

Joint FAO/WHO Food Standards Programme

CODEX ALIMENTARIUS COMMISSION

PROCEDURAL MANUAL

Nineteenth edition



**World Health
Organization**



**Food and Agriculture
Organization of
the United Nations**

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WORLD HEALTH ORGANIZATION
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

Rome, 2010

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INTRODUCTION

The Procedural Manual of the Codex Alimentarius Commission describes the legal foundations and practical functioning of the Commission and its subsidiary bodies. Knowledge of the contents of this Manual is essential for Codex members and observers to participate effectively in the work of the Commission. The Manual has been organized into seven sections and one appendix as follows:

- **Section I: Basic Texts and Definitions** sets out the Commission's Statutes, Rules of Procedure and the General Principles of the Codex Alimentarius, as well as definitions of terms for the Purpose of the Codex Alimentarius which assist in the uniform interpretation of these texts.
- **Section II: Elaboration of Codex Standards and Related Texts** contains the Uniform Procedure for the Elaboration of Codex Standards and Related Texts, the criteria for the establishment of work priorities and subsidiary bodies, guidance on relations between Commodity Committees and General Committees, a format for Codex Commodity standards, procedures for consideration of food additive provisions, guidelines on the elaboration or revision of codes of hygienic practice and principles for selection of methods of analysis and sampling procedures.
- **Section III: Guidelines for Subsidiary Bodies** contains guidelines for the smooth and transparent operation of Codex Committees, *ad hoc* Task Forces and physical and electronic working groups
- **Section IV: Risk Analysis** – contains general and specific texts on risk analysis for application in the framework of the Codex Alimentarius Commission and its subsidiary bodies dealing with the protection of consumers' health and to the joint FAO/WHO expert bodies and consultations.
- **Section V: Codex Structure and Session History**, lists the Commission's subsidiary bodies with their Terms of Reference and the dates and places of the sessions held.
- **Section VI: Membership**, includes the membership list of the Commission (with year of accession where available) as well as the Core Functions of the Codex Contact Points.
- **Section VII: Relations with other Organizations** outlines the Principles and Guidelines governing the relations between the Codex Alimentarius Commission and international intergovernmental and non-governmental organizations.
- **Appendix: General Decisions of the Commission** contains the Statements of Principle concerning the Role of Science in the Codex decision-making process and the extent to which other factors are taken into account, the Statements of Principle relating to the Role of Food Safety Risk Assessment and the Measures to facilitate consensus.

This Nineteenth Edition of the Procedural Manual was prepared by the Secretariat following the Thirty-second Session of the Codex Alimentarius Commission, Rome, 2009. 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

BASIC TEXTS AND DEFINITIONS

- Statutes of the Codex Alimentarius Commission
(Adopted in 1961 by the 11th Session of the FAO Conference and in 1963 by the 16th Session of the World Health Assembly. Revised in 1966 and 2006)
- Rules of Procedure of the Codex Alimentarius Commission
(Adopted in 1963 at the first session of the Commission. Amended in 1964, 1965, 1966, 1968, 1969, 1970, 1999, 2003, 2005, 2006 and 2007)
- General Principles of the Codex Alimentarius
(Adopted in 1965. Amended in 1966, 1969, 1993, 1995 and 2007)
- Definitions

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.

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.

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.

Section I: Basic texts and definitions

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:
 - (a) 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;
 - (b) 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;
 - (c) 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.

Section I: Basic texts and definitions

2. Sessions of the Commission shall be convened and the place of the meeting shall be determined by the Directors-General of FAO and WHO after consultation, where appropriate, with the authorities of the host country.
3. Notice of the date and place of each session of the Commission shall be communicated to all Members of the Commission at least two months before the session.
4. Each Member of the Commission shall have one representative, who may be accompanied by one or more alternates and advisers.
5. In plenary meetings of the Commission, the representative of a Member may designate an alternate who shall have the right to speak and vote in the name of his or her delegation on any question. Moreover, upon the request of the representative or any alternate so designated, the Chairperson may allow an adviser to speak on any particular point.
6. Meetings of the Commission shall be held in public, unless the Commission decides otherwise.
7. The majority of the Members of the Commission shall constitute a quorum for the purposes of making recommendations for amendments to the Statutes of the Commission and of adopting amendments of, or additions to, the present Rules in accordance with Rule XV.1. For all other purposes the majority of the Members of the Commission attending the session shall constitute a quorum, provided that such a majority shall be not less than 20 percent of the total membership of the Commission, nor less than 25 Members. In addition, in the case of amendment or adoption of a proposed standard for a given region or group of countries, the quorum of the Commission shall include one third of the Members belonging to the region or group of countries concerned.

Rule VII Agenda

1. The Directors-General of FAO and WHO, after consultation with the Chairperson of the Commission or with the Executive Committee, shall prepare a Provisional Agenda for each session of the Commission.
2. The first item on the Provisional Agenda shall be the adoption of the Agenda.
3. Any Member of the Commission may request the Directors-General of FAO or WHO to include specific items in the Provisional Agenda.
4. The Provisional Agenda shall be circulated by the Directors-General of FAO or WHO to all Members of the Commission at least two months before the opening of the session.
5. Any Member of the Commission, and the Directors-General of FAO and WHO, may, after the dispatch of the Provisional Agenda, propose the inclusion of specific items in the Agenda with respect to matters of an urgent nature. These items shall be placed on a supplementary list, which, if time permits before the opening of the session, shall be dispatched by the Directors-General of FAO and WHO to all Members of the Commission, failing which the supplementary list shall be communicated to the Chairperson for submission to the Commission.

6. No items included in the Agenda by the governing bodies or the Directors-General of FAO and WHO shall be deleted therefrom. After the Agenda has been adopted, the Commission may, by a two-thirds majority of the votes cast, amend the Agenda by the deletion, addition or modification of any other item.

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

Rule VIII Voting and Procedures

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

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

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

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

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

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

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

Rule IX Observers

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

Section I: Basic texts and definitions

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;

Section I: Basic texts and definitions

- (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.

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 texts³ 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 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.

³ These include codes of practice, guidelines and other recommendations.

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 (MRL) 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 (MRL) 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 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.

SECTION II

ELABORATION OF CODEX STANDARDS AND RELATED TEXTS

- Procedures for the Elaboration of Codex Standards and Related Texts. (Adopted in 1965. Revised in 1993 and 2004. Amended in 1966, 1969, 1976, 1981, 2005, 2006 and 2008)
- Criteria for the Establishment of Subsidiary Bodies of the Codex Alimentarius Commission. (Adopted in 1969. Revised in 1999)
- Criteria for the Establishment of Work Priorities. (Adopted in 1969. Revised in 1999 and 2005)
- Relations between Commodity Committees and General Committees. (Amended in 1995, 1997, 1999, 2001 and 2008)
- Format for Codex Commodity Standards. (Adopted in 1969. Amended in 2007 and 2008)
- Guidelines for the Inclusion of Specific Provisions in Codex Standards and Related Texts
 - *Procedures for consideration of entry and review of Food Additive Provisions in the General Standard for Food Additives. (Adopted in 2007)*
 - *Guidelines on the Elaboration and/or Revision of Codes of Hygienic Practice for Specific Commodities. (Adopted in 1997)*
 - *Principles for the Establishment of Codex Methods of Analysis. (Adopted in 1964. Amended in 1969, 1979, 2001, 2003, 2004, 2008, 2009)*
 - *Principles for the Establishment or Selection of Codex Sampling Procedures. (Adopted in 1993. Amended 2007)*
 - *The use of Analytical Results: Sampling Plans, Relationship between the Analytical Results, the measurement uncertainty, recovery factors and provisions in Codex Standards. (Adopted in 2006)*

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 Additives⁴, the General Standard on Contaminants and Toxins in Food and Feed⁵, 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:

⁴ including related methods of analysis and sampling plans

⁵ including related methods of analysis and sampling plans

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

Part 3. Uniform Procedure for the Elaboration of Codex Standards and Related Texts

Step 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.

Step 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).

Step 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 standard⁶. 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 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.

⁶ 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.

Part 4. Uniform Accelerated Procedure for the Elaboration of Codex Standards and Related Texts**Step 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.⁷ 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.

Step 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).

Step 3

The proposed draft standard is sent to Members of the Commission and interested international organizations for comment on all aspects including possible implications of the proposed draft standard for their economic interests. When standards are subject to an accelerated procedure, this fact shall be notified to the Members of the Commission and the interested international organizations.

Step 4

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

Step 5

In the case of standards identified as being subject to an accelerated elaboration procedure, the 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,

⁷ 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.

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 Worldwide Codex Standard.

- (a) A request to convert a regional standard into a worldwide standard may arise immediately after adoption of the regional standard at Step 8, or some time thereafter.
- (b) The conversion of a regional standard into a worldwide standard may contemplate the following situations as per status of the relevant commodity committee:
 - (i) When the relevant commodity committee is active: Requests for conversion of a regional standard into a worldwide standard should preferably be made by the commodity committee concerned, substantiated by a Project Document. This Project Document will be reviewed by the Executive Committee in the framework of the Critical Review Process, taking into account the programme of work of the commodity committee concerned. If the Codex Alimentarius Commission approves the proposal, taking into account the outcome of the Critical Review by the Executive Committee, the regional standard usually enters the Uniform Accelerated Procedure at Step 3, for consideration at Step 4 at the subsequent session of the commodity committee concerned.
 - (ii) When the relevant commodity committee is not active: When the commodity committee concerned is not active (i.e., not holding physical sessions), the proposal for conversion of a regional standard into a worldwide standard should preferably come through the originating coordinating committee, substantiated by a Project Document; it may also come from Codex members in the form of a Project Document for consideration by the Executive Committee in the framework of the Critical Review process. If the Codex Alimentarius Commission approves the proposal, taking into account the outcome of the Critical Review by the Executive Committee, the regional standard usually enters the Uniform Accelerated Procedure at Step 3, for consideration at Step 4 by the commodity committee concerned. In this case, the Executive Committee should give consideration to how to proceed with the work either by

correspondence, or by reconvening the adjourned committee. In the latter situation, the Executive Committee should recommend to the Commission the reactivation of the committee adjourned *sine die* to undertake the new work.

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.

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 body⁸, 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.

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.

⁸ The Commission may wish to consider extending the Terms of Reference of an appropriate existing body to accommodate the proposal.

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.⁹

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.

⁹ 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).

RELATIONS BETWEEN COMMODITY COMMITTEES AND GENERAL SUBJECT COMMITTEES

Codex Committees may ask the advice and guidance of general subject committees having responsibility for matters applicable to all foods on any points coming within their province, in accordance with their Terms of Reference. In particular, due referral should take place between commodity committees (in this document “commodity committees” are meant to include coordinating committees and other subsidiary bodies of the Commission in so far as they elaborate commodity standards) and general subject committees during the elaboration of Codex commodity standards.

Codex general subject committees which include the Committees on Food Labelling; Food Additives; Contaminants in Foods; Pesticides Residues; Residues of Veterinary Drugs in Foods; Food Hygiene; Methods of Analysis and Sampling; 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 general provisions should only be incorporated into Codex Commodity Standards by reference unless there is a need for doing otherwise (see “*Format for Codex Commodity Standards*”).

Where commodity committees are of the opinion that the general provisions are not applicable to one or more commodity standards, they may request the responsible general subject 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 food additives, contaminants, hygiene, labelling, 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 general subject committees at the most suitable and earliest time in the Procedure for the Elaboration of Codex Standards and Related Texts, though such referral should not be allowed to delay the progress of the standard to the subsequent Steps of the Procedure.

Food Labelling

Commodity committees shall refer any exemptions from, or additions to, the reference to the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) as indicated in the section on food labelling in the *Format for Codex Commodity Standards* to the Committee on Food Labelling for endorsement.

In respect of date marking (Section 4.7 of the General Standard for the Labelling of Prepackaged Foods), a commodity 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 Committee on Food Labelling.

Food Additives

Commodity committees shall examine the General Standard for Food Additives (CODEX STAN 192-1995) with a view toward incorporating a reference to the General Standard. All proposals for additions or amendments to the General Standard for Food Additives in order to establish a reference to the General Standard for Food Additives shall be referred to the Committee on Food Additives. The Committee on Food Additives shall consider such proposals for endorsement.

Revisions of a substantive nature that are endorsed by the Committee on Food Additives 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 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 Committee on Food Additives for consideration and endorsement. The commodity committee shall provide a justification for why a general reference to the General Standard for Food Additives would not be appropriate in light of the criteria for the use of food additives established in the Preamble of the General Standard for Food Additives, in particular Section 3.

All provisions in respect of food additives (including processing aids) contained in Codex commodity standards should be referred to the 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 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 the General Standard for Food Additives.

When forwarding a food additive section of a commodity standard for endorsement by the 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 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 Committee on Food Additives for endorsement and inclusion in the General Standard for Food Additives. When the 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 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 Committee on Food Additives .

Contaminants in Foods

Commodity committees shall examine the General Standard for Contaminants and Toxins in Food and Feed (*CODEX STAN 193-1995*) with a view towards incorporating a reference to the General Standard.

Should the commodity committee consider that a general reference to the General Standard for Contaminants and Toxins in Food and Feed does not serve its purpose, a proposal should be prepared and forwarded to the Committee on Contaminants in Foods for consideration of starting new work, amendments to the General Standard for Contaminants and Toxins in Food and Feed, or endorsement of proposed provisions, as appropriate.

When doing so, the commodity committee shall provide a justification why a general reference to the General Standard for Contaminants and Toxins in Food and Feed would not be appropriate for products concerned.

All proposals should be referred to the Committee on Contaminants in Foods, preferably before the advancement of the draft commodity standards concerned to Step 5 of the Procedure for 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.

The Committee on Contaminants in Foods shall consider all proposals for additions or amendments to the General Standard or endorsement of proposed provisions and take action where necessary and appropriate.

Pesticide residues / residues on veterinary drugs in Foods

Commodity committees shall examine the provisions on residue limits of pesticides and of veterinary drugs adopted by the Codex Alimentarius Commission with a view towards incorporating a general reference as indicated in the section on contaminants in the *Format for Codex Commodity Standards*.

Should the commodity committee consider that the general reference above does not serve its purpose, a proposal should be prepared and forwarded to the Committees on Pesticide Residues or on Residues of Veterinary Drugs in Foods as appropriate, for consideration of new work or revision of the adopted residue limits.

Food Hygiene

Commodity committees should examine the provisions on food hygiene adopted by the Codex Alimentarius Commission, with a view towards incorporating a general reference as indicated in the section on food hygiene in the *Format for Codex Commodity Standards*. Commodity committees shall refer any exemptions from, or additions to, the general reference above to the Committee on Food Hygiene for endorsement.

Methods of Analysis and Sampling

Normal Practice

Except for methods of analysis and sampling associated with microbiological criteria, when commodity committees have included provisions on methods of analysis or sampling in a Codex commodity standard, these should be referred to the 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 commodity committee should, whenever possible, provide information to the 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 commodity committee should, whenever possible, provide information to the 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, commodity committees should discuss and report to the 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 Specifications for Food Additives (CAC/MISC 6) 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 and veterinary drugs in food

The methods for determining the levels of pesticide residues and veterinary drug residues in food need not be referred to the Committee on Methods of Analysis and Sampling for endorsement. The Committees on Pesticide Residues and Residues of Veterinary Drugs in foods are responsible for carrying out the steps of the Procedure.

Microbiological methods of analysis and sampling

When commodity 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.

Food Import and Export Inspection and Certification Systems

General subject and commodity committees should refer to the principles and guidelines developed by the 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.

FORMAT FOR CODEX COMMODITY STANDARDS

Introduction

The Format is 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

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.

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 Subject Committees*, and 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

This section should contain only the following reference to the General Standard for Contaminants and Toxins in Food and Feed without reference to specific provisions on contaminants:

"The products covered by this Standard shall comply with the Maximum Levels of the Codex General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995)."

For residues of pesticides and veterinary drugs, if applicable to products concerned, this section should contain a general reference which should take the following form, without reference to specific provisions on residues of pesticides and veterinary drugs:

“The products covered by this Standard shall comply with the maximum residue limits for pesticides and/or veterinary drugs established by the Codex Alimentarius Commission.”

Hygiene

This Section should contain the following general reference to the *Recommended International Code of Practice – General Principles of Food Hygiene* and the *Principles for the Establishment and Application of Microbiological Criteria for Foods* without reference to specific provisions on food hygiene:

“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), 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).”

Reference should also be made to applicable codes of hygienic practice.

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. Provisions should be included by reference to the General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985).

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.

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 Pre-packaged 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 pre-packaged foods, a provision for labelling of non retail containers may be included.

In such cases the provision may specify that:

“Information on ...¹⁰ 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.”¹¹

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 for the Labelling of Prepackaged Foods), if a Codex commodity committee, 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, a relevant provision may be included.

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 Subject 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.

¹⁰ Codex Committees should decide which provisions are to be included.

¹¹ 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.

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

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.

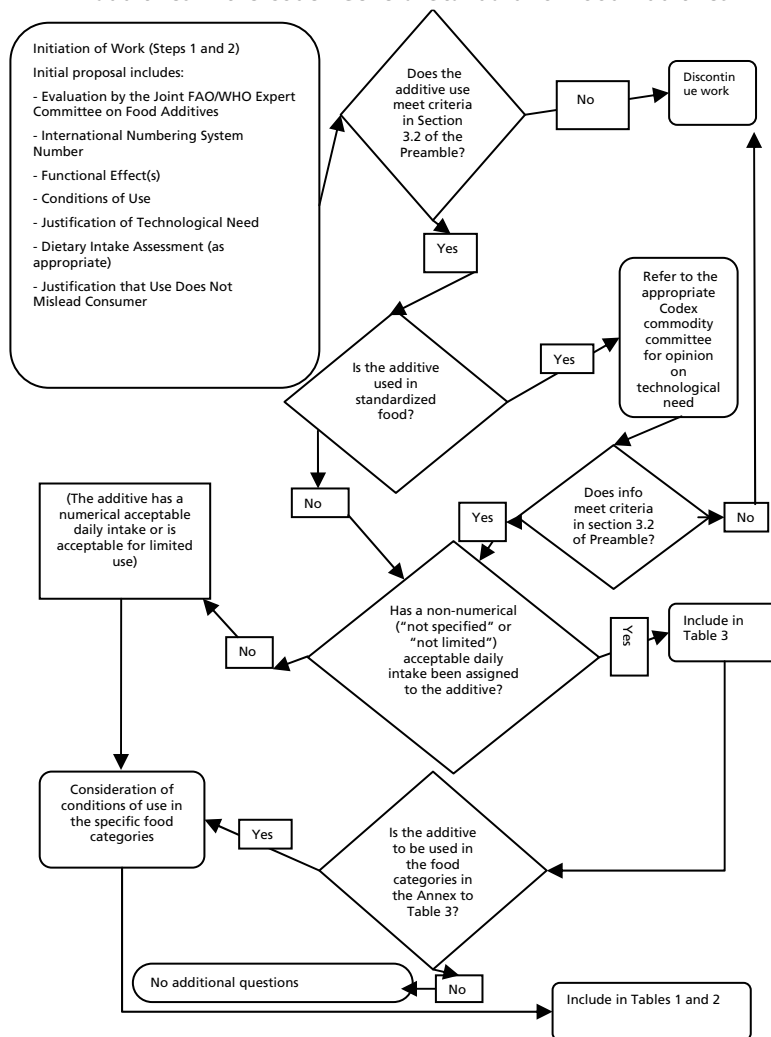
4. When establishing the acceptable maximum level of use for an additive in a specified food category, the Committee on Food Additives considers the technological justification for the proposed level and the exposure assessment in accordance with Sections 3.1 and 3.2 of the Preamble of the General Standard 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



***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) selectivity
 - (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 Committee may continue to propose an appropriate method of analysis for determining the chemical entity and/or develop a set of criteria to which a method used for the determination must comply. In either case the specified maximum level, minimum level, any other normative level or the concentration range of interest has to be stated.

