established. The Codex Contact Point acts as the liaison point with the food industry, consumers, traders and all other concerned to ensure that the government is provided with an appropriate balance of policy and technical advice upon which to base decisions relating to issues raised in the context of the Codex work;

6. Act as a channel for the exchange of information and coordination of activities with other Codex Members;

7. Receive the invitation to Codex sessions and inform the relevant chairpersons and the Codex Secretariat of the names of participants from their own countries;

8. Maintain a library of Codex final texts; and

9. Promote Codex activities throughout their own countries.