When a Codex Committee decides that a set of criteria should be developed, in some cases the 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 standard. If a Codex Committee wishes to develop the criteria, it should follow instructions given for the development of specific criteria as outlined in Table 1.

Note: These criteria are applicable to fully validated methods except for methods such as PCR and ELISA, which require other set of criteria.

Table 1: Guidelines for establishing numeric values for the criteria:

Applicability:	The method has to be applicable for the specified provision, specified commodity and the specified level(s) (maximum and/or minimum) (ML). The minimum applicable range of the method depends on the specified level (ML) to be assessed, and can either be expressed in terms of the reproducibility standard deviation (s_R) or in terms of LOD and LOQ.
Minimum applicable range:	For $ML \geq 0.1$ mg/kg, $[ML - 3 s_R, ML + 3 s_R]$ For $ML < 0.1$ mg/kg, $[ML - 2 s_R, ML + 2 s_R]$ s_R^{12} = standard deviation of reproducibility
Limit of Detection (LOD):	For $ML \geq 0.1$ mg/kg, $LOD \leq ML \cdot 1/10$ For $ML < 0.1$ mg/kg, $LOD \leq ML \cdot 1/5$
Limit of Quantification (LOQ):	For $ML \geq 0.1$ mg/kg, $LOQ \leq ML \cdot 1/5$ For $ML < 0.1$ mg/kg, $LOQ \leq ML \cdot 2/5$

Precision:	For $ML \geq 0.1$ mg/kg, HorRat value ≤ 2 For $ML < 0.1$ mg/kg, the $RSD_{TR} < 22\%$. RSD_R^{13} = relative standard deviation of reproducibility. $RSD_R \leq 2$, $PRSD_R$			
Recovery (R):	Concentration	Ratio	Unit	Recovery (%)
	100	1	100% (100 g/100g)	98 – 102
	≥ 10	10^{-1}	$\geq 10\%$ (10 g/100g)	98 – 102
	≥ 1	10^{-2}	$\geq 1\%$ (1 g/100g)	97 – 103
	≥ 0.1	10^{-3}	$\geq 0.1\%$ (1 mg/g)	95 – 105
	0.01	10^{-4}	100 mg/kg	90 – 107
	0.001	10^{-5}	10 mg/kg	80 – 110
	0.0001	10^{-6}	1 mg/kg	80 – 110
	0.00001	10^{-7}	100 µg/kg	80 – 110
	0.000001	10^{-8}	10 µg/kg	60 – 115
	0.0000001	10^{-9}	1 µg/kg	40 – 120
Trueness	Other guidelines are available for expected recovery ranges in specific areas of analysis. In cases where recoveries have been shown to be a function of the matrix other specified requirements may be applied. For the evaluation of trueness preferably certified reference material should be used.			

The criteria in Table 1 must be approved for the determination in question.

However, the primary responsibility for supplying information about the specified Codex level(s), methods of analysis and criteria resides with the referring Committee. If the Committee fails to provide a method of analysis or criteria despite numerous requests, then the CCMAS may establish appropriate criteria as above.

¹² The s_R should be calculated from the Horwitz / Thompson equation. When the Horwitz/ Thompson equation is not applicable (for an analytical purpose or according to a regulation) or when "converting" methods into criteria then it should be based on the s_R from an appropriate method performance study.

¹³ The RSD_R should be calculated from the Horwitz/Thompson equation. When the Horwitz/Thompson equation is not applicable (for an analytical purpose or according to a regulation) or when "converting" methods into criteria then it should be based on the $RSDs_R$ from an appropriate method performance study.

GUIDELINES FOR ESTABLISHING NUMERIC VALUES FOR METHOD CRITERIA AND/OR ASSESSING METHODS FOR COMPLIANCE THEREOF

1. Recommendations for establishing numeric values for method criteria

Only the provision for the commodity along with its ML (maximum level, minimum level, normative level or concentration range) is needed when establishing numeric values for method criteria.

Note: These criteria are applicable to fully validated methods except for methods such as PCR and ELISA, which require other set of criteria.

1.1 The applicability

The method has to be applicable to the particular analyte(s)/provision(s) in the specified matrix/ commodity or food category. For horizontal methods the relevant food categories should have been tested. Furthermore, it should have been shown that the method is applicable for concentrations levels around the specified ML, i.e. the ML should be within the validated range.

- For $ML \geq 10^{-7}$, the minimum applicable range should be: $ML \pm 3s_R$
- For $ML < 10^{-7}$, the minimum applicable range should be: $ML \pm 2s_R$

The minimum applicable concentration range should correspond to an interval containing a large fraction of the expected variation (due to measurement uncertainty) in the results around the specified limit (ML). For collaboratively validated methods the expected variation would be the reproducibility standard deviation (s_R) multiplied with a coverage factor. A coverage factor of 2 corresponds to a confidence level of approx. 95%, and a coverage factor of 3 corresponds to a confidence level about 99%. As 99% is often used as an action level in control charts, a coverage factor of 3 is recommended for concentration ratios at or above 10^{-7} , (≥ 0.1 mg/kg). For concentrations lower than 0.1 mg/kg, a coverage factor of 2 is recommended, as a coverage factor of 3 would make it hard to find applicable methods for certain analytes/provisions due to the low level.

Calculation of the minimum applicable range for specified MLs:

The minimum applicable range can be estimated based on the Horwitz/Thompson equation for reproducibility standard deviation, s_R .

1.1.1 For concentration ratios $\geq 10^{-7}$ (≥ 0.1 mg/kg) the Horwitz' equation is applied:

$$PRSD_R (\%) = 100 \cdot s_R/c = 2C^{-0.1505}$$

where

$PRSD_R$ is the "predicted" relative standard deviation,
 s_R is the predicted standard deviation
 c is the concentration of interest, which here is the ML and
 C is the concentration ratio, i.e. the concentration ratio of ML (C_{ML})

By rearranging the equation with respect of s_R , the following equation is obtained:

$$S_R = \frac{c \cdot 2C^{-0.1505}}{100} = \frac{ML \cdot 2 \cdot C_{ML}^{-0.1505}}{100}$$

Example 1: ML = 0.1 mg/kg, $C_{ML} = 10^{-7}$:

$$0.1 \pm 3 \cdot S_R = 0.1 \pm 3 \cdot \frac{0.1 \cdot 2 \cdot (0.0000001)^{-0.1505}}{100} = 0.1 \pm 0.07 \text{ mg/kg}$$

The minimum applicable range for a ML of 0.1 mg/kg is then 0.03 to 0.17 mg/kg

Example 2: For a ML of 1 mg/kg (i.e. 10^{-6}):

$$1.0 \pm 3 \cdot S_R = 1.0 \pm 3 \cdot \frac{1.0 \cdot 2 \cdot (0.000001)^{-0.1505}}{100} = 1.0 \pm 0.48 \text{ mg/kg}$$

The minimum applicable range for ML of 1 mg/kg is then 0.5 to 1.5 mg/kg

1.1.2 For concentration ratios $< 10^{-7}$, the Thompson theory is applied, i.e. $PRSD_R = 22\%$ and hence $s_R = 0.22 \cdot ML$

Example 3: ML = 0.01 mg/kg (i.e. 10^{-8}):

$$0.01 \pm 2 \cdot s_R = 0.01 \pm 2 \cdot (0.22 \cdot ML) = 0.01 \pm 0.44 \cdot 0.01 = 0.01 \pm 0.0044 \text{ mg/kg}$$

The minimum applicable range for a ML of 0.01 mg/kg is then 0.006 to 0.014 mg/kg.

In Table 1, a number of minimum applicable concentration ranges for specified MLs are given.

Table 1: Recommended criteria for minimum application range for specified MLs

ML (mg/kg)	0.01	0.02	0.05	0.1	1	10	100
Lower level:	0.006	0.011	0.028	0.03	0.52	6.6	76
Upper level: *	0.014	0.029	0.072	0.17	1.48	13.3	124

* Upper level will seldom be the limiting factor like the lower level.

1.2 Limit of Detection (LOD) and limit of Quantification (LOQ)

As an alternative to establishing minimum applicable range, the criteria could be numeric values for LOD and LOQ.

The numeric value for the limit of detection (LOD), should be:

- no more than 1/10 of the specified ML for levels at or above 0.1 mg/kg, and
- no more than 1/5 of the specified ML for levels below 0.1 mg/kg.

The numeric value for the limit of quantification (LOQ) should be:

- no more than 1/5 of the specified ML for levels at or above 0.1 mg/kg, and
- no more than 2/5 of the specified ML for levels below 0.1 mg/kg.

1.3 The method precision, derived from collaborative method performance studies

The precision should be expressed as the obtained relative reproducibility standard deviation (RSD_R) obtained from collaborative method performance studies, which is compared to the predicted relative reproducibility standard deviation ($PRSD_R$)

According to Horwitz, the ratio between the found and the predicted value should be ≤ 2 (known as the HorRat value), this is also applicable for Thompson equation of $PRSD_R = 22\%$:

$$\frac{RSD_R}{PRSD_R} \leq 2 \Leftrightarrow RSD_R \leq 2 \cdot PRSD_R$$

The numeric values for the precision given in table 2 are also based on the Horwitz/Thompson equation. For some analyses, using advanced techniques, a better precision can be obtained.

Table 2. Precision requirement at different concentrations based on the Horwitz/Thompson equation.

	Thompson	Horwitz equation ($2C^{-0.1505}$)							
Concentration ratio (C)	$< 10^{-7}$	10^{-7}	10^{-6}	10^{-5}	10^{-4}	10^{-3}	10^{-2}	10^{-1}	1
Concentration unit	< 0.1 mg/kg	0.1 mg/kg	1 mg/kg	10 mg/kg	0.1 g/kg	1 g/kg	10 g/kg	100 g/kg	1000 g/kg
$PRSD_R$ (%)	22	22	16	11	8	6	4	3	2
$RSD_R \leq 2 \cdot PRSD_R$ (%)	≤ 44	≤ 44	≤ 32	≤ 22	≤ 16	≤ 12	≤ 8	≤ 6	≤ 4

$PRSD_R$ = predicted value for relative standard deviation of reproducibility.

RSD_R = found value for the relative standard deviation of reproducibility in a collaborative study.

1.4 Recovery

Evaluation and estimation of recovery is included in the method validation. Whether or not recovery is of relevance depends on the method procedure.

1.5 Trueness

For the evaluation of trueness preferably appropriate certified reference materials (CRMs) should be analysed and demonstrated to give the certified value (allowing for measurement uncertainty) is achieved.

1.6 Examples on how to establish criteria for a provision

In order to illustrate how to set criteria for a provision the following example is used:

According to Codex Standard 1993-1995, Rev 2-2006, General Standard for contaminants and toxins in food, the ML for lead in fruit juices is 0.05 mg/kg. According to the recommendations for obtaining numeric values for the characteristics based on the ML, the criteria would be those in table 3:

Table 3. Recommendation for numeric criteria values for lead in fruit juice

Applicability: Analyte:	Lead
Matrix/provision:	Juice
ML:	0.05 mg/kg
Lower level of min. application range:	$\leq 0.03 \text{ mg/kg}$ ($= \text{ML} - 2s_R = 0.05 \text{ mg/kg} - 0.44 \cdot 0.05 \text{ mg/kg}$). See Table 1
LOD:	$\leq 0.01 \text{ mg/kg}$ ($= \text{ML} \cdot 1/5 = 0.05 \text{ mg/kg} \cdot 1/5$)
LOQ:	$\leq 0.02 \text{ mg/kg}$ ($= \text{ML} \cdot 2/5 = 0.05 \text{ mg/kg} \cdot 2/5$)
Precision:	For concentration at 0.05 mg/kg, the $\text{RSD}_R \leq 44\%$, See Table 2
Recovery:	The method procedure does not include an extraction step and hence recovery is of no relevance.
Trueness:	Use of CRM.

2. Method criteria at different MLs (maximum level, minimum level, normative level or concentration range)

In table 4 examples on method criteria are given for certain MLs.

Table 4: Method criteria for MLs at increasing orders of magnitude.

ML unit	0.001 mg/kg	0.01 mg/kg	0.1 mg/kg	1 mg/kg	10 mg/kg	100 mg/kg	1 g/kg	10 g/kg
Concentration ratio of ML (C_{ML})	10^{-9}	10^{-8}	10^{-7}	10^{-6}	10^{-5}	10^{-4}	10^{-3}	10^{-2}
Minimum applicable Range	From 0.0006 to 0.0014 (mg/kg)	From 0.006 to 0.014 (mg/kg)	From 0.03 to 0.17 (mg/kg)	From 0.52 to 1.48 (mg/kg)	From 6.6 to 13.3 (mg/kg)	From 76 to 124 (mg/kg)	From 0.83 to 1.2 (g/kg)	From 8.8 to 11 (g/kg)
LOD (\leq mg/kg)	0.0002	0.002	0.01	0.1	1	10	100	1000
LOQ (\leq mg/kg)	0.0004	• 0.004	0.02	0.2	2	20	200	2000
RSD_R (\leq %)	44	44	44	32	22	16	12	8
Recovery (%) *	40 - 120	60 - 115	80 - 110	80-110	80 - 110	90 - 107	95 - 105	97 - 103

* Other guidelines are available for expected recovery ranges in specific areas of analysis. In cases where recoveries have been shown to be a function of the matrix other specified requirements may be applied.

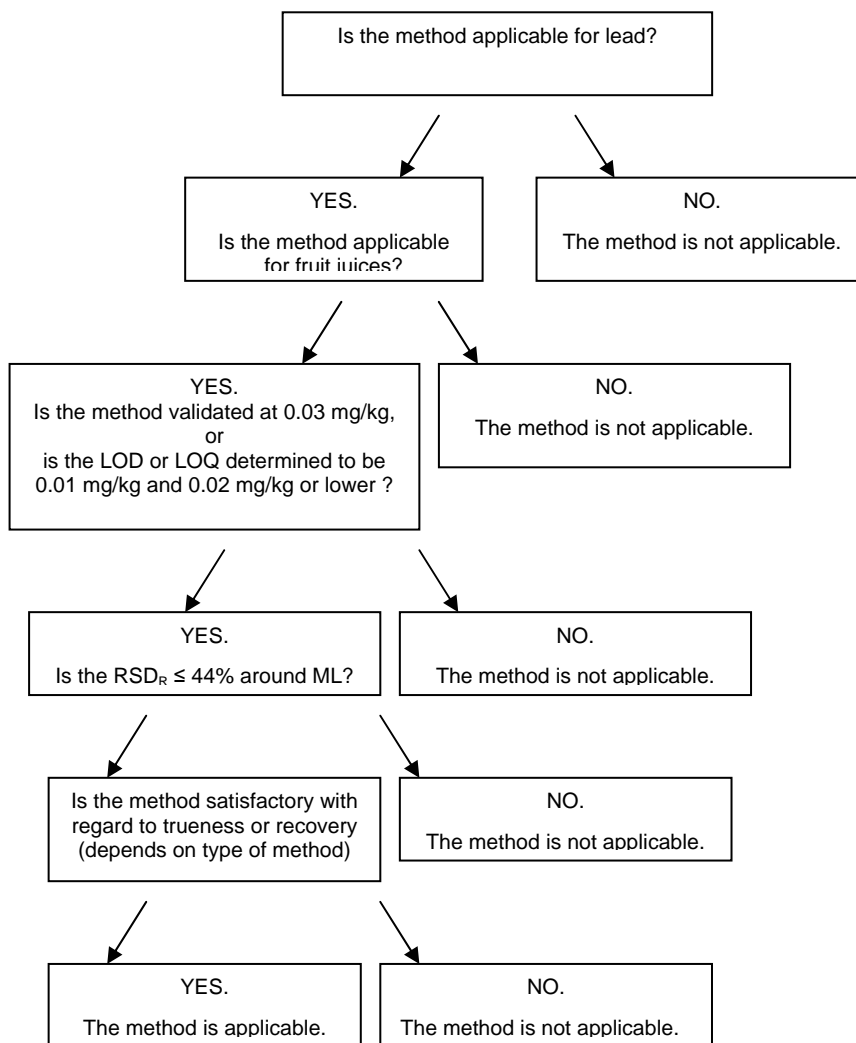
2.1 How to elucidate a method's compliance with the criteria.

To review a method for possible compliance with the established criteria, the method performance characteristics have to be assessed. The result of a method performance study is available in the method and/or published in an international journal.

2.1.1 Example on assessing methods for compliance

Continuing the example above on lead in fruit juice, having ML of 0.05 mg/kg, the methods considered should be able to quantify lead in fruit juice as low as 0.03 mg/kg, with a precision, $PRSD_R$ of 22%, the RSD_R obtained from the method performance study should then not be higher than 44% (corresponding to a 95% confidence interval).

When assessing a method for compliance, the following steps should be considered:



In order to find appropriate methods for this purpose, information are collected on methods for determination of lead. (As this is an example in the Procedural Manual, the methods' identification is omitted):

Table 5: Collaboratively validated methods for analysis of lead

Method No	Applicability	Principle	Assessed level (mg/kg)	LOD (mg/kg)	RSD _R (%)	Applicable Yes/No and why
1	All foods	Flame AAS	2.2 – 29		4.9-36	NO Flame AAS will not be able to detect at 0.05 mg/kg
2	All Foods (Chicken, apple)	Anodic stripping voltammetry	0.03-2.8	0.03	17-106	NO The RSD _R is 106% (not <44%) at 0.03 mg/kg
3	Sugars	GF-AAS	0.03-0.50		12-30	YES Even if the applicability does not say Juice (or all foods) it should be considered applicable as fruit juice contains a lot of sugar. The precision is satisfactory.
4	Fats and Oils	GF-AAS	0.018-0.090		5.9-30	NO The method describes sample prep. for fats and oils only.
5	Natural mineral water	AAS	0.0197-0.977	< 0.01	2.8-4.2	NO The method describes sample prep. for water only.
6	All foods	GF-AAS after dry ashing	0.045-0.25	< 0.01	26-40	NO The lowest validated level is not low enough, however as the technique is GF-AAS, it should be applicable for 0.03 mg/kg.
7	All foods except oils, fats and extremely fatty products.	AAS after microwave oven digestion under pressure.	0.005-1.62	0.014	26-44	YES Validation level and RSD _R are ok
8	All foods	ICP-MS after pressure digestion	0.013-2.45	< 0.01	8-47	YES Validation level and RSD _R are ok for levels of 0.03 mg/kg and above.

AAS = Atomic Absorption Spectrometry

GF-AAS = Graphite Furnace Atomic Absorption Spectrometry

ICP-MS = Inductive Coupled Plasma - Mass Spectrometry

Conclusion: Methods No. 3, 7 and 8 are found applicable for the determination of lead in fruit juices for the given ML of 0.05 mg/kg. Assessing methods for compliance requires knowledge about the methods; sample preparation, procedures and instrumentation. Thus the methods cannot be “judged” by numeric values for the criteria alone.

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 specified Codex level(s) along with the provision to enable the CCMAS to convert it into suitable generalized analytical characteristics:

- trueness
- applicability (matrix, concentration range and preference given to 'general' methods)
- limit of detection
- limit of quantification
- 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 method performance studies 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 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).

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.

SECTION III

GUIDELINES FOR SUBSIDIARY BODIES

- Guidelines to Host Governments of Codex Committees and *ad hoc* Intergovernmental Task Forces. (Adopted in 2004)
- Guidelines on the conduct of meetings of Codex Committees and *ad hoc* Intergovernmental Task Forces. (Adopted in 2004. Amended in 2006)
- Guidelines to Chairpersons of Codex Committees and *ad hoc* Intergovernmental Task Forces (including the Criteria for the Appointment of Chairpersons). (Adopted in 2004. Amended in 2009)
- Guidelines on Physical Working Groups. (Adopted in 2005)
- Guidelines on Electronic Working Groups. (Adopted in 2005)

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

SECTION III: Guidelines for Subsidiary Bodies

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

Invitations should include the following:

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

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

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

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

The work of the Committee and the length of the meeting should be so arranged as to

leave sufficient time at the end of the session for a report of the Committee's transactions to be agreed.

Organization of Work

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

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

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

Preparation and Distribution of Papers

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

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

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

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

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

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

¹⁴ See Section V for references for Codex Documents.

SECTION III: Guidelines for Subsidiary Bodies

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 Codes *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.

Consensus¹⁵

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

¹⁵ Reference is made to the *Measures to facilitate consensus* (see Appendix: General Decisions of the Codex Alimentarius Commission).

SECTION III: Guidelines for Subsidiary Bodies

chairperson should consider:

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

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

- (a) ensuring that: (i) the scientific basis is well established on current data including, wherever possible, scientific data and intake and exposure information from the developing countries; (ii) where data from developing countries are not available, an explicit request for collecting and making available such data is made; and (iii) where necessary, further studies are carried out in order to clarify controversial issues;
- (b) ensuring that issues are thoroughly discussed at meetings of the Committees concerned;
- (c) organizing informal meetings of the parties concerned where disagreements arise, provided that the objectives of any such meetings are clearly defined by the Committee concerned and that participation is open to all interested delegations and observers in order to preserve transparency;
- (d) requesting the Commission, where possible, for a redefinition of the scope of the subject matter being considered for the elaboration of standards in order to cut out issues on which consensus cannot be reached;
- (e) ensuring that matters are not progressed from step to step until all relevant concerns are taken into account and adequate compromises worked out¹⁶;
- (f) facilitating increased involvement and participation of developing countries.

Where there is a deadlock in the standards development, the Chairperson should consider acting as a facilitator, or appointing a facilitator in agreement with the relevant Codex Committee, working during a session or between sessions to work with members to reach consensus. The facilitator should orally report on the activity undertaken and the outcome of the facilitation to the plenary.

- The committee concerned should clearly state the terms of reference of the facilitator.
- The facilitator should be experienced in Codex matters but neutral on the matter concerned.
- All parties participating in the process should agree on the selection of the facilitator.

¹⁶ 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.¹⁷

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").

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*¹⁸.

¹⁷ 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.

¹⁸ Reference is made to the Guidelines to Chairpersons of Codex Committees and *ad hoc* Intergovernmental Task Forces.

SECTION III: Guidelines for Subsidiary Bodies

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 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.¹⁹

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

Organization and Procedures

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.

¹⁹ 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.

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.

SECTION IV

RISK ANALYSIS

- Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. (Adopted in 2003)
- Definitions of Risk Analysis Terms related to Food Safety. (Adopted in 1997. Amended in 1999, 2003, 2004)
- Risk Analysis Principles Applied by the Committee on Food Additives and the Committee on Contaminants in Foods. (Adopted in 2005, amended in 2007)
- Policy of the Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups. (Adopted in 2005. Amended in 2007)
- Risk Analysis Principles applied by the Committee on Residues of Veterinary Drugs in Foods. (Adopted in 2007)
- Risk Assessment Policy for the setting of Maximum Limits for residues of Veterinary Drugs in Foods. (Adopted in 2007)
- Risk Analysis Principles applied by the Committee on Pesticide Residues (including Annex on Risk Management Policies used by the JMPR). (Adopted in 2007)
- Criteria for the prioritization process of compounds for evaluation by JMPR. (Amended in 2006)
- Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses (Adopted in 2009)

WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION IN THE FRAMEWORK OF THE CODEX ALIMENTARIUS

SCOPE

1. These principles for risk analysis are intended for application in the framework of the Codex Alimentarius.
2. The objective of these Working Principles is to provide guidance to the Codex Alimentarius Commission and the joint FAO/WHO expert bodies and consultations, so that food safety and health aspects of Codex standards and related texts are based on risk analysis.
3. Within the framework of the Codex Alimentarius Commission and its procedures, the responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies (risk managers), while the responsibility for risk assessment lies primarily with the joint FAO/WHO expert bodies and consultations (risk assessors).

RISK ANALYSIS - GENERAL ASPECTS

4. The risk analysis used in Codex should be:
 - applied consistently;
 - open, transparent and documented;
 - conducted in accordance with both the Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account and the Statements of Principle Relating to the Role of Food Safety Risk Assessment²⁰; and
 - evaluated and reviewed as appropriate in the light of newly generated scientific data.
5. The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission²¹, each component being integral to the overall risk analysis.

²⁰ See Appendix: General Decisions of the Commission

²¹ See Definitions of Risk Analysis Terms Related to Food Safety

6. The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties²².
7. Effective communication and consultation with all interested parties should be ensured throughout the risk analysis.
8. The three components of risk analysis should be applied within an overarching framework for management of food related risks to human health.
9. There should be a functional separation of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.
10. When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.
11. Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.
12. The needs and situations of developing countries should be specifically identified and taken into account by the responsible bodies in the different stages of the risk analysis.

²² For the purpose of the present document, the term "interested parties" refers to "risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations" (see definition of "Risk Communication")

RISK ASSESSMENT POLICY

13. Determination of risk assessment policy should be included as a specific component of risk management.
14. Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent.
15. The mandate given by risk managers to risk assessors should be as clear as possible.
16. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

RISK ASSESSMENT²³

17. The scope and purpose of the particular risk assessment being carried out should be clearly stated and in accordance with risk assessment policy. The output form and possible alternative outputs of the risk assessment should be defined
18. Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise, experience, and their independence with regard to the interests involved. The procedures used to select these experts should be documented including a public declaration of any potential conflict of interest. This declaration should also identify and detail their individual expertise, experience and independence. Expert bodies and consultations should ensure effective participation of experts from different parts of the world, including experts from developing countries.
19. Risk assessment should be conducted in accordance with the Statements of Principle Relating to the Role of Food Safety Risk Assessment and should incorporate the four steps of the risk assessment, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.
20. Risk assessment should be based on all available scientific data. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.
21. Risk assessment should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.
22. Risk assessment should seek and incorporate relevant data from different parts of the world, including that from developing countries. These data should particularly include epidemiological surveillance data, analytical and exposure data. Where relevant data are not available from developing countries, the Commission should request that FAO/WHO initiate time-bound studies for this purpose. The conduct of the risk assessment should not be inappropriately

²³ Reference is made to the Statements of Principle Relating to the Role of Food Safety Risk Assessment: See Appendix: General Decisions of the Commission.

delayed pending receipt of these data; however, the risk assessment should be reconsidered when such data are available.

23. Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.
24. Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.
25. The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.
26. The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

RISK MANAGEMENT

27. While recognizing the dual purposes of the Codex Alimentarius are protecting the health of consumers and ensuring fair practices in the food trade, Codex decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers. Unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.
28. Risk management should follow a structured approach including preliminary risk management activities²⁴, evaluation of risk management options, monitoring and review of the decision taken. The decisions should be based on risk assessment, and taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles²⁵.

²⁴ For the purpose of these Principles, preliminary risk management activities are taken to include: identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment.

²⁵ See Appendix: General Decisions of the Commission.

Section IV: Risk Analysis

29. The Codex Alimentarius Commission and its subsidiary bodies, acting as risk managers in the context of these Working Principles, should ensure that the conclusion of the risk assessment is presented before making final proposals or decisions on the available risk management options, in particular in the setting of standards or maximum levels, bearing in mind the guidance given in paragraph 10.
30. In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.
31. The risk management process should be transparent, consistent and fully documented. Codex decisions and recommendations on risk management should be documented, and where appropriate clearly identified in individual Codex standards and related texts so as to facilitate a wider understanding of the risk management process by all interested parties.
32. The outcome of the preliminary risk management activities and the risk assessment should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk.
33. Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.
34. In order to avoid unjustified trade barriers, risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, the Commission and its subsidiary bodies should seek and take into consideration the potential impact of such measures on trade among its Member countries and select measures that are no more trade-restrictive than necessary.
35. Risk management should take into account the economic consequences and the feasibility of risk management options. Risk management should also recognize the need for alternative options in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health. In taking these elements into consideration, the Commission and its subsidiary bodies should give particular attention to the circumstances of developing countries.
36. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. Food standards and related texts should be reviewed regularly and updated as necessary to reflect new scientific knowledge and other information relevant to risk analysis.

RISK COMMUNICATION

37. Risk communication should :
- (i) promote awareness and understanding of the specific issues under consideration during the risk analysis;
 - (ii) promote consistency and transparency in formulating risk management options/recommendations;
 - (iii) provide a sound basis for understanding the risk management decisions proposed;
 - (iv) improve the overall effectiveness and efficiency of the risk analysis ;
 - (v) strengthen the working relationships among participants;
 - (vi) foster public understanding of the process, so as to enhance trust and confidence in the safety of the food supply;
 - (vii) promote the appropriate involvement of all interested parties; and
 - (viii) exchange information in relation to the concerns of interested parties about the risks associated with food.
38. Risk analysis should include clear, interactive and documented communication, amongst risk assessors (Joint FAO/WHO expert bodies and consultations) and risk managers (Codex Alimentarius Commission and its subsidiary bodies), and reciprocal communication with member countries and all interested parties in all aspects of the process.
39. Risk communication should be more than the dissemination of information. Its major function should be to ensure that all information and opinion required for effective risk management is incorporated into the decision making process.
40. Risk communication involving interested parties should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The need for specific standards or related texts and the procedures followed to determine them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis, and minority opinions that had been expressed in the course of the risk assessment (see para. 25).
41. The guidance on risk communication in this document is addressed to all those involved in carrying out risk analysis within the framework of Codex Alimentarius. However, it is also of importance for this work to be made as transparent and accessible as possible to those not directly engaged in the process and other interested parties while respecting legitimate concerns to preserve confidentiality (see para. 6)

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.

RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON FOOD ADDITIVES AND THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Section 1. Scope

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

Section 2. CCFA/CCCF and JECFA

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

Section 3. CCFA/CCCF

7. CCFA/CCCF are primarily responsible for recommending risk management proposals for adoption by the CAC.
8. CCFA/CCCF shall base their risk management recommendations to the CAC on JECFA's risk assessments, including safety assessments²⁶, of food additives, naturally occurring toxicants, and contaminants in food.
9. In cases where JECFA has performed a safety assessment and CCFA/CCCF or the CAC determines that additional scientific guidance is necessary, CCFA/CCCF or CAC may make a more specific request to JECFA to obtain the scientific guidance necessary for a risk management decision.
10. CCFA's risk management recommendations to the CAC with respect to food

²⁶ A Safety Assessment is defined as a scientifically-based process consisting of: 1) the determination of a NOEL (No Observed Effect Level) for a chemical, biological, or physical agent from animal feeding studies and other scientific considerations; 2) the subsequent application of safety factors to establish an ADI or tolerable intake; and 3) comparison of the ADI or tolerable intake with probable exposure to the agent (Temporary definition to be modified when JECFA definition is available).

additives shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Food Additives.

11. CCCF's risk management recommendations to the CAC with respect to contaminants and naturally occurring toxicants shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Contaminants and Naturally Occurring Toxins in Food.

12. CCFA/CCCF's risk management recommendations to the CAC that involve health and safety aspects of food standards shall be based on JECFA's risk assessments and other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*.

13. CCFA/CCCF's risk management recommendations to the CAC shall take into account the relevant uncertainties and safety factors described by JECFA.

14. CCFA shall endorse maximum use levels only for those additives for which 1) JECFA has established specifications of identity and purity and 2) JECFA has completed a safety assessment or has performed a quantitative risk assessment.

15. CCCF shall endorse maximum levels only for those contaminants for which 1) JECFA has completed a safety assessment or has performed a quantitative risk assessment and 2) the level of the contaminant in food can be determined through appropriate sampling plans and analysis methods, as adopted by Codex. CCCF should take into consideration the analytical capabilities of developing countries unless public health considerations require otherwise.

16. CCFA/CCCF shall take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending maximum use levels for additives or maximum levels for contaminants and naturally occurring toxicants in food.

17. Before finalising proposals for maximum levels for contaminants and naturally occurring toxicants, CCCF shall seek the scientific advice of JECFA about the validity of the analysis and sampling aspects, about the distribution of concentrations of contaminants and naturally occurring toxicants in foods and about other relevant technical and scientific aspects, including dietary exposure, as necessary to provide for a suitable scientific basis for its advice to CCCF.

18. When establishing its standards, codes of practice, and guidelines, CCFA/CCCF shall clearly state when it applies any other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*, in addition to JECFA's risk assessment, and specify its reasons for doing so.

19. CCFA/CCCF's risk communication with JECFA includes prioritising substances for JECFA review with the view towards obtaining the best available risk assessment for purposes of elaborating safe conditions of use for food additives and elaborating safe maximum levels or codes of practice for contaminants and naturally occurring toxicants in food.

20. CCFA/CCCF shall consider the following when preparing its priority list of substances for JECFA review:

- Consumer protection from the point of view of health and prevention of

Section IV: Risk Analysis

- unfair trade practices;
- CCFA/CCCF's Terms of Reference;
- JECFA's Terms of Reference;
- The Codex Alimentarius Commission's Strategic Plan, its relevant plans of work and *Criteria for the Establishment of Work Priorities*;
- The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;
- The prospect of completing the work in a reasonable period of time;
- The diversity of national legislation and any apparent impediments to international trade;
- The impact on international trade (i.e., magnitude of the problem in international trade);
- The needs and concerns of developing countries; and,
- Work already undertaken by other international organizations;

21. When referring substances to JECFA, CCFA/CCCF shall provide background information and clearly explain the reasons for the request when chemicals are nominated for evaluation;

22. CCFA/CCCF may also refer a range of risk management options, with a view toward obtaining JECFA's guidance on the attendant risks and the likely risk reductions associated with each option.

23. CCFA/CCCF requests JECFA to review any methods and guidelines being considered by CCFA/CCCF for assessing maximum use levels for additives or maximum levels for contaminants and naturally occurring toxicants. CCFA/CCCF makes any such request with a view toward obtaining JECFA's guidance on the limitations, applicability, and appropriate means for implementation of a METHOD OR GUIDELINE FOR CCFA/CCCF'S WORK.

Section 4. JECFA

24. JECFA is primarily responsible for performing the risk assessments upon which CCFA/CCCF and ultimately the CAC base their risk management decisions.

25. JECFA's scientific experts should be selected on the basis of their competence and independence, taking into account geographical representation to ensure that all regions are represented.

26. JECFA should strive to provide CCFA/CCCF with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCFA/CCCF's risk-management discussions. For contaminants and naturally occurring toxicants, JECFA should determine to the extent possible the risks associated with various levels of intake. Because of the lack of appropriate information, including data in humans, however, this may be possible in only a few cases for the foreseeable future. For additives, JECFA should continue to use its safety assessment process for establishing ADIs.

27. JECFA should strive to provide CCFA/CCCF with science-based quantitative risk assessments and safety assessments for food additives, contaminants, and naturally occurring toxicants in a transparent manner.

28. JECFA should provide CCFA/CCCF with information on the applicability and any constraints of the risk assessment to the general population to particular sub-populations and should as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g. children, women of child-bearing age, the elderly).

29. JECFA should also strive to provide CCFA with specifications of identity and purity essential to assessing risk associated with the use of additives.
30. JECFA should strive to base its risk assessments on global data, including data from developing countries. These data should include epidemiological surveillance data and exposure studies.
31. JECFA is responsible for evaluating exposure to additives, contaminants, and naturally occurring toxicants.
32. When evaluating intake of additives or contaminants and naturally occurring toxicants during its risk assessment, JECFA should take into account regional differences in food consumption patterns.
33. JECFA should provide to CCCF its scientific views on the validity and the distribution aspects of the available data regarding contaminants and naturally occurring toxicants in foods which have been used for exposure assessments, and should give details on the magnitude of the contribution to the exposure from specific foods as may be relevant for risk management actions or options of CCCF.
34. JECFA should communicate to CCFA/CCCF the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA should provide CCFA/CCCF with a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment.
35. JECFA should communicate to CCFA/CCCF the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.
36. JECFA's risk assessment output to CCFA/CCCF is limited to presenting its deliberations and the conclusions of its risk assessments and safety assessments in a complete and transparent manner. JECFA's communication of its risk assessments should not include the consequences of its analyses on trade or other non-public health consequence. Should JECFA include risk assessments of alternative risk management options, JECFA should ensure that these are consistent with the Working Principles for Risk Analysis for the Application in the Framework of the Codex Alimentarius and Risk Analysis Principles applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods.
37. When establishing the agenda for a JECFA meeting, the JECFA Secretariat work closely with CCFA/CCCF to ensure that CCFA/CCCF's risk management priorities are addressed in a timely manner. With respect to food additives, the JECFA Secretariat should normally give first priority to compounds that have been assigned a temporary ADI, or equivalent. Second priority should normally be given to food additives or groups of additives that have previously been evaluated and for which an ADI, or equivalent, has been estimated, and for which new information is available. Third priority should normally be given to food additives that have not been previously evaluated. With respect to contaminants and naturally occurring toxicants, the JECFA Secretariat should give priority to substances that present both a significant risk to public health and are a known or expected problem in international trade.
38. When establishing the agenda for a JECFA meeting, the JECFA Secretariat should give priority to substances that are known or expected problems in international trade or that present an emergency or imminent public health risk.

POLICY OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS FOR EXPOSURE ASSESSMENT OF CONTAMINANTS AND TOXINS IN FOODS OR FOOD GROUPS

Section 1. Introduction

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

Section 2. Estimation of Total Dietary Exposure to a Contaminant or Toxin from Foods/Food Groups

5. JECFA uses available data from member countries and from GEMS/Food Operating Program for analytical laboratories system on contaminant levels in foods and the amount of foods consumed to estimate total dietary exposure to a contaminant or toxin. This is expressed as a percentage of the tolerable intake (e.g. PTDI, PTWI, or other appropriate toxicological reference point). For a carcinogen with no clear threshold, JECFA uses available data on intake combined with data on carcinogenic potency to estimate potential population risks.
6. Median/mean contaminant levels in foods are determined from available analytical data submitted by countries and from other sources. These data are combined with information available for the GEMS/Food Consumption Cluster Diets to generate dietary exposure estimates for regions in the world. JECFA provides an estimate as to which of the GEMS/Food Consumption Cluster Diets are likely to approach or exceed the tolerable intake.

7. In some cases, available national contaminant and/or individual food consumption data may be used by JECFA to provide more accurate estimates of total dietary exposure, particularly for vulnerable groups such as children.

8. JECFA performs exposure assessments if requested by CCCF using the GEMS/Food Consumption Cluster Diets and, if needed, available national consumption data to estimate the impact on dietary exposure of proposed alternative maximum levels to inform CCCF about these risk management options.

Section 3. Identification of Foods/Food Groups that Contribute significantly to Total Dietary Exposure of the Contaminant or Toxin

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

10. The CCCF determines criteria for selecting foods/food groups that contribute significantly to total dietary exposure of a contaminant or toxin. These criteria are based upon the percentage of the tolerable intake (or similar health hazard endpoint) that is contributed by a given food/food group and the number of geographic regions (as defined by the GEMS/Food Consumption Cluster Diets) for which dietary exposures exceed that percentage.

11. The criteria are as follows:

- a) Foods or food groups for which exposure to the contaminant or toxin contributes approximately 10%²⁷ or more of the tolerable intake (or similar health hazard endpoint) in one of the GEMS/Food Consumption Cluster Diets;

or,

- b) Foods or food groups for which exposure to the contaminant or toxin contributes approximately 5% or more of the tolerable intake (or similar health hazard endpoint) in two or more of the GEMS/Food Consumption Cluster Diets;

or,

- c) Foods or food groups that may have a significant impact on exposure for specific groups of consumers, although exposure may not exceed 5% of the tolerable intake (or similar health hazard endpoint) in any of the GEMS/Food Consumption Cluster Diets. These would be considered on a case-by-case basis.

²⁷ Rounded to the nearest 1/10th of a percent.

Section 4. Generation of Distribution Curves for Concentrations of the Contaminant in Specific Foods/Food Groups (concurrent with Section 2, or subsequent Step)

12. If requested by CCCF, JECFA uses available analytical data on contaminant or toxin levels in foods/food groups identified as significant contributors to dietary exposure to generate distribution curves of contaminant concentrations in individual foods. CCCF will take this information into account when considering risk management options and, if appropriate, for proposing the lowest achievable levels for contaminants/toxins in food on a global basis.

13. Ideally, individual data from composite samples or aggregated analytical data would be used by JECFA to construct the distribution curves. When such data are not available, aggregated data would be used (for example mean and geometric standard deviation). However, methods to construct distribution curves using aggregated data would need to be validated by JECFA.

14. In presenting the distribution curves to CCCF, JECFA should, to the extent possible, provide a comprehensive overview of the ranges of contamination of foods (i.e., both the maximum and outlier values) and of the proportion of foods/food groups that contain contaminants/toxins at those levels.

Section 5. Assessment of the Impact of Agricultural and Production Practices on Contaminant Levels in Foods/Food Groups (concurrent with Section 2, or subsequent Step)

15. If requested by CCCF, JECFA assesses the potential impact of different agricultural and production practices on contaminant levels in foods to the extent that scientific data are available to support such assessments. CCCF takes this information into account when considering risk management options and for proposing Codes of Practice.

16. Taking this information into account, CCCF proposes risk management decisions. To refine them, CCCF may request JECFA to undertake a second assessment to consider specific exposure scenarios based on proposed risk management options. The methodology for assessing potential contaminant exposure in relation to proposed risk management options needs to be further developed by JECFA.

RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

1 - Purpose – Scope

1. The purpose of this document is to specify Risk Analysis Principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods.

2 - Parties involved

2. The *Working Principles for Risk Analysis for application in the framework of the Codex Alimentarius* has defined the responsibilities of the various parties involved. The responsibility for providing advice on risk management concerning residues of veterinary drugs lies with the Codex Alimentarius Commission and its subsidiary body, the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), while the responsibility for risk assessment lies primarily with the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

3. According to its mandate, the responsibilities of the CCRVDF regarding veterinary drug residues in food are:

- (a) to determine priorities for the consideration of residues of veterinary drugs in foods;
- (b) to recommend maximum residue limits (MRLs) for such veterinary drugs;
- (c) to develop codes of practice as may be required;
- (d) to consider methods of sampling and analysis for the determination of veterinary drug residues in foods.

4. The CCRVDF shall base its risk management recommendations to the Codex Alimentarius Commission on JECFA's risk assessments of veterinary drugs in relation to proposed MRLs.

5. The CCRVDF is primarily responsible for recommending risk management proposals for adoption by the Codex Alimentarius Commission.

6. JECFA is primarily responsible for providing independent scientific advice, the risk assessment, upon which the CCRVDF base their risk management decisions. It assists the CCRVDF by evaluating the available scientific data on the veterinary drug prioritised by the CCRVDF. JECFA also provides advice directly to FAO and WHO and to Member governments.

7. Scientific experts from JECFA are selected in a transparent manner by FAO and WHO under their rules for expert committees on the basis of the competence, expertise, experience in the evaluation of compounds used as veterinary drugs and their independence with regard to the interests involved, taking into account geographical representation where possible.

3 - Risk Management in CCRVDF

8. Risk management should follow a structured approach including:
- preliminary risk management activities;
 - evaluation of risk management options; and
 - monitoring and review of decisions taken.
9. The decisions should be based on risk assessment, and take into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for fair practices in food trade, in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*²⁸.

3.1 - Preliminary risk management activities

10. This first phase of risk management covers:
- Establishment of risk assessment policy for the conduct of the risk assessments;
 - Identification of a food safety problem;
 - Establishment of a preliminary risk profile;
 - Ranking of the hazard for risk assessment and risk management priority;
 - Commissioning of the risk assessment; and
 - Consideration of the result of the risk assessment.

3.1.1 - Risk Assessment Policy for the Conduct of the Risk Assessment

11. The responsibilities of the CCRVDF and JECFA and their interactions along with core principles and expectations of JECFA evaluations are provided in *Risk Assessment Policy for the Setting of MRLs in Food*, established by the Codex Alimentarius Commission.

3.1.2 - Establishment of Priority List

12. The CCRVDF identifies, with the assistance of Members, the veterinary drugs that may pose a consumer safety problem and/or have a potential adverse impact on international trade. The CCRVDF establishes a priority list for assessment by JECFA.
13. In order to appear on the priority list of veterinary drugs for the establishment of a MRL, the proposed veterinary drug shall meet some or all of the following criteria:
- A Member has proposed the compound for evaluation;
 - A Member has established good veterinary practices with regard to the compound;
 - The compound has the potential to cause public health and/or international trade problems;
 - It is available as a commercial product; and
 - There is a commitment that a dossier will be made available.

²⁸ Statements of Principle Concerning the Role of Science in the Codex Decision-making Process and the Extent to Which Other Factors are Taken into Account, Codex Procedural Manual Appendix

14. The CCRVDF takes into account the protection of confidential information in accordance with WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) - Section 7: Protection of Undisclosed Information - Article 39, and makes every effort to encourage the willingness of sponsors to provide data for JECFA assessment.

3.1.3 - Establishment of a Preliminary Risk Profile

15. Member(s) request(s) the inclusion of a veterinary drug on the priority list. The available information for evaluating the request shall be provided either directly by the Member(s) or by the sponsor. A preliminary risk profile shall be developed by the Member(s) making the request, using the template presented in the Annex.

16. The CCRVDF considers the preliminary risk profile and makes a decision on whether or not to include the veterinary drug in the priority list.

3.1.4 - Ranking of the Hazard for Risk Assessment and Risk Management Priority

17. The CCRVDF establishes an ad-hoc Working Group open to all its Members and observers, to make recommendations on the veterinary drugs to include into (or to remove from) the priority list of veterinary drugs for the JECFA assessment. The CCRVDF considers these recommendations before agreeing on the priority list, taking into account pending issues such as temporary Acceptable Daily Intakes (ADIs) and/or MRLs. In its report, the CCRVDF shall specify the reasons for its choice and the criteria used to establish the order of priority.

18. Prior to development of MRLs for new veterinary drugs not previously evaluated by JECFA, a proposal for this work shall be sent to the Codex Alimentarius Commission with a request for approval as new work in accordance with the *Procedures for the Elaboration of Codex Standards and Related Texts*.

3.1.5 - Commissioning of the Risk Assessment

19. After approval by the Codex Alimentarius Commission of the priority list of veterinary drugs as new work, the CCRVDF forwards it to JECFA with the qualitative preliminary risk profile as well as specific guidance on the CCRVDF risk assessment request. JECFA, WHO and FAO experts then proceed with the assessment of risks related to these veterinary drugs, based on the dossier provided and/or all other available scientific information.

3.1.6 - Consideration of the Result of the Risk Assessment

20. When the JECFA risk assessment is completed, a detailed report is prepared for the subsequent session of the CCRVDF for consideration. This report shall clearly indicate the choices made during the risk assessment with respect to scientific uncertainties and the level of confidence in the studies provided.

Section IV: Risk Analysis

21. When the data are insufficient, JECFA may recommend temporary MRL on the basis of a temporary ADI using additional safety considerations²⁹. If JECFA cannot propose an ADI and/or MRLs due to lack of data, its report should clearly indicate the gaps and a timeframe in which data should be submitted, in order to allow Members to make an appropriate risk management decision.

22. The JECFA assessment reports related to the concerned veterinary drugs should be made available in sufficient time prior to a CCRVDF meeting to allow for careful consideration by Members. If this is, in exceptional cases, not possible, a provisional report should be made available.

23. JECFA should, if necessary, propose different risk management options. In consequence, JECFA should present, in its report, different risk management options for the CCRVDF to consider. The reporting format should clearly distinguish between the risk assessment and the evaluation of the risk management options.

24. The CCRVDF may ask JECFA any additional explanation.

25. Reasons, discussions and conclusions (or the absence thereof) on risk assessment should be clearly documented, in JECFA reports, for each option reviewed. The risk management decision taken by the CCRVDF (or the absence thereof) should also be fully documented.

3.2 - Evaluation of Risk Management Options

26. The CCRVDF shall proceed with a critical evaluation of the JECFA proposals on MRLs and may consider other legitimate factors relevant for health protection and fair trade practices in the framework of the risk analysis. According to the 2nd statement of principle, the criteria for the consideration of other factors should be taken into account. These other legitimate factors are those agreed during the 12th session of the CCRVDF³⁰ and subsequent amendments made by this Committee.

27. The CCRVDF either recommends the MRLs as proposed by JECFA, modifies them in consideration of other legitimate factors, considers other measures or asks JECFA for reconsideration of the residue evaluation for the veterinary drug in question.

28. Particular attention should be given to availability of analytical methods used for residue detection.

3.3 - Monitoring and Review of the Decisions Taken

29. Members may ask for the review of decisions taken by the Codex Alimentarius Commission. To this end, veterinary drugs should be proposed for inclusion in the priority list. In particular, review of decisions may be necessary if they pose difficulties in the application of the *Guidelines for the Establishment of a Regulatory Programme for the Control of Veterinary Drug Residues in Foods* (CAC/GL 16-1993).

30. The CCRVDF may request JECFA to review any new scientific knowledge and other information relevant to risk assessment and concerning decisions already taken, including the established MRLs.

²⁹ Definition of "Codex maximum limit for residues of veterinary drugs", Codex Procedural Manual.

³⁰ ALINORM 01/31 paragraph 11.

31. The risk assessment policy for MRL shall be reconsidered based on new issues and experience with the risk analysis of veterinary drugs. To this end, interaction with JECFA is essential. A review may be undertaken of the veterinary drugs appearing on prior JECFA agendas for which no ADI or MRL has been recommended.

4 - Risk Communication in the Context of Risk Management

32. In accordance with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*, the CCRVDF, in cooperation with JECFA, shall ensure that the risk analysis process is fully transparent and thoroughly documented and that results are made available in a timely manner to Members. The CCRVDF recognises that communication between risk assessors and risk managers is critical to the success of risk analysis activities.

33. In order to ensure the transparency of the assessment process in JECFA, the CCRVDF provides comments on the guidelines related to assessment procedures being drafted or published by JECFA.

ANNEX

**TEMPLATE FOR INFORMATION NECESSARY FOR PRIORITIZATION BY
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**

Administrative information

1. Member(s) submitting the request for inclusion
2. Veterinary drug names
3. Trade names
4. Chemical names
5. Names and addresses of basic producers

Purpose, scope and rationale

6. Identification of the food safety issue (residue hazard)
7. Assessment against the criteria for the inclusion on the priority list

Risk profile elements

8. Justification for use
9. Veterinary use pattern
10. Commodities for which Codex MRLs are required

Risk assessment needs and questions for the risk assessors

11. Identify the feasibility that such an evaluation can be carried out in a reasonable framework
12. Specific request to risk assessors

Available information³¹

13. Countries where the veterinary drugs is registered
14. National/Regional MRLs or any other applicable tolerances
15. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available

Timetable

16. Date when data could be submitted to JECFA

³¹ When preparing a preliminary risk profile, Member(s) should take into account the updated data requirement, to enable evaluation of a veterinary drug for the establishment of an ADI and MRLs, published by JECFA.

RISK ASSESSMENT POLICY FOR THE SETTING OF MAXIMUM LIMITS FOR RESIDUES OF VETERINARY DRUGS IN FOODS

Role of JECFA

1. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an independent scientific expert body convened by both Directors-General of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on veterinary drug residues in food.
2. This annex applies to the work of JECFA in the context of Codex and in particular as it relates to advice requests from the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).
 - (a) JECFA provides CCRVDF with science-based risk assessments conducted in accordance with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* and incorporating the four steps of risk assessment. JECFA should continue to use its risk assessment process for establishing Acceptable Daily Intakes (ADIs) and proposing Maximum Residues Limits (MRLs).
 - (b) JECFA should take into account all available scientific data to establish its risk assessment. It should use available quantitative information to the greatest extent possible and also qualitative information.
 - (c) Constraints, uncertainties and assumptions that have an impact on the risk assessment need be clearly communicated by JECFA.
 - (d) JECFA should provide CCRVDF with information on the applicability, public health consequences and any constraints of the risk assessment to the general population and to particular sub-populations and, as far as possible, should identify potential risks to specific group of populations of potentially enhanced vulnerability (e.g. children).
 - (e) Risk assessment should be based on realistic exposure scenarios.
 - (f) When the veterinary drug is used both in veterinary medicine and as a pesticide, a harmonised approach between JECFA and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) should be followed.
 - (g) MRLs, that are compatible with the ADI, should be set for all species based on appropriate consumption figures. When requested by CCRVDF, extension of MRLs between species will be considered if appropriate data are available.

Data Protection

3. Considering the importance of intellectual property in the context of data submission for scientific evaluation, JECFA has established procedures to cover the confidentiality of certain data submitted. These procedures enable the sponsor to declare which data is to be considered as confidential. The procedure includes a formal consultation with the sponsor.

Expression of risk assessment results in terms of MRLs

4. MRLs have to be established for target animal tissues (e.g. muscle, fat, or fat and skin, kidney, liver), and specific food commodities (e.g. eggs, milk, honey) originating from the target animals species to which a veterinary drug can be administered according to good veterinary practice.
5. However, if residue levels in various target tissues are very different, JECFA is requested to consider MRLs for a minimum of two. In this case, the establishment of MRLs for muscle or fat is preferred to enable the control of the safety of carcasses moving in international trade.
6. When the calculation of MRLs to be compatible with the ADI may be associated with a lengthy withdrawal period, JECFA should clearly describe the situation in its report.

RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES

Scope

1. This document addresses the respective applications of risk analysis principles by the Codex Committee on Pesticide Residues (CCPR) as the risk management body and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) as the risk assessment body and facilitates the uniform application of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. This document should be read in conjunction with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

Roles CCPR and JMPR in Risk Analysis

Interaction between CCPR and JMPR

2. In addressing pesticide residue issues in Codex, providing advice on risk management is the responsibility of the Codex Alimentarius Commission (CAC) and CCPR while conducting risk assessment is the responsibility of JMPR.

3. CCPR and JMPR recognize that an adequate communication between risk assessors and risk managers is an essential requirement for successfully performing their risk analysis activities.

4. CCPR and JMPR should continue to develop procedures to enhance communication between the two bodies.

5. CCPR and JMPR should ensure that their respective contributions to the risk analysis process result in outputs that are scientifically based, fully transparent, thoroughly documented and available in a timely manner to members³².

6. JMPR, in consultation with CCPR, should continue to explore developing minimum data requirements necessary for JMPR to perform risk assessments.

7. These requirements should be used by CCPR as a fundamental criterion as described in the Annex in preparing its Priority List for JMPR. The JMPR Secretariat should consider whether these minimum data requirements have been met when preparing the provisional agenda for meetings of JMPR.

Role of CCPR

8. CCPR is primarily responsible for recommending risk management proposals for adoption by the CAC.

9. CCPR shall base its risk management recommendations, such as MRLs, to the CAC following JMPR's risk assessments of the respective pesticides, and considering, where appropriate, other legitimate factors such as relevant to the health protection of consumers and for the promotion of fair practices in food trade.

10. In cases where JMPR has performed a risk assessment and CCPR or the CAC determines that additional scientific guidance is necessary, CCPR or CAC may

³² Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant Production and Protection Paper, 170, 2002, ISBN 92-5-104759-6

Section IV: Risk Analysis

make a specific request to JMPR to provide further scientific guidance necessary for a risk management decision.

11. CCPR's risk management recommendations to the CAC shall take into account the relevant uncertainties as described by JMPR.

12. CCPR shall consider maximum residue limits (MRLs) only for those pesticides for which JMPR has completed a full safety evaluation.

13. CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns on a global scale when recommending MRLs in food. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by members.

14. When establishing its standards, CCPR shall clearly state when it applies any considerations based on other legitimate factors in addition to JMPR's risk assessment and recommended maximum residue levels and specify its reasons for doing so.

15. CCPR shall consider the following when preparing its priority list of compounds for JMPR evaluation:

- CCPR's Terms of Reference;
- JMPR's Terms of Reference;
- The Codex Alimentarius Commission's Strategic Plan;
- The Criteria for the Establishment of Work Priorities;
- The Criteria for Inclusion of Compounds on the Priority List;
- The Criteria for Selecting Food Commodities for which Codex MRLs or Extraneous Maximum Residue Limits (EMRLs) should be Established;
- The Criteria for Evaluation of New Chemicals;
- The Criteria for Prioritization Process of Compounds for Evaluation by JMPR
- A commitment to provide the necessary data for the evaluation in time.

16. When referring substances to JMPR, the CCPR shall provide background information and clearly specify the reasons for the request when chemicals are nominated for evaluation.

17. When referring substances to JMPR, the CCPR may also refer a range of risk management options, with a view toward obtaining JMPR's guidance on the attendant risks and the likely risk reductions associated with each option.

18. CCPR shall request JMPR to review any methods and guidelines being considered by CCPR for assessing maximum limits for pesticides.

Role of JMPR

19. The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) consists of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. It is an independent scientific expert body convened by both Directors General of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on pesticide residues.
20. This guidance document applies to the work of JMPR in the context of Codex and in particular as it relates to advice requests from CCPR.
21. JMPR is primarily responsible for performing the risk assessments upon which CCPR and ultimately the CAC base their risk management decisions. JMPR also proposes MRLs based on Good Agricultural Practices (GAPs)/registered uses or in specific cases, such as EMRLs, based on monitoring data.
22. JMPR provides CCPR with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCPR's risk-management discussions. JMPR should continue to use its risk assessment process for establishing Acceptable Daily Intakes (ADIs) and Acute Reference Doses (ARfDs) where appropriate.
23. JMPR should identify and communicate to CCPR in its assessments any information on the applicability and any constraints of the risk assessment to the general population and to particular sub-populations and will as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g. children).
24. JMPR is responsible for evaluating exposure to pesticides. JMPR should strive to base its exposure assessment and hence the dietary risk assessments on global data, including that from developing countries. In addition to GEMS/Food data, monitoring data and exposure studies may be used. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the available high percentile consumption data as provided by members.
25. JMPR should communicate to CCPR the magnitude and source of uncertainties in its risk assessments. When communicating this information, JMPR should provide CCPR a description of the methodology and procedures by which JMPR estimated any uncertainty in its risk assessment.
26. JMPR should communicate to CCPR the basis for all assumptions used in its risk assessments.

ANNEX: LIST OF RISK MANAGEMENT POLICIES USED BY CCPR

1. This part of the document addresses the risk management policy that is used by the Codex Committee on Pesticides Residues (CCPR) when discussing the risk assessments, the exposure to pesticides and the proposals for MRLs which are the outcomes of the Joint FAO/WHO Meeting on Pesticides Residues (JMPR).

ESTABLISHMENT OF MRLs/EMRLs

Procedure for Proposing Pesticides for Codex Priority Lists

2. CCPR has developed a policy document in relation to establishing a priority list of pesticides for evaluation or re-evaluation by JMPR³³.
3. Before a pesticide can be considered for the Priority List, it must:
 - be available for use as a commercial product; and
 - not have been already accepted for consideration.
4. To meet the criteria for inclusion in the priority list, the use of the pesticide 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.
5. When prioritising 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.
6. When prioritising 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;

³³ Criteria for Prioritization Process of Compounds for Evaluation by JMPR, Procedural Manual

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.
7. Once the JMPR has reviewed a chemical, three scenarios may occur:
- the data confirm the existing Codex MRL, it remains in place, or
 - a new MRL is recommended or an amendment of an existing MRL. The new or amended proposal enters at Step 3 of the Codex procedure. The existing MRL remains in place for no more than four years, or
 - insufficient data have been submitted to confirm or amend an existing Codex MRL. The Codex MRL is recommended for withdrawal. However, the manufacturer or countries may provide a commitment to the JMPR and CCPR to provide the necessary data for review within four years. The existing Codex MRL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted.

MRLs for Commodities of Animal Origin

8. Farm animal metabolism studies are required whenever a pesticide is applied directly to livestock, to animal premises or housing, or when significant residues remain in crops or commodities used in animal feed, in forage crops, or in plant parts that could be used in animal feeds. The results of farm animal feeding studies and residues in animal feed serve also as a primary source of information for estimating maximum residue levels in animal products.

9. If no adequate studies are available, no MRLs will be established for commodities of animal origin. MRLs for feeds (and the primary crops) should not be established in the absence of animal transfer data. Where the exposure of livestock to pesticides through feeds leads to residues at the limit of quantitation, MRLs at the LOQ must be established for animal commodities. MRLs should be established for all mammalian species where pesticides on feeds are concerned and for specific species (e.g. cattle, sheep) where direct treatments of pesticides are concerned.

10. Where the recommended maximum residue limits for animal commodities resulting from direct treatment of the animal, regardless of whether they are recommended by JMPR or JECFA, and from residues in animal feed do not agree, the higher recommendation will prevail.

MRLs for Processed or Ready-to-eat Foods or Feeds

11. CCPR agreed not to establish MRLs for processed foods and feeds unless separate higher MRLs are necessary for specific processed commodities.

MRLs for spices

12. CCPR agreed that MRLs for spices can be established on the basis of monitoring data in accordance with the guidelines established by JMPR.

MRLs for fat-soluble pesticides

13 If a pesticide is determined as “fat soluble” after consideration of the following factors, it is indicated with the text “The residues are fat soluble” in the residue definition:

- When available, it is the partitioning of the residue (as defined) in muscle versus fat in the metabolism studies and livestock feeding studies that determines the designation of a residue as being “fat soluble”.
- In the absence of useful information on the distribution of residues in muscle and fat, residues with $\log Pow > 3$ are likely to be “fat soluble”.

14. For fat soluble pesticides, two MRLs are recommended if data permit: one for whole milk and one for milk fat. For enforcement purposes, a comparison can be made either of the residue in milk fat with the MRL for milk fat or of the residue in whole milk with the MRL for milk.

Establishment of MRLs

15. The CCPR is entrusted with the elaboration of Maximum Residue Limits (MRLs) of pesticide residues in food and feed. The JMPR is using the WHO Guidelines for predicting dietary intake of pesticides residues (revised)(1997)³⁴. The JMPR is recommending MRLs establishing Supervised Trial Median Residues (STMRs) for new and periodic review compounds for dietary intake purposes. In cases the intake exceeds the Acceptable Daily Intake (ADI) in one or more of the regional diets, the JMPR, when recommending MRLs, flags this situation indicating the type of data which may be useful to further refine the dietary intake estimate.

16. When the ADI is exceeded in one or more regional diets, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level. If further refinement is not possible then MRLs are withdrawn until the remaining MRLs give no longer rise to intake concerns. This procedure should be reviewed at regular interval.

17. The JMPR is currently routinely establishing acute reference doses (ARfDs), where appropriate, and indicates cases where an ARfD is not necessary. The 1999 JMPR for the first time calculated the short-term dietary intake estimates following an approach using the International and National Estimates of Short-term Intake (IESTI, NESTI). The procedure allows for estimating the short-term risk for relevant subgroups of the population, like children. The JMPR flags cases when the IESTI for a given commodity exceeds the acute RfD.

18. When the ARfD is exceeded for a given commodity, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level.

19. When a Draft MRL has been returned to Step 6 three times, the CCPR should ask JMPR to examine residue data from other appropriate GAPs and to recommend MRLs which cause no dietary intake concerns if possible.

20. If further refinement is not possible then MRLs are withdrawn. More sophisticated methodologies such as probabilistic approaches are under investigation at the moment.

³⁴ Programme of Food Safety and Food Aid; WHO/FSF/FOS/97.7

21. The estimate of the short-term dietary intake requires substantial food consumption data that currently are only sparsely available. Governments are urged to generate relevant consumption data and to submit these data to the WHO.

Utilization of Steps 5/8 for elaboration of MRLs

22. Preconditions for utilization of Step 5/8 Procedure

- New MRL circulated at Step 3
- JMPR report available electronically by early February
- No intake concerns identified by JMPR

23. Steps 5/8 Procedure (Recommendation to omit Steps 6 and 7 and adopt the MRL at Step 8)

- If the preconditions listed above are met.
- If a delegation has a concern with advancing a given MRL, a concern form should be completed detailing the concern along with a description of the data that will be submitted to substantiate the concern preferably as comments at Step 3, or at the latest, one month after the CCPR session.
- If the JMPR Secretariat or the CCPR can address that concern at the upcoming CCPR session, and the JMPR position remains unchanged, the CCPR will decide if the MRL will be advanced to Step 5/8.
- If the concern cannot be addressed at the meeting, the MRL will be advanced to Step 5 at the CCPR session and the concern will be addressed by the JMPR as soon as possible but the rest of the MRLs should be advanced to Step 5/8.
- The result of the consideration of the concern by the JMPR will be considered at the next CCPR session. If the JMPR position remains unchanged, the CCPR will decide if the MRL will be advanced to Step 8.

Establishment of EMRLs

24. The Extraneous Maximum Residue Limit (EMRL) refers to a pesticide residue or a contaminant arising from environmental sources (including former agricultural uses) other than the use of the pesticide or contaminant substance directly or indirectly on the commodity. It is the maximum concentration of a pesticide residue that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food, agricultural commodity or animal feed.

25. Chemicals for which EMRLs are most likely to be needed are persistent in the environment for a relatively long period after uses have been discontinued and are expected to occur in foods or feeds at levels of sufficient concern to warrant monitoring.

26. All relevant and geographically representative monitoring data (including nil-residue results) are required to make reasonable estimates to cover international trade. JMPR has developed a standard format for reporting pesticide residues monitoring data³⁵.

27. The JMPR compares data distribution in terms of the likely percentages of violations that might occur if a given EMRL is proposed to the CCPR.

28. Because residues gradually decrease, CCPR evaluates every 5 years, if possible, the existing EMRLs, based on the reassessments of the JMPR.

29. The CCPR generally agreed at the 30th Session on the potential elements for inclusion in a set of criteria for estimation of EMRLs while it also agreed not to initiate a full exercise of criteria elaboration.

Periodic Review Procedure

30. The Committee agreed on the Periodic Review Procedure, which was endorsed by the CAC and attached to the list of MRLs prepared for each session of the CCPR. Those Codex MRLs confirmed by JMPR under the Periodic Review shall be distributed to members and interested organizations for comments.

Deleting Codex MRLs

31. Every year new compounds are introduced. These compounds are often new pesticides which are safer than existing ones. Old compounds are then no longer supported/produced by industry and existing Codex MRLs can be deleted.

32. If information is delivered between two sessions of CCPR, that a certain compound is no longer supported, this information will be shared during the first coming session ($t=0$). The proposal will be to delete the existing MRLs at the following session ($t=0+1$ year).

33. It may happen that compounds are no longer supported in Codex, but are supported in some selected countries. If there is no international trade in commodities where the active compounds may have been used, CCPR will not establish MRLs.

MRLs AND METHODS OF ANALYSIS

34. JMPR needs data and information for their evaluations. Among these are methods of analysis. Methods should include specialized methods used in supervised trials and enforcement methods.

35. If no methods of analysis are available for enforcing MRLs for a specific compound, no MRLs will be established by CCPR.

³⁵ Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant Production and Protection Paper, 170, 2002, ISBN 92-5-104759-6

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:

- (i) If the chemical has a reduced acute and/or chronic toxicity risk to humans compared with other chemicals in its classification (insecticide, fungicide, herbicide);
- (ii) The date when the chemical was nominated for evaluation;
- (iii) Commitment by the sponsor of the compound to provide supporting data for review with a firm date for data submission;
- (iv) The availability of regional/national reviews and risk assessments, and coordination with other regional/national lists; and
- (v) 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:

- (i) If the intake and/or toxicity profile indicate some level of public health concern;
- (ii) 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;
- (iii) The year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation – Not Yet Scheduled;
- (iv) The date that data will be submitted;
- (v) Whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;
- (vi) If there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently; and
- (vii) 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:

- (i) The date the request was received;
- (ii) Commitment by the sponsor to provide the required data for review with a firm date of submission;
- (iii) Whether the data is submitted under the 4-year rule for evaluations; and
- (iv) 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.
- (vii) A serious public health concern may emerge in relation to a particular pesticide for which MRLs exist. In such cases, government members should notify the WHO Joint Secretary of the JMPR promptly and provide appropriate data to the WHO Joint Secretary.

NUTRITIONAL RISK ANALYSIS PRINCIPLES AND GUIDELINES FOR APPLICATION TO THE WORK OF THE COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

1 – BACKGROUND

1. The *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (hereafter cited as “Working Principles”) has established general guidance on risk analysis to Codex Alimentarius. These Working Principles were adopted in 2003 and published in this Procedural Manual.
2. The objective of the Working Principles is “to provide guidance to the Codex Alimentarius Commission and the joint FAO/WHO expert bodies and consultations so that food safety and health aspects of Codex standards and related texts are based on risk analysis”. By its reference to health aspects in addition to food safety, the objective provides clearer direction for risk analysis to apply to nutritional matters that are within the mandate of the Codex Alimentarius Commission and its subsidiary bodies.
3. The Nutritional Risk Analysis Principles are established to guide the Codex Alimentarius Commission and its subsidiary bodies - primarily but not exclusively the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) - in applying nutritional risk analysis to their work. This guidance may be used for the work of other Committees since CCNFSDU is also mandated, in accordance with its 4th term of reference, “to consider, amend if necessary, and endorse provisions on nutritional aspects” of foods including those resulting from application of nutritional risk analysis that are developed by other Codex subsidiary bodies.

2 – INTRODUCTION

4. Codex nutritional risk analysis addresses nutrients³⁶ and related substances³⁷ and the risk to health from their inadequate and/or excessive intake. Nutritional risk analysis applies the same general approach as traditional food safety risk analysis to consideration of excessive intakes of nutrients and related substances. However, unlike many constituents of food that are the subject of traditional food safety risk analysis (such as food additives, chemical (pesticide and veterinary drug) residues, microbiological pathogens, contaminants and allergens) nutrients and related substances are biologically essential (in the case of essential nutrients) or in other ways potentially favourable to health.

³⁶ **Nutrient** is defined by Codex *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 09-1987) to mean: any substance normally consumed as a constituent of food:

- (a) which provides energy; or
- (b) which is needed for growth and development and maintenance of healthy life; or
- (c) a deficit of which will cause characteristic biochemical or physiological changes to occur.

Essential nutrient means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be synthesized in adequate amounts by the body.

³⁷ **A related substance** is a constituent of food (other than a nutrient) that has a favourable physiological effect.

Nutritional risk analysis therefore adds a new dimension to traditional risk analysis by also considering risks directly posed by inadequate intakes.

5. The *Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses* presented in this document (hereafter cited as “Nutritional Risk Analysis Principles”) are subsidiary to and should be read in conjunction with the Working Principles.
6. These Nutritional Risk Analysis Principles are framed within the three-component structure of the Working Principles, but with an added initial step to formally recognize Problem Formulation as an important preliminary risk management activity.

3 – SCOPE AND APPLICATION

7. Nutritional risk analysis considers the risk of adverse health effects from inadequate and/or excessive intakes of nutrients and related substances, and the predicted reduction in risk from proposed management strategies. In situations that address inadequate intakes, such a reduction in risk through addressing the inadequacy might be referred to as a nutritional benefit.
8. The food constituents of primary interest in nutritional risk analysis are inherent components of food and/or intentionally added to food and are identified as:
 - nutrients that may reduce the risk of inadequacy and those that may increase the risk of adverse health effects; and/or
 - related substances³⁷ that may increase the risk of adverse health effects at excessive intake and may also reduce the risk of other adverse health effects at lower intake.
9. When favourable effects of the nutrient or related substance of primary interest are being assessed, consideration should be given to whether the food matrix could increase the risk of an adverse health effect.
10. Where appropriate, the application of quantitative nutritional risk assessment may guide decision making on quantitative content provisions for nutrients and related substances in certain Codex texts.
11. Nutritional risk assessment should be as quantitative as possible, although a qualitative risk-based approach drawing on the principles of nutritional risk analysis could assist the development of Codex texts in such situations as:
 - formulating general principles related to nutritional composition (e.g. principles for the addition of nutrients to foods);
 - formulating general principles for assessing or managing risks related to foods for which a nutrition or health claim has been requested;

- managing risks by labelling advice in relation to consumption of foods of certain nutrient-related³⁸ composition, including foods for special dietary use; and
- advising on risk-risk analysis (e.g. risk associated with a significantly reduced or entirely avoided consumption of a nutritious, staple food in response to a dietary hazard such as a contaminant present in that food).

4 – DEFINITIONS

12. The *Definitions of Risk Analysis Terms Related to Food Safety* in this Procedural Manual provide suitable generic definitions of risk analysis, risk assessment, risk management, risk communication and risk assessment policy. When applied in a nutritional risk analysis context, these high-level risk analysis terms should be prefaced by 'nutritional' and their existing definitions appropriately adapted by replacement of relevant existing terms and definitions with those listed below.
13. However, other *Definitions of Risk Analysis Terms Related to Food Safety* have been modified to reference inadequate intake as a nutritional risk factor. Some new terms also have been defined to provide further clarity. The modified or newly developed subsidiary definitions are as follows:

Nutritional risk – A function of the probability of an adverse health effect associated with inadequate or excessive intake of a nutrient or related substance and the severity of that effect, consequential to a nutrient-related hazard(s) in food.

Adverse health effect³⁹ – A change in the morphology, physiology, growth, development, reproduction or life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences.

Nutrient-related³⁸ hazard – A nutrient or related substance in food that has the potential to cause an adverse health effect depending on inadequate or excessive level of intake.

Nutrient-related hazard identification – The identification of a nutrient-related hazard in a particular food or group of foods.

Nutrient-related hazard characterization – The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with a nutrient-related hazard.

Dose response assessment – The determination of the relationship between the magnitude of intake of (or exposure to) (i.e. dose) a nutrient or related substance and the severity and/or frequency of associated adverse health effects (i.e. response).

³⁸ For the purpose of these Nutritional Risk Analysis Principles, the descriptive term 'nutrient-related' refers to one or more nutrients and/or related substances, as the case may be.

³⁹ *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances*. Report of a joint FAO/WHO technical workshop 2005, WHO, 2006.

Upper level of intake³⁹ – the maximum level of habitual intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans.

Highest observed intake³⁹ – the highest level of intake observed or administered as reported within a stud(ies) of acceptable quality. It is derived only when no adverse health effects have been identified.

Intake (Exposure) assessment – The qualitative and/or quantitative evaluation of the likely intake of a nutrient or related substance from food as well as intake from other relevant sources such as food supplements.

Nutrient-related 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 nutrient-related hazard identification, nutrient-related hazard characterization and intake assessment.

Bioavailability⁴⁰ – The proportion of the ingested nutrient or related substance that is absorbed and utilised through normal metabolic pathways. Bioavailability is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, and food processing/preparation; and host-related intestinal and systemic factors.

Homeostatic mechanism³⁹ – A mechanism effected through a system of controls activated by negative feedback that allow the maintenance of normal body functions in the presence of a variable nutrition environment.

5 – PRINCIPLES FOR NUTRITIONAL RISK ANALYSIS

14. Nutritional risk analysis comprises three components: risk assessment, risk management and risk communication. Particular emphasis is given to an initial step of Problem Formulation as a key preliminary risk management activity.

PRELIMINARY NUTRITIONAL RISK MANAGEMENT ACTIVITIES

15. Preliminary nutritional risk management activities should have regard to the particular sections in the Working Principles titled General Aspects of Risk Analysis, and Risk Assessment Policy.

Nutritional Problem Formulation³⁹

16. Nutritional Problem Formulation is necessary to identify the purpose of a nutritional risk assessment and is a key component of preliminary nutritional risk management activity because it fosters interactions between risk managers and risk assessors to help ensure common understanding of the problem and the purpose of the risk assessment.
17. Such considerations should include whether a nutritional risk assessment is needed and if so:
 - the priority it should be accorded;

⁴⁰ Gibson R.S. The role of diet- and host-related factors in nutrient bioavailability and thus in nutrient-based dietary requirement estimates. Food and Nutrition Bulletin 2007;28 (suppl): S77-100.

Section IV: Risk Analysis

- who should conduct and be involved in the nutritional risk assessment, nutritional risk management and nutritional risk communication processes;
 - the need for development of nutritional risk assessment policy;
 - how the nutritional risk assessment will provide the information necessary to support the nutritional risk management decision;
 - whether data are available to embark on an evaluation of nutritional risks;
 - what level of resources are available; and
 - the timeline for completing the assessment.
18. Specific information to be gathered for nutritional problem formulation may include:
- a detailed inventory of prior knowledge;
 - identification of the (sub)populations to be the focus for the risk assessment, geographical areas or consumer settings to be covered;
 - relevant source(s) of intake; and
 - the health endpoints to be considered.

NUTRITIONAL RISK ASSESSMENT

19. The risk assessment section of the *Codex Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* is generally applicable to nutritional risk assessment. Additional nutritional risk assessment principles to consider within the Codex framework are identified below.

Nutrient-Related Hazard Identification and Hazard Characterization

20. These two steps are often globally relevant because they are based on available scientific and medical literature that contribute data from diverse population groups. This global relevance for characterization of hazard does not, however, preclude the possibility of a (sub)population-specific hazard.
21. Nutritional risk assessment should take into consideration the nutrient-related hazard(s) posed by both inadequate and excessive intakes. This may include consideration of hazard(s) posed by excessive intakes of accompanying risk-increasing nutrients in the food vehicle(s) under consideration.
22. Nutrient-related hazard identification and characterization should recognize current methodological differences in assessment of nutritional risk of inadequate and excessive intakes, and scientific advances in these methodologies.
23. Nutrient-related hazard characterization should take into account homeostatic mechanisms for essential nutrients, and limitations in the capacity for homeostatic adaptations. It may also take into account bioavailability including factors affecting the bioavailability of nutrients and related substances such as different chemical forms.
24. Nutrient reference standards that may be used to characterize nutrient-related hazard(s) related to adequacy include measures of average requirement. Some

globally applicable nutrient reference standards for average requirement have been published by FAO/WHO. Official regional and national nutrient reference standards are also available and have been periodically updated to reflect scientific advances. These are more likely to relate to nutrients than to related substances.

25. Nutrient reference standards that may be used to characterize nutrient-related hazard(s) related to excessive intakes include upper levels of intake. Some globally applicable reference standards of upper level of intake have been published by FAO/WHO. In addition, the establishment of international upper levels of intake and highest observed intake that build on recommendations³⁹ may be considered in the future. Some periodically-updated nutrient reference standards are available from regional and national authorities. For some related substances, such standards developed from a systematic review of the evidence are available only in the peer-reviewed scientific literature.
26. The assessment of inadequate and excessive levels of intake of particular nutrients and related substances should take into account the availability of all such scientifically determined reference sources, as appropriate. When using such reference standards for nutrient and related substances in nutritional risk assessment, the basis for their derivation should be explicitly described.

Nutrient-Related Intake Assessment and Risk Characterization

27. These two steps are generally specific to the (sub)population(s) under consideration for risk assessment. The populations relevant to Codex consideration are populations at large in Codex member countries or particular subpopulation groups in these countries defined according to physiological parameters such as age or state of health.
28. Nutrient-related intake assessment and risk characterization should be applied within a total diet context. Where feasible, it would typically involve the evaluation of the distribution of habitual total daily intakes for the target population(s). This approach recognizes that nutrient-related risks are often associated with total intakes from multiple dietary sources, including fortified foods, food supplements⁴¹, and in the case of certain minerals, water. It may also take into account the bioavailability and stability of nutrients and related substances in the foods consumed.

NUTRITIONAL RISK MANAGEMENT

29. The risk management section of the Codex *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* is generally applicable to nutritional risk management. Additional nutritional risk management principles to consider within the Codex framework are identified below.

⁴¹ Codex *Guidelines for Vitamin and Mineral Food Supplements* (CAC/GL 55 – 2005) define food supplements as sources in concentrated forms of those nutrients or related substances alone or in combinations, marketed in forms such as capsules, tablets, powders solution, etc., that are designed to be taken in measured small unit quantities but are not in a conventional food form and whose purpose is to supplement the intake of nutrients or related substances from the diet.

30. Nutritional risk management can be effected through quantitative measures or qualitative guidance elaborated in Codex texts. Such risk management could involve decisions about nutrient composition, consideration of the suitability of foods containing risk-increasing nutrients for certain purposes or (sub) populations, labelling advice intended to mitigate nutritional risks to public health, and formulation of relevant general principles.

Nutritional risk management decisions should take into account their impact on dietary patterns and consumer behaviour. Such information should be supported by relevant research.

31. Nutritional risk assessment policy should be articulated as appropriate for the selected risk assessor prior to the conduct of the nutritional risk assessment.

NUTRITIONAL RISK COMMUNICATION

32. The risk communication section of the *Codex Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* is generally applicable to nutritional risk communication.

6 – SELECTION OF RISK ASSESSOR BY CCNFSDU

33. Consistent with their important role in providing scientific advice to the Codex Alimentarius Commission and its subsidiary bodies, FAO and WHO are acknowledged as the primary source of nutritional risk assessment advice to Codex Alimentarius. This acknowledgement however, does not preclude the possible consideration of recommendations arising from other internationally recognised expert bodies, as approved by the Commission.
34. All requests for risk assessment advice should be accompanied by terms of reference and where appropriate risk assessment policy to provide guidance to the risk assessor. These parameters should be established by CCNFSDU.

SECTION V

CODEX INTERGOVERNMENTAL STRUCTURE AND SESSION HISTORY

- Table of Committees and Document References
- Terms of reference of committees and date and place of sessions.

OVERVIEW

Commission and Executive Committee			
Acronym	Name	Id	Document reference
CAC	Codex Alimentarius Commission	CX-701	Until 32 nd session: ALINORM From 33 rd Session: CX/CAC
CCEXEC	Executive Committee	CX-702	CX/EXEC

General Subject Committees				
Acronym	Codex Committee on	Id	Document reference	Host country
CCCF	Contaminants in Foods	CX-735	CX/CF	Netherlands
CCFA	Committee on Food Additives	CX-711	CX/FA	China
CCFH	Food Hygiene	CX-712	CX/FH	United States
CCFICS	Food Import and Export Certification and Inspection Systems	CX-733	CX/FICS	Australia
CCFL	Food Labelling	CX-714	CX/FL	Canada
CCGP	General Principles	CX-716	CX/GP	France
CCMAS	Methods of Analysis and Sampling	CX-715	CX/MAS	Hungary
CCNFSDU	Nutrition and Foods for Special Dietary Uses	CX-720	CX/NFSDU	Germany
CCPR	Pesticide Residues	CX-718	CX/PR	China
CCRVDF	Residues of Veterinary Drugs in Foods	CX-730	CX/RVDF	United States

Commodity Committees (active)				
Acronym	Codex Committee on	Id	Document reference	Host country
CCFO	Fats and Oils	CX-709	CX/FO	Malaysia
CCFFP	Fish and Fishery Products	CX-722	CX/FFP	Norway
CCFFV	Fresh Fruits and Vegetables	CX-731	CX/FFV	Mexico
CCMMP	Milk and Milk Products	CX-703	CX/MMP	New Zealand
CCPFV	Processed Fruits and Vegetables	CX-713	CX/PFV	United States

Commodity Committees (adjourned sine die)				
Acronym	Codex Committee on	Id	Document reference	Host country
CCCPC	Cocoa Products and Chocolate	CX-708	CX/CPC	Switzerland
CCCPL	Cereals, Pulses and Legumes	CX-729	CX/CPL	United States
CCMH	Meat Hygiene	CX-723	CX/MH	New Zealand
CCNMW	Natural Mineral Waters	CX-719	CX/NMW	Switzerland
CCS	Sugars	CX-710	CX/S	
CCVP	Vegetable Proteins	CX-728	CX/VP	Canada

Commodity Committees (abolished)			
Acronym	Codex Committee on	Id	Document reference
CCIE	Edible Ices	CX-724	CX/IE
CCM	Meat	CX-717	CX/M
CCPMPP	Processed Meat and Poultry Products	CX-721	CX/PMPP
CCSB	Soups and Broths	CX-726	CX/SB

<i>ad hoc</i> Intergovernmental Task Forces (active)				
Acronym	<i>ad hoc</i> Codex Intergovernmental Task Force on	Id	Document reference	Host country
TFAMR	Antimicrobial Resistance	CX-804	CX/AMR	Republic of Korea

<i>ad hoc</i> Codex Intergovernmental Task Forces (dissolved)				
Acronym	<i>ad hoc</i> Codex Intergovernmental Task Force on	Id	Document reference	Host country
TFAF	Animal Feeding	CX-803	CX/AF	Denmark
TFFBT	Foods Derived from Biotechnology	CX-802	CX/GBT	Japan
TFFJ	Fruit and Vegetable Juices	CX-801	CX/FJ	Brazil
TFPHQFF	The Processing and Handling of Quick Frozen Foods	CX-805	CX/PHQFF	Thailand

FAO/WHO Coordinating Committees				
Acronym	FAO/WHO Coordinating Committee for	Id	Document reference	Present coordinator
CCAFRICA	Africa	CX-707	CX/AFRICA	Ghana
CCASIA	Asia	CX-727	CX/ASIA	Indonesia
CCEURO	Europe	CX-706	CX/EURO	Poland
CCLAC	Latin America and the Caribbean	CX-725	CX/LAC	Mexico
CCNEA	The Near East	CX-734	CX/NEA	Tunisia
CCNASWP	North America and the South West Pacific	CX-732	CX/NASWP	Tonga

Committee established under Rule XI.1(a) (renamed and re-established)			
Acronym	Name	Id	Document reference
CGECPMMP	Joint FAO/WHO Committee of Government Experts on the Code of Principles concerning Milk and Milk Products	CX-703	CX/CPMMP

Joint Meetings with other Organizations (abolished)			
Acronym	Name	Id	Document reference
CXTO	Joint Codex/IOOC Meeting on the Standardization of Table Olives		CX/TO
GEFJ	Joint UNECE/Codex Alimentarius Groups of Experts on Standardization of Fruit Juices	CX-704	CX/FJ
GEQFF	Joint UNECE/Codex Alimentarius Groups of Experts on Standardization Quick Frozen Foods	CX-705	CX/QFF

COMMISSION AND EXECUTIVE COMMITTEE

CAC	Codex Alimentarius Commission			
Sessions	1	Rome	25 June - 3 July	1963
	2	Geneva	28 September - 7 October	1964
	3	Rome	19-28 October	1965
	4	Rome	7-14 November	1966
	5	Rome	20 February - 1 March	1968
	6	Geneva	4-14 March	1969
	7	Rome	7-17 April	1970
	8	Geneva	30 June - 9 July	1971
	9	Rome	6-17 November	1972
	10	Rome	1-11 July	1974
	11	Rome	29 March - 9 April	1976
	12	Rome	17-28 April	1978
	13	Rome	3-14 December	1979
	14	Geneva	29 June - 10 July	1981
	15	Rome	4-15 July	1983
	16	Geneva	1-12 July	1985
	17	Rome	29 June - 10 July	1987
	18	Geneva	3-12 July	1989
	19	Rome	1-10 July	1991
	20	Geneva	28 June - 7 July	1993
	21	Rome	3-8 July	1995
	22	Geneva	23-28 June	1997
	23	Rome	28 June - 3 July	1999
	24	Geneva	2-7 July	2001
	25	Geneva	13-15 February	2003extraordinary
	26	Rome	30 June – 7 July	2003
	27	Geneva	28 June - 3 July	2004
	28	Rome	4-9 July	2005
	29	Geneva	3-7 July	2006
	30	Rome	2-7 July	2007
	31	Geneva	30 June – 4 July	2008
	32	Rome	29 June - 4 July	2009

CCEXEC	Executive Committee of the Codex Alimentarius Commission			
Sessions	1	Rome	3 July	1963
	2	Washington D.C.	25-26 May	1964
	3	Geneva	25-26 September	1964
	4	Geneva	7 October	1964
	5	Rome	3-4 June	1965
	6	Rome	18 October	1965
	7	Rome	28 October	1965
	8	Rome	14-16 June	1966
	9	Rome	4 November	1966
	10	Rome	16-18 May	1967
	11	Rome	19 February	1968
	12	Rome	5-7 June	1968
	13	Geneva	3 March	1969
	14	Rome	17-19 September	1969

CCEXEC (cont'd)	15	Rome	3 April	1970
	16	Geneva	9-11 February	1971
	17	Geneva	25 June	1971
	18	Rome	15-18 May	1972
	19	Geneva	3-5 July	1973
	20	Rome	28 June	1974
	21	Geneva	17-19 June	1975
	22	Rome	23-24 March	1976
	23	Geneva	12-15 July	1977
	24	Rome	13-14 April	1978
	25	Geneva	10-13 July	1979
	26	Rome	26-27 November	1979
	27	Geneva	13-17 October	1980
	28	Geneva	25-26 June	1981
	29	Geneva	12-16 July	1982
	30	Rome	30 June – 1 July	1983
	31	Geneva	25-29 June	1984
	32	Geneva	27-28 June	1985
	33	Rome	30 June – 4 July	1986
	34	Rome	25-26 June	1987
	35	Geneva	4-8 July	1988
	36	Geneva	29-30 June	1989
	37	Rome	3-6 July	1990
	38	Rome	27-28 June	1991
	39	Geneva	30 June – 3 July	1992
	40	Geneva	24-25 June	1993
	41	Rome	28-30 June	1994
	42	Rome	28-30 June	1995
	43	Geneva	4-7 June	1996
	44	Geneva	19-20 June	1997
	45	Rome	3-5 June	1998
	46	Rome	24-25 June	1999
	47	Geneva	28-30 June	2000
	48	Geneva	28-29 June	2001
	49	Geneva	26-27 September	2001extraordinary
	50	Rome	26-28 June	2002
	51	Geneva	10-11 February	2003extraordinary
	52	Rome	26-27 June	2003
	53	Geneva	4-6 February	2004
	54	Geneva	24-26 June	2004
	55	Rome	9-11 February	2005
	56	Rome	30 June – 2 July	2005
	57	Geneva	6-9 December	2005
	58	Geneva	28 June – 1 July	2006
	59	Rome	26-29 June	2007
	60	Rome	4-7 December	2008
	61	Geneva	24-27 June	2008
	62	Rome	23-26 June	2009

GENERAL SUBJECT COMMITTEES

CCCF	Codex Committee on Contaminants in Foods		
Host country:	Netherlands		
Terms of reference	<p>(a) to establish or endorse permitted maximum levels, and where necessary revise existing guidelines levels, for contaminants and naturally occurring toxicants in food and feed;</p> <p>(b) to prepare priority lists of contaminants and naturally occurring toxicants for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives;</p> <p>(c) to consider and elaborate methods of analysis and sampling for the determination of contaminants and naturally occurring toxicants in food and feed;</p> <p>(d) to consider and elaborate standards or codes of practice for related subjects; and</p> <p>(e) to consider other matters assigned to it by the Commission in relation to contaminants and naturally occurring toxicants in food and feed.</p>		
Sessions	1	Beijing, China	16-20 April 2007
	2	The Hague	31 March – 4 April 2008
	3	Rotterdam	23-27 March 2009

CCFA	Codex Committee on Food Additives		
Host country	China from 39 th session Netherlands from session 1 to 38		
Terms of reference	<p>(a) to establish or endorse acceptable maximum levels for individual food additives;</p> <p>(b) to prepare priority lists of food additives for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives;</p> <p>(c) to assign functional classes to individual food additives;</p> <p>(d) to recommend specifications of identity and purity for food additives for adoption by the Commission;</p> <p>(e) to consider methods of analysis for the determination of additives in food; and</p> <p>(f) to consider and elaborate standards or codes for related subjects such as the labelling of food additives when sold as such.</p>		
Notes	Renamed as Codex Committee on Food Additives and Contaminants by the 17 th Session of the Commission (1987); renamed again by the 29 th Session of the Commission (2006) as Codex Committee on Food Additives, due to the creation of a Committee on Contaminants in Foods (CX-735).		
Sessions	1	The Hague	19-22 May 1964
	2	The Hague	10-14 May 1965
	3	The Hague	9-13 May 1966

CCFA (cont'd)	4	The Hague	11-15 September	1967
	5	Arnhem	18-22 March	1968
	6	Arnhem	15-22 October	1969
	7	The Hague	12-16 October	1970
	8	Wageningen	29 May – 2 June	1972
	9	Wageningen	10-14 December	1973
	10	The Hague	2-7 June	1975
	11	The Hague	31 May – 6 June	1977
	12	The Hague	10-16 October	1978
	13	The Hague	11-17 September	1979
	14	The Hague	25 November – 1 December	1980
	15	The Hague	16-22 March	1982
	16	The Hague	22-28 March	1983
	17	The Hague	10-16 April	1984
	18	The Hague	5-11 November	1985
	19	The Hague	17-23 March	1987
	20	The Hague	7-12 March	1988
	21	The Hague	13-18 March	1989
	22	The Hague	19-24 March	1990
	23	The Hague	4-9 March	1991
	24	The Hague	23-28 March	1992
	25	The Hague	22-26 March	1993
	26	The Hague	7-11 March	1994
	27	The Hague	20-24 March	1995
	28	Manila, Philippines	18-22 March	1996
	29	The Hague	17-21 March	1997
	30	The Hague	9-13 March	1998
	31	The Hague	22-26 March	1999
	32	Beijing, China	20-24 March	2000
	33	The Hague	12-16 March	2001
	34	Rotterdam	11-15 March	2002
	35	Arusha, Tanzania	17-21 March	2003
	36	Rotterdam	22-26 March	2004
	37	The Hague	25-29 April	2005
	38	The Hague	24-28 April	2006
	39	Beijing, China	24-28 April	2007
	40	Beijing, China	21-25 April	2008
	41	Shanghai, China	16-20 March	2009

CCFH	Codex Committee on Food Hygiene
Host country	United States
Terms of reference	<p>(a) to draft basic provisions on food hygiene applicable to all food;</p> <p>(b) to consider, amend if necessary and endorse provisions on hygiene prepared by Codex commodity committees and contained in Codex commodity standards, and</p> <p>(c) to consider, amend if necessary, and endorse provisions on hygiene prepared by Codex commodity committees and contained in Codex codes of practice unless, in specific cases, the Commission has decided otherwise, or</p> <p>(d) to draft provisions on hygiene applicable to specific food items or food groups, whether coming within the terms of reference of a Codex commodity committee or not;</p> <p>(e) to consider specific hygiene problems assigned to it by the Commission,</p>

Section V: Structure and sessions

CCFH (cont'd)	(f) to suggest and prioritize areas where there is a need for microbiological risk assessment at the international level and to develop questions to be addressed by the risk assessors;		
	(g) to consider microbiological risk management matters in relation to food hygiene, including food irradiation, and in relation to the risk assessment of FAO and WHO. *The term "hygiene" includes, where necessary, microbiological specifications for food and associated methodology.		
Sessions	1	Washington D.C.	27-28 May 1964
	2	Rome	14-16 June 1965
	3	Rome	31 May – 3 June 1966
	4	Washington D.C.	12-16 June 1967
	5	Washington D.C.	6-10 May 1968
	6	Washington D.C.	5-9 May 1969
	7	Washington D.C.	25-29 May 1970
	8	Washington D.C.	14-18 June 1971
	9	Washington D.C.	19-23 June 1972
	10	Washington D.C.	14-18 May 1973
	11	Washington D.C.	10-14 June 1974
	12	Washington D.C.	12-16 May 1975
	13	Rome	10-14 May 1976
	14	Washington D.C.	29 August – 2 September 1977
	15	Washington D.C.	18-22 September 1978
	16	Washington D.C.	23-27 July 1979
	17	Washington D.C.	17-21 November 1980
	18	Washington D.C.	22-26 February 1982
	19	Washington D.C.	26-30 September 1983
	20	Washington D.C.	1-5 October 1984
	21	Washington D.C.	23-27 September 1985
	22	Washington D.C.	20-24 October 1986
	23	Washington D.C.	21-25 March 1988
	24	Washington D.C.	16-20 October 1989
	25	Washington D.C.	28 October – 1 November 1991
	26	Washington D.C.	1-5-March 1993
	27	Washington D.C.	17-21 October 1994
	28	Washington D.C.	27 November – 1 December 1995
	29	Washington D.C.	21-25 October 1996
	30	Washington D.C.	20-24 October 1997
	31	Orlando, Florida	26-30 October 1998
	32	Washington D.C.	29 November – 4 December 1999
	33	Washington D.C.	23-28 October 2000
	34	Bangkok, Thailand	8-13 October 2001
	35	Orlando, Florida	27 January – 1 February 2003
	36	Washington D.C.	29 March – 3 April 2004
	37	Buenos Aires, Argentina	14-19 March 2005
	38	Houston	4-9 December 2006
	39	New Delhi, India	30 October – 4 November 2007
	40	Guatemala City, Guatemala	1-5 December 2008

CCFICS	Codex Committee on Food Import and Export Certification and Inspection Systems		
Host country	Australia		
Terms of reference	<p>(a) to develop principles and guidelines for food import and export inspection and certification systems with a view to harmonising methods and procedures which protect the health of consumers, ensure fair trading practices and facilitate international trade in foodstuffs;</p> <p>(b) to develop principles and guidelines for the application of measures by the competent authorities of exporting and importing countries to provide assurance where necessary that foodstuffs comply with requirements, especially statutory health requirements;</p> <p>(c) to develop guidelines for the utilisation, as and when appropriate, of quality assurance systems* to ensure that foodstuffs conform with requirements and to promote the recognition of these systems in facilitating trade in food products under bilateral/multilateral arrangements by countries;</p> <p>(d) to develop guidelines and criteria with respect to format, declarations and language of such official certificates as countries may require with a view towards international harmonization;</p> <p>(e) to make recommendations for information exchange in relation to food import/export control;</p> <p>(f) to consult as necessary with other international groups working on matters related to food inspection and certification systems;</p> <p>(g) to consider other matters assigned to it by the Commission in relation to food inspection and certification systems.</p> <p>*Quality assurance means all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality (ISO-8402 Quality - Vocabulary)</p>		
Sessions	1	Canberra	21-25 September 1992
	2	Canberra	29 November – 3 December 1993
	3	Canberra	27 February – 3 March 1995
	4	Sydney	19-23 February 1996
	5	Sydney	17-21 February 1997
	6	Melbourne	23-27 February 1998
	7	Melbourne	22-26 February 1999
	8	Adelaide	21-25 February 2000
	9	Perth	11-15 December 2000
	10	Brisbane	25 February – 1 March 2002
	11	Adelaide	2-6 December 2002
	12	Brisbane	1-5 December 2003
	13	Melbourne	6-10 December 2004

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	14	Melbourne	28 November – 2 December	2005
	15	Mar del Plata, Argentina	6-10 November	2006
	16	Surfers Paradise, Queensland	26-30 November	2007
	17	Cebu, Philippines	24-28 November	2008

CCFL	Codex Committee on Food Labelling			
Host country	Canada			
Terms of reference	(a) to draft provisions on labelling applicable to all foods; (b) to consider, amend if necessary, and endorse draft specific provisions on labelling prepared by the Codex Committees drafting standards, codes of practice and guidelines; (c) to study specific labelling problems assigned to it by the Commission; (d) to study problems associated with the advertisement of food with particular reference to claims and misleading descriptions.			
	1	Ottawa	21-25 June	1965
	2	Ottawa	25-29 July	1966
	3	Ottawa	26-30 June	1967
	4	Ottawa	23-28 September	1968
	5	Rome	6 April	1970
	6	Geneva	28-29 June	1971
	7	Ottawa	5-10 June	1972
	8	Ottawa	28 May – 1 June	1973
	9	Rome	26-27 June	1974
	10	Ottawa	26-30 May	1975
	11	Rome	25-26 March	1976
	12	Ottawa	16-20 May	1977
	13	Ottawa	16-20 July	1979
	14	Rome	28-30 November	1979
	15	Ottawa	10-14 November	1980
	16	Ottawa	17-21 May	1982
	17	Ottawa	12-21 October	1983
	18	Ottawa	11-18 March	1985
	19	Ottawa	9-13 March	1987
	20	Ottawa	3-7 April	1989
	21	Ottawa	11-15 March	1991
	22	Ottawa	26-30 April	1993
	23	Ottawa	24-28 October	1994
	24	Ottawa	14-17 May	1996
	25	Ottawa	15-18 April	1997
	26	Ottawa	26-29 May	1998
	27	Ottawa	27-30 April	1999
	28	Ottawa	5-9 May	2000
	29	Ottawa	1-4 May	2001
	30	Halifax	6-10 May	2002
	31	Ottawa	28 April – 2 May	2003
	32	Montréal	10-14 May	2004
	33	Kota Kinabalu, Malaysia	9-13 May	2005
	34	Ottawa	1-5 May	2006
	35	Ottawa	30 April – 4 May	2007
	36	Ottawa	28 April – 2 May	2008
	37	Calgary	4-8 May	2009

CCGP	Codex Committee on General Principles			
Host country	France			
Terms of reference	To deal with such procedural and general matters as are referred to it by the Codex Alimentarius Commission. Such matters have included the establishment of the General Principles which define the purpose and scope of the Codex Alimentarius, the nature of Codex standards and the forms of acceptance by countries of Codex standards; the development of Guidelines for Codex Committees; the development of a mechanism for examining any economic impact statements submitted by governments concerning possible implications for their economies of some of the individual standards or some of the provisions thereof; the establishment of a Code of Ethics for the International Trade in Food.			
Sessions	1	Paris	4-8 October	1965
	2	Paris	16-19 October	1967
	3	Paris	9-13 December	1968
	4	Paris	4-8 March	1974
	5	Paris	19-23 January	1976
	6	Paris	15-19 October	1979
	7	Paris	6-10 April	1981
	8	Paris	24-28 November	1986
	9	Paris	24-28 April	1989
	10	Paris	7-11 September	1992
	11	Paris	25-29 April	1994
	12	Paris	25-28 November	1996
	13	Paris	7-11 September	1998
	14	Paris	19-23 April	1999
	15	Paris	10-14 April	2000
	16	Paris	23-27 April	2001
	17	Paris	15-19 April	2002
	18	Paris	7-11 April	2003
	19	Paris	17-21 November	2003 ^{extraordinary}
	20	Paris	3-7 May	2004
	21	Paris	8-12 November	2004 ^{extraordinary}
	22	Paris	11-15 April	2005
	23	Paris	10-14 April	2006
	24	Paris	2-6 April	2007
	25	Paris	30 March - 3 April	2009

CCMAS	Codex Committee on Methods of Analysis and Sampling			
Host country	Hungary			
Terms of reference	<p>(a) to define the criteria appropriate to Codex Methods of Analysis and Sampling;</p> <p>(b) to serve as a coordinating body for Codex with other international groups working in methods of analysis and sampling and quality assurance systems for laboratories;</p>			

CCMAS (cont'd)	<p>(c) to specify, on the basis of final recommendations submitted to it by the other bodies referred to in (b) above, Reference Methods of Analysis and Sampling appropriate to Codex Standards which are generally applicable to a number of foods;</p> <p>(d) to consider, amend, if necessary, and endorse, as appropriate, methods of analysis and sampling proposed by Codex (Commodity) Committees, except that methods of analysis and sampling for residues of pesticides or veterinary drugs in food, the assessment of micro biological quality and safety in food, and the assessment of specifications for food additives, do not fall within the terms of reference of this Committee;</p> <p>(e) to elaborate sampling plans and procedures, as may be required;</p> <p>(f) to consider specific sampling and analysis problems submitted to it by the Commission or any of its Committees;</p> <p>(g) to define procedures, protocols, guidelines or related texts for the assessment of food laboratory proficiency, as well as quality assurance systems for laboratories.</p>																																																																																																																										
Sessions	<table border="1"> <tr><td>1</td><td>Berlin</td><td>23-24 September</td><td>1965</td></tr> <tr><td>2</td><td>Berlin</td><td>20-23 September</td><td>1966</td></tr> <tr><td>3</td><td>Berlin</td><td>24-27 October</td><td>1967</td></tr> <tr><td>4</td><td>Berlin</td><td>11-15 November</td><td>1968</td></tr> <tr><td>5</td><td>Cologne</td><td>1-6 December</td><td>1969</td></tr> <tr><td>6</td><td>Bonn Bad Godesberg</td><td>24-28 January</td><td>1971</td></tr> <tr><td>7</td><td>Budapest</td><td>12-18 September</td><td>1972</td></tr> <tr><td>8</td><td>Budapest</td><td>3-7 September</td><td>1973</td></tr> <tr><td>9</td><td>Budapest</td><td>27-31 October</td><td>1975</td></tr> <tr><td>10</td><td>Budapest</td><td>24-28 October</td><td>1977</td></tr> <tr><td>11</td><td>Budapest</td><td>2-6 July</td><td>1979</td></tr> <tr><td>12</td><td>Budapest</td><td>11-15 May</td><td>1981</td></tr> <tr><td>13</td><td>Budapest</td><td>29 November - 3 December</td><td>1982</td></tr> <tr><td>14</td><td>Budapest</td><td>26-30 November</td><td>1984</td></tr> <tr><td>15</td><td>Budapest</td><td>10-14 November</td><td>1986</td></tr> <tr><td>16</td><td>Budapest</td><td>14-19 November</td><td>1988</td></tr> <tr><td>17</td><td>Budapest</td><td>8-12 April</td><td>1991</td></tr> <tr><td>18</td><td>Budapest</td><td>9-13 November</td><td>1992</td></tr> <tr><td>19</td><td>Budapest</td><td>21-25 March</td><td>1994</td></tr> <tr><td>20</td><td>Budapest</td><td>2-6 October</td><td>1995</td></tr> <tr><td>21</td><td>Budapest</td><td>10-14 March</td><td>1997</td></tr> <tr><td>22</td><td>Budapest</td><td>23-27 November</td><td>1998</td></tr> <tr><td>23</td><td>Budapest</td><td>26 February – 2 March</td><td>2001</td></tr> <tr><td>24</td><td>Budapest</td><td>18-22 November</td><td>2002</td></tr> <tr><td>25</td><td>Budapest</td><td>8-12 March</td><td>2004</td></tr> <tr><td>26</td><td>Budapest</td><td>4-8 April</td><td>2005</td></tr> <tr><td>27</td><td>Budapest</td><td>15-19 May</td><td>2006</td></tr> <tr><td>28</td><td>Budapest</td><td>5-9 March</td><td>2007</td></tr> <tr><td>29</td><td>Budapest</td><td>10-14 March</td><td>2008</td></tr> <tr><td>30</td><td>Balatonalmadi</td><td>9-13 March</td><td>2009</td></tr> </table>			1	Berlin	23-24 September	1965	2	Berlin	20-23 September	1966	3	Berlin	24-27 October	1967	4	Berlin	11-15 November	1968	5	Cologne	1-6 December	1969	6	Bonn Bad Godesberg	24-28 January	1971	7	Budapest	12-18 September	1972	8	Budapest	3-7 September	1973	9	Budapest	27-31 October	1975	10	Budapest	24-28 October	1977	11	Budapest	2-6 July	1979	12	Budapest	11-15 May	1981	13	Budapest	29 November - 3 December	1982	14	Budapest	26-30 November	1984	15	Budapest	10-14 November	1986	16	Budapest	14-19 November	1988	17	Budapest	8-12 April	1991	18	Budapest	9-13 November	1992	19	Budapest	21-25 March	1994	20	Budapest	2-6 October	1995	21	Budapest	10-14 March	1997	22	Budapest	23-27 November	1998	23	Budapest	26 February – 2 March	2001	24	Budapest	18-22 November	2002	25	Budapest	8-12 March	2004	26	Budapest	4-8 April	2005	27	Budapest	15-19 May	2006	28	Budapest	5-9 March	2007	29	Budapest	10-14 March	2008	30	Balatonalmadi	9-13 March	2009
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27	Budapest	15-19 May	2006																																																																																																																								
28	Budapest	5-9 March	2007																																																																																																																								
29	Budapest	10-14 March	2008																																																																																																																								
30	Balatonalmadi	9-13 March	2009																																																																																																																								

CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses		
Host country	Germany		
Terms of reference	<p>(a) to study specific nutritional problems assigned to it by the Commission and advise the Commission on general nutrition issues;</p> <p>(b) to draft general provisions, as appropriate, concerning the nutritional aspects of all foods;</p> <p>(c) to develop standards, guidelines or related texts for foods for special dietary uses, in cooperation with other committees where necessary;</p> <p>(d) to consider, amend if necessary, and endorse provisions on nutritional aspects proposed for inclusion Codex standards, guidelines and related texts.</p>		
Sessions	1	Freiburg in Breisgau	2-5 May 1966
	2	Freiburg in Breisgau	6-10 November 1967
	3	Cologne	14-18 October 1968
	4	Cologne	3-7 November 1969
	5	Bonn	30 November – 4 December 1970
	6	Bonn	6-10 December 1971
	7	Cologne	10-14 October 1972
	8	Bonn Bad Godesberg	9-14 September 1974
	9	Bonn	22-26 September 1975
	10	Bonn	28 February - 4 March 1977
	11	Bonn Bad Godesberg	23-27 October 1978
	12	Bonn Bad Godesberg	29 September – 3 October 1980
	13	Bonn Bad Godesberg	20-24 September 1982
	14	Bonn Bad Godesberg	24 January – 1 February 1985
	15	Bonn Bad Godesberg	12-16 January 1987
	16	Bonn Bad Godesberg	29 September – 7 October 1988
	17	Bonn Bad Godesberg	18-22 February 1991
	18	Bonn Bad Godesberg	28 September – 2 October 1992
	19	Bonn Bad Godesberg	27-31 March 1995
	20	Bonn Bad Godesberg	7-11 October 1996
	21	Berlin	21-25 September 1998
	22	Berlin	19-23 June 2000
	23	Berlin	26-30 November 2001
	24	Berlin	4-8 November 2002
	25	Bonn	3-7 November 2003
	26	Bonn	1-5 November 2004
	27	Bonn	21-25 November 2005
	28	Chiang Mai, Thailand	30 October – 3 November 2006
	29	Bad Neuenahr-Ahrweiler	12-16 November 2007
	30	Cape Town, South Africa	3 – 7 November 2008
	31	Düsseldorf	2 – 6 November 2009

CCPR	Codex Committee on Pesticide Residues		
Host country	China from 39 th session Netherlands from session 1 to 38		
Terms of reference	<p>(a) to establish maximum limits for pesticide residues in specific food items or in groups of food;</p> <p>(b) to establish maximum limits for pesticide residues in certain animal feeding stuffs moving in international trade where this is justified for reasons of protection of human health;</p> <p>(c) to prepare priority lists of pesticides for evaluation by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR);</p> <p>(d) to consider methods of sampling and analysis for the determination of pesticide residues in food and feed;</p> <p>(e) to consider other matters in relation to the safety of food and feed containing pesticide residues; and</p> <p>(f) to establish maximum limits for environmental and industrial contaminants showing chemical or other similarity to pesticides, in specific food items or groups of food.</p>		
Sessions	1	The Hague	17-21 January 1966
	2	The Hague	18-22 September 1967
	3	Arnhem	30 September – 4 October 1968
	4	Arnhem	6-14 October 1969
	5	The Hague	28 September - 6 October 1970
	6	The Hague	16-23 October 1972
	7	The Hague	4-9 February 1974
	8	The Hague	3-8 March 1975
	9	The Hague	14-21 February 1977
	10	The Hague	29 May – 5 June 1978
	11	The Hague	11-18 June 1979
	12	The Hague	2-9 June 1980
	13	The Hague	15-20 June 1981
	14	The Hague	14-21 June 1982
	15	The Hague	3-10 October 1983
	16	The Hague	24 May – 4 June 1984
	17	The Hague	25 March – 1 April 1985
	18	The Hague	21 -28 April 1986
	19	The Hague	6-13 April 1987
	20	The Hague	18-25 April 1988
	21	The Hague	10-17 April 1989
	22	The Hague	23-30 April 1990
	23	The Hague	15-22 April 1991
	24	The Hague	6-13 April 1992
	25	The Hague	19-26 April 1993
	26	Havana, Cuba	11-18 April 1994
	27	The Hague	24 April – 1 May 1995
	28	The Hague	15-20 April 1996
	29	The Hague	7-12 April 1997
	30	The Hague	20-25 April 1998
	31	The Hague	12-17 April 1999

CCPR (cont'd)	32	The Hague	1-8 May	2000
	33	The Hague	2-7 April	2001
	34	The Hague	13-18 May	2002
	35	Rotterdam	31 March – 5 April	2003
	36	New Delhi, India	19-24 April	2004
	37	The Hague	18-23 April	2005
	38	Fortaleza, Brazil	3-8 April	2006
	39	Beijing	7-12 May	2007
	40	Hangzhou	14-19 April	2008
	41	Beijing	20-25 April	2009

CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods			
Host country	United States of America			
Terms of reference	<p>(a) to determine priorities for the consideration of residues of veterinary drugs in foods;</p> <p>(b) to recommend maximum levels of such substances;</p> <p>(c) to develop codes of practice as may be required;</p> <p>(d) to consider methods of sampling and analysis for the determination of veterinary drug residues in foods.</p>			
Sessions	1	Washington D.C.	27-31 October	1986
	2	Washington D.C.	30 November – 4 December	1987
	3	Washington D.C.	31 October – 4 November	1988
	4	Washington D.C.	24-27 October	1989
	5	Washington D.C.	16-19 October	1990
	6	Washington D.C.	22-25 October	1991
	7	Washington D.C.	20-23 October	1992
	8	Washington D.C.	7-10 June	1994
	9	Washington D.C.	5-8 December	1995
	10	San José (Costa Rica)	29 October – 1 November 1996	1996
	11	Washington D.C.	15-18 September	1998
	12	Washington D.C.	28-31 March	2000
	13	Charleston, South Carolina	4-7 December	2001
	14	Arlington, Virginia	4-7 March	2003
	15	Alexandria, Virginia	26-29 October	2004
	16	Cancun, Mexico	8-12 May	2006
	17	Beckenridge, Colorado	3-7 September	2007
	18	Natal, Brazil	11-15 May	2009

COMMODITY COMMITTEES (ACTIVE)

CCFO	Codex Committee on Fats and Oils			
Host country	Malaysia from 21 st session United Kingdom from session 1 to 20			
Terms of reference	To elaborate worldwide standards for fats and oils of animal, vegetable and marine origin including margarine and olive oil.			
Sessions	1	London	25-27 February	1964
	2	London	6-8 April	1965
	3	London	29 March – 1 April	1966
	4	London	24-28 April	1967
	5	London	16-20 September	1968
	6	Madrid	17-20 November	1969
	7	London	25-29 March	1974
	8	London	24-28 November	1975
	9	London	28 November - 2 December	1977
	10	London	4-8 December	1978
	11	London	23-27 June	1980
	12	London	19-23 April	1982
	13	London	23-27 February	1987
	14	London	27 September – 1 October	1993
	15	London	4-8 November	1996
	16	London	8-12 March	1999
	17	London	19-23 February	2001
	18	London	3-7 February	2003
	19	London	21-25 February	2005
	20	London	19-23 February	2007
	21	Kota Kinabalu (Malaysia)	16-20 February	2009

CCFFP	Codex Committee on Fish and Fishery Products			
Host country	Norway			
Terms of reference	To elaborate worldwide standards for fresh, frozen (including quick frozen) or otherwise processed fish, crustaceans and mollusc.			
Sessions	1	Bergen	29 August – 2 September	1966
	2	Bergen	9-13 October	1967
	3	Bergen	7-11 October	1968
	4	Bergen	29 September – 8 October	1969
	5	Bergen	5-10 October	1970
	6	Bergen	4-8 October	1971
	7	Bergen	2-7 October	1972
	8	Bergen	1-6 October	1973
	9	Bergen	30 September – 5 October	1974
	10	Bergen	29 September – 4 October	1975
	11	Bergen	27 September – 2 October	1976
	12	Bergen	3-8 October	1977
	13	Bergen	7-11 May	1979
	14	Bergen	5-10 May	1980
	15	Bergen	3-8 May	1982

CCFFP (cont'd)	16	Bergen	7-11 May	1984
	17	Oslo	5-9 May	1986
	18	Bergen	2-6 May	1988
	19	Bergen	11-15 June	1990
	20	Bergen	1-5 June	1992
	21	Bergen	2-6 May	1994
	22	Bergen	6-10 May	1996
	23	Bergen	8-12 June	1998
	24	Ålesund	5-9 June	2000
	25	Ålesund	3-7 June	2002
	26	Ålesund	13 -17 October	2003
	27	Cape Town, South Africa	28 February – 4 March	2005
	28	Beijing, China	18-22 September	2006
	29	Trondheim	18-23 February	2008

CCFFV	Codex Committee on Fresh Fruits and Vegetables
Host country	Mexico
Terms of reference	<p>(a) to elaborate worldwide standards and codes of practice as may be appropriate for fresh fruits and vegetables;</p> <p>(b) to consult with the UNECE Working Party on Agricultural Quality Standards in the elaboration of worldwide standards and codes of practice with particular regard to ensuring that there is no duplication of standards or codes of practice and that they follow the same broad format;</p> <p>(c) to consult, as necessary, with other international organizations which are active in the area of standardization of fresh fruits and vegetables.</p> <p>*The Working Party on Agricultural Quality Standards of the United Nations Economic Commission for Europe:</p> <ol style="list-style-type: none"> 1. may recommend that a worldwide Codex standard for fresh fruits and vegetables should be elaborated and submit its recommendation either to the Codex Committee on Fresh Fruits and Vegetables for consideration or to the Commission for approval; 2. may prepare "proposed draft standards" for fresh fruits or vegetables at the request of the Codex Committee on Fresh Fruits and Vegetables or of the Commission for distribution by the Codex Secretariat at Step 3 of the Codex Procedure, and for further action by the Codex Committee on Fresh Fruits and Vegetables; 3. may wish to consider "proposed draft standards" and "draft standards" for fresh fruits and vegetables and transmit comments on them to the Codex Committee on Fresh Fruits and Vegetables at Steps 3 and 6 of the Codex Procedure; and 4. may perform specific tasks in relation to the elaboration of standards for fresh fruits and vegetables at the request of the Codex Committee on Fresh Fruits and Vegetables. <p>Codex "proposed draft standards" and "draft standards" for fresh fruits and vegetables at Steps 3 and 6 of the Codex Procedure should be submitted to the UNECE Secretariat for obtaining comments.</p>

Section V: Structure and sessions

CCFFV (cont'd)	Established by the 17 th Session of the Commission (1987) as the Codex Committee on Tropical Fresh Fruits and Vegetables. Its name and Terms of Reference were amended by the 21 st Session of the Commission (1995).			
Note				
Sessions	1	Mexico City	6-10 June	1988
	2	Mexico City	5-9 March	1990
	3	Mexico City	23-27 September	1991
	4	Mexico City	1-5 February	1993
	5	Mexico City	5-9 September	1994
	6	Mexico City	29 January – 2 February	1996
	7	Mexico City	8-12 September	1997
	8	Mexico City	1-5 March	1999
	9	Mexico City	9-13 October	2000
	10	Mexico City	10-14 June	2002
	11	Mexico City	8-12 September	2003
	12	Mexico City	16-20 May	2005
	13	Mexico City	25-29 September	2006
	14	Mexico City	12-17 May	2008
	15	Mexico City	19 – 23 October	2009

CCMMP	Codex Committee on Milk and Milk Products			
Host country	New Zealand			
Terms of reference	To establish international codes and standards concerning milk and milk products.			
Sessions	1	Rome	28 November – 2 December	1994
	2	Rome	27-31 May	1996
	3	Montevideo, Uruguay	18-22 May	1998
	4	Wellington	28 February – 3 March	2000
	5	Wellington	8-12 April	2002
	6	Auckland	26-30 April	2004
	7	Queenstown	27 March – 1 April	2006
	8	Queenstown	4-8 February	2008

CCPFV	Codex Committee on Processed Fruits and Vegetables		
Host country	United States		
Terms of reference	To elaborate worldwide standards for all types of processed fruits and vegetables including dried products, canned dried peas and beans, jams and jellies, but not dried prunes, or fruit and vegetable juices. The Commission has also allocated to this Committee the work of revision of standards for quick frozen fruits and vegetables.		
Sessions	1	Washington D.C.	29-30 May 1964
	2	Rome	8-11 June 1965
	3	Rome	6-10 June 1966
	4	Washington D.C.	19-23 June 1967
	5	Washington D.C.	13-17 May 1968
	6	Washington D.C.	12-16 May 1969
	7	Washington D.C.	1-5 June 1970
	8	Washington D.C.	7-11 June 1971
	9	Washington D.C.	12-16 June 1972
	10	Washington D.C.	21-25 May 1973
	11	Washington D.C.	3-7 June 1974
	12	Washington D.C.	19-23 May 1975
	13	Washington D.C.	9-13 May 1977
	14	Washington D.C.	25-29 September 1978
	15	Washington D.C.	17-21 March 1980
	16	Washington D.C.	22-26 March 1982
	17	Washington D.C.	13-17 February 1984
	18	Washington D.C.	10-14 March 1986
	19	Washington D.C.	16-20 March 1998
	20	Washington D.C.	11-15 September 2000
	21	San Antonio, Texas	23-27 September 2002
	22	Washington D.C.	27 September – 1 October 2004
	23	Arlington, Virginia	16-21 October 2006
	24	Arlington, Virginia	15-20 September 2008

COMMODITY COMMITTEES (ADJOURNED SINE DIE)

CCCPC	Codex Committee on Cocoa Products and Chocolate		
Host country	Switzerland		
Terms of reference	To elaborate worldwide standards for cocoa products and chocolate.		
Sessions	1	Neuchâtel,	5-6 November 1963
	2	Montreux	22-24 April 1964
	3	Zürich	10-12 March 1965
	4	Berne	15-17 March 1966
	5	Lugano	9-12 May 1967
	6	Montreux	2-5 July 1968
	7	Horgen, (Zürich)	23-27 June 1969
	8	Lucerne	29 June – 3 July 1970
	9	Neuchâtel	27 September – 1 October 1971
	10	Lausanne	7-11 May 1973
	11	Zürich	2-6 December 1974
	12	Bienne	1-5 November 1976
	13	Aarau	2-6 April 1979
	14	Lausanne	21-25 April 1980
	15	Neuchâtel	29 March – 2 April 1982
	16	Thun	20 September – 2 October 1996
	17	Berne	16-18 November 1998
	18	Fribourg	2-4 November 2000
	19	Fribourg	3-5 October 2001

CCCPL	Codex Committee on Cereals Pulses and Legumes		
Host country	United States		
Terms of reference	To elaborate worldwide standards and/or codes of practice as appropriate for cereals, pulses, legumes and their products.		
Sessions	1	Washington D.C.	24-28 March 1980
	2	Washington D.C.	27 April – 1 May 1981
	3	Washington D.C.	25-29 October 1982
	4	Washington D.C.	24-28 September 1984
	5	Washington D.C.	17-21 March 1986
	6	Washington D.C.	24-28 October 1988
	7	Washington D.C.	22-26 October 1990
	8	Washington D.C.	26-30 October 1992
	9	Washington D.C.	31 October - 4 November 1994

CCMH	Codex Committee on Meat Hygiene			
Host country	New Zealand			
Terms of reference	To elaborate worldwide standards and/or codes of practice as appropriate for meat hygiene.			
Note	Established as the Codex Committee on Meat Hygiene by the 8 th Session of the Codex Alimentarius Commission (1971). The terms of reference and the name of the Committee were amended by the 24 th Session of the Commission (2001) to include poultry. The specific reference to poultry in the name and terms of reference was removed by the 26 th Session of the Commission (2003).			
Sessions	1	London	10-15 April	1972
	2	London	18-22 June	1973
	3	London	25-29 November	1974
	4	London	18-22 May	1981
	5	London	11-15 October	1982
	6	Rome	14-18 October	1991
	7	Rome	29 March – 2 April	1993
	8	Wellington	18-22 February	2002
	9	Wellington	17-21 February	2003
	10	Auckland	16-20 February	2004
	11	Christchurch	14-17 February	2005

CCMMW	Codex Committee on Natural Mineral Waters			
Host country	Switzerland			
Terms of reference	To elaborate regional standards for natural mineral waters.			
Note	The Committee was established by the Commission as a Regional (European) Codex Committee, but has since been allocated the task of elaborating worldwide standards for natural mineral waters and bottled (packaged) water other than natural mineral water.			
Sessions	1	Baden, Aargau	24-25 February	1966
	2	Montreux	6-7 July	1967
	3	Bad Ragaz	7-9 May	1968
	4	Vienna	12-13 June	1972
	5	Thun	3-5 October	1996
	6	Berne	19-21 November	1998
	7	Fribourg	30 October – 1 November	2000
	8	Lugano	11-15 February	2008

CCS	Codex Committee on Sugars			
Host country	United Kingdom			
Terms of reference	To elaborate worldwide standards for all types of sugars and sugar products.			
Sessions	1	London	3-5 March	1964
	2	London	2-4 March	1965
	3	London	1-3 March	1966
	4	London	18-21 April	1967
	5	London	10-12 September	1968
	6	London	19-22 March	1974
	7	London	9-11 February	2000

CCVP	Codex Committee on Vegetable Proteins			
Host country	Canada			
Terms of reference	To elaborate worldwide standards for all types of sugars and sugar products. To elaborate definitions and worldwide standards for vegetable protein products deriving from any member of the plant kingdom as they come into use for human consumption, and to elaborate guidelines on utilization of such vegetable protein products in the food supply system, on nutritional requirements and safety, on labelling and on other aspects as may seem appropriate.			
Sessions	1	Ottawa	3-7 November	1980
	2	Ottawa	1-5 March	1983
	3	Ottawa	6-10 February	1984
	4	Havana	2-6 February	1987
	5	Ottawa	6-10 February	1989

COMMODITY COMMITTEES (ABOLISHED)

CCEI	Codex Committee on Edible Ices		
Host country	Sweden		
Terms of reference	To elaborate worldwide standards as appropriate for all types of edible ices, including mixes and powders used for their manufacture.		
Note	Abolished by the 22 nd Session of the Commission (1997)		
Sessions	1 Stockholm	18-22 February	1974
	2 Stockholm	23-27 June	1975
	3 Stockholm	11-15 October	1976

CCM	Codex Committee on Meat		
Host country	Germany		
Terms of reference	To elaborate worldwide standards and/or descriptive texts and/or codes of practice as may seem appropriate for the classification, description and grading of carcasses and cuts of beef, veal, mutton, lamb and pork.		
Note	Abolished by the 16 th Session of the Commission (1985).		
Sessions	1 Kulmbach	28-30 October	1965
	2 Kulmbach	5-8 July	1966
	3 Kulmbach	15-17 November	1967
	4 Kulmbach	18-20 June	1969
	5 Bonn	16-20 November	1970
	6 Kulmbach	1-5 November	1971
	7 Kulmbach	25-29 June	1973

CCPMPP	Codex Committee on Processed Meat and Poultry Products			
Host country	Denmark			
Terms of reference	To elaborate worldwide standards for processed meat products, including consumer packaged meat, and for processed poultry meat products.			
Sessions	1	Kulmbach	4-5 July	1966
	2	Copenhagen	2-6 October	1967
	3	Copenhagen	24-28 June	1968
	4	Copenhagen	9-13 June	1969
	5	Copenhagen	23-27 November	1970
	6	Copenhagen	17-21 April	1972
	7	Copenhagen	3-7 December	1973
	8	Copenhagen	10-14 March	1975
	9	Copenhagen	29 November – 3 December	1976
	10	Copenhagen	20-24 November	1978
	11	Copenhagen	22-26 September	1980
	12	Copenhagen	4-8 October	1982
	13	Copenhagen	23-26 October	1984
	14	Copenhagen	12-16 September	1988
	15	Copenhagen	8-12 October	1990

CCSB	Codex Committee on Soups and Broths			
Host country	Switzerland			
Terms of reference	To elaborate worldwide standards for soups, broths, bouillons and consommés.			
Note	Abolished by the 24 th Session of the Commission (2001).			
Sessions	1	Berne	3-7 November	1975
	2	St. Gallen	7-11 November	1977

AD HOC INTERGOVERNMENTAL TASK FORCES (ACTIVE)

TFAMR	Ad hoc Codex intergovernmental Task Force on Antimicrobial Resistance			
Host country	Republic of Korea			
Objectives	<p>To develop science based guidance, taking full account of its risk analysis principles and the work and standards of other relevant international Organizations, such as FAO, WHO and OIE. The intent of this guidance is to assess the risks to human health associated with the presence in food and feed including aquaculture and the transmission through food and feed of antimicrobial resistant microorganisms and antimicrobial resistance genes and to develop appropriate risk management advice based on that assessment to reduce such risk. The Task Force should attempt to put into perspective the risk of increase of antimicrobial resistance in human beings and animals, generated by different areas of use of antimicrobials such as veterinary applications, plant protection or food processing:</p> <p>The objectives were modified by the 31st Session of the Commission (2008).</p>			
Terms of reference	To develop guidance on methodology and processes for risk assessment, its application to the antimicrobials used in human and veterinary medicine as provided by FAO/WHO through JEMRA, and in close cooperation with OIE, with subsequent consideration of risk management options. In this process work undertaken in this field at national, regional and international levels should be taken into account.			
Time frame	The Task Force shall complete its work within four sessions, starting in 2007.			
Sessions	1	Seoul	23-26 October	2007
	2	Seoul	20-24 October	2008

AD HOC INTERGOVERNMENTAL TASK FORCES (DISSOLVED)

TFAF	Ad hoc Codex intergovernmental Task Force on Animal Feeding			
Host country	Denmark			
Objectives	With the aim of ensuring the safety and quality of foods of animal origin, the Task Force should develop guidelines or standards as appropriate on Good Animal Feeding practices.			
Terms of reference	<p>(a) To complete and extend the work already done by relevant Codex Committees on the Draft Code of Practice for Good Animal Feeding.</p> <p>(b) To address other aspects which are important for food safety, such as problems related to toxic substances, pathogens, microbial resistance, new technologies, storage, control measures, traceability, etc.</p> <p>(c) To take full account of and collaborate with, as appropriate, work carried out by relevant Codex Committees, and other relevant international bodies, including FAO, WHO, OIE and IPPC.</p>			
Note	Dissolved by the 27 th Session of the Commission (2004) upon completion of its mandate.			
Sessions	1	Copenhagen	13-15 June	2000
	2	Copenhagen	19-21 March	2001
	3	Copenhagen	17-20 June	2002
	4	Copenhagen	25-28 March	2003
	5	Copenhagen	17-20 May	2004

TFFBT	Ad hoc Codex intergovernmental Task Force on Foods Derived from Biotechnology			
Host country	Japan			
Objectives (1999-2003)	To develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology or traits introduced into foods by biotechnology, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair trade practices.			

TFFBT (cont'd) Objectives (2004-2008)	To develop standards, guidelines or recommendations, as appropriate, for foods derived from modern biotechnology or traits introduced into foods by modern biotechnology, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair practices in the food trade.		
Terms of reference (1999-2003)	<p>(a) To elaborate standards, guidelines, or other principles, as appropriate, for foods derived from biotechnology;</p> <p>(b) To coordinate and closely collaborate, as necessary, with appropriate Codex Committees within their mandate as relates to foods derived from biotechnology; and</p> <p>(c) To take full account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora.</p>		
Terms of reference (2004-2008)	<p>(a) To elaborate standards, guidelines, or other principles, as appropriate, for foods derived from modern biotechnology, taking account, in particular, of the Principles for the Risk Analysis of Foods derived from Modern Biotechnology;</p> <p>(b) To coordinate and closely collaborate, as necessary, with appropriate Codex Committees within their mandate as relates to foods derived from modern biotechnology; and</p> <p>(c) To take account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora.</p>		
Note	<p>The <i>ad hoc</i> Codex Intergovernmental Task Force on Foods Derived from Biotechnology was dissolved by the 26th Session of the Commission (2003) upon completion of its initial mandate.</p> <p>The Task Force was re-established by the 27th Session of the Commission (2004).</p> <p>The Task Force was dissolved by the 31st Session of the Commission (2008).</p>		
Sessions	1	Chiba	14-17 March 2000
	2	Chiba	25-29 March 2001
	3	Yokohama	4-8 March 2002
	4	Yokohama	11-14 March 2003
	5	Chiba	19-23 September 2005
	6	Chiba	27 November – 1 December 2006
	7	Chiba	24-28 September 2007

TFFJ	Ad hoc Codex intergovernmental Task Force on Fruit and Vegetable Juices			
Host country	Brazil			
Terms of reference	<p>The <i>ad hoc</i> Task Force shall:</p> <p>(a) revise and consolidate the existing Codex standards and guidelines for fruit and vegetable juices and related products, giving preference to general standards;</p> <p>(b) revise and up-date the methods of analysis and sampling for these products;</p> <p>(c) complete its work prior to the 28th Session of the Commission (2005).</p>			
Note	Dissolved by the 28 th Session of the Commission (2005) upon completion of its mandate.			
Sessions	1	Brasilia	18-22 September	2000
	2	Rio de Janeiro	23-26 April	2002
	3	Salvador (Bahia)	6-10 May	2003
	4	Fortaleza	11-15 October	2004

TFPHQFF	Ad hoc Codex intergovernmental Task Force on the Processing and Handling of Quick frozen Foods			
Host country	Thailand			
Objectives	To finalize the International Code of Practice for the Processing and Handling of Quick Frozen Foods.			
Terms of reference	To resolve all outstanding issues including quality and safety provisions with a view to the advancement of the Code to Step 8.			
Note	Dissolved by the 31 st Session of the Commission (2008) upon completion of its mandate.			
Sessions	1	Bangkok	25-29 February	2008

FAO/WHO COORDINATING COMMITTEES

Terms of reference of FAO/WHO Coordinating Committees	
(a)	defines the problems and needs of the region concerning food standards and food control;
(b)	promotes within the Committee contacts for the mutual exchange of information on proposed regulatory initiatives and problems arising from food control and stimulates the strengthening of food control infrastructures;
(c)	recommends to the Commission the development of worldwide standards for products of interest to the region, including products considered by the Committee to have an international market potential in the future;
(d)	develops regional standards for food products moving exclusively or almost exclusively in intra regional trade;
(e)	draws the attention of the Commission to any aspects of the Commission's work of particular significance to the region;
(f)	promotes coordination of all regional food standards work undertaken by international governmental and non-governmental organizations within the region;
(g)	exercises a general coordinating role for the region and such other functions as may be entrusted to it by the Commission;
(h)	promotes the use of Codex standards and related texts by members.

CCAFRICA		FAO/WHO Coordinating Committee for Africa		
Membership		Membership of the Committee is open to all Member Nations and Associate Members of FAO and/or WHO which are members of the Codex Alimentarius Commission, within the geographic location of Africa.		
		Sessions		Coordinator
1	Rome, Italy	24-27 June	1974	Ghana
2	Accra	15-19 September	1975	Ghana
3	Accra	26-30 September	1977	Ghana
4	Dakar	3-7 September	1979	Senegal
5	Dakar	25-29 May	1981	Senegal
6	Nairobi	31 October – 5 November	1983	Kenya
7	Nairobi	12-18 February	1985	Kenya
8	Cairo	29 November – 3 December	1988	Egypt
9	Cairo	3-7 December	1990	Egypt
10	Abuja	3-6 November	1992	Nigeria
11	Abuja	8-11 May	1995	Nigeria
12	Harare	19-22 November	1996	Zimbabwe
13	Harare	3-6 November	1998	Zimbabwe
14	Kampala	27-30 November	2000	Uganda
15	Kampala	26-29 November	2002	Uganda
16	Rome, Italy	25-28 January	2005	Morocco
17	Rabat	23-26 January	2007	Morocco
18	Accra	24-27 February	2009	Ghana

Section V: Structure and sessions

CCASIA		FAO/WHO Coordinating Committee for Asia		
Membership		Membership of the Committee is open to all Member Nations and Associate Members of FAO and/or WHO which are members of the Codex Alimentarius Commission, within the geographic location of Asia.		
Session				Coordinator
1	New Delhi, India	10-16 January	1978	Malaysia
2	Manila	20-26 March	1979	Philippines
3	Colombo, Sri Lanka	2-8 February	1982	Thailand
4	Phetchaburi	28 February – 5 March	1984	Thailand
5	Yogyakarta	8-14 April	1986	Indonesia
6	Denpasar	26 January – 1 February	1988	Indonesia
7	Chiang-Mai	5-12 February	1990	Thailand
8	Kuala Lumpur	27-31 January	1992	Malaysia
9	Beijing	24-27 May	1994	China
10	Tokyo	5-8 March	1996	Japan
11	Chiang Rai	16-19 December	1997	Thailand
12	Chiang-Mai	23-26 November	1999	Thailand
13	Kuala Lumpur	17-20 September	2002	Malaysia
14	Jeju-Do	7-10 September	2004	Republic of Korea
15	Seoul	21-24 November	2006	Republic of Korea
16	Denpasar	17-21 November	2008	Indonesia

CCEURO		FAO/WHO Coordinating Committee for Europe		
Membership		Membership of the Committee is open to all Member Nations and Associate Members of FAO and/or WHO which are members of the Codex Alimentarius Commission, within the geographic location of Europe including Israel, Turkey and the Russian Federation.		
Session				Coordinator
1	Berne	1-2 July	1965	Switzerland
2	Rome, Italy	20 October	1965	Switzerland
3	Vienna	24-27 May	1966	Austria
4	Rome, Italy	8 November	1966	Austria
5	Vienna	6-8 September	1967	Austria
6	Vienna	4-8 November	1968	Austria
7	Vienna	7-10 October	1969	Austria
8	Vienna	27-29 October	1971	Austria
9	Vienna	14-16 June	1972	Austria
10	Vienna	13-17 June	1977	Austria
11	Innsbruck	28 May – 1 June	1979	Austria
12	Innsbruck	16-20 March	1981	Austria
13	Innsbruck	27 September – 1 October	1982	Austria
14	Thun	4-8 June	1984	Switzerland
15	Thun	16-20 June	1986	Switzerland
16	Vienna	27 June – 1 July	1988	Austria
17	Vienna	28 May – 1 June	1990	Austria
18	Stockholm	11-15 May	1992	Sweden
19	Stockholm	16-20 May	1994	Sweden
20	Uppsala	23-26 April	1996	Sweden
21	Madrid	5-8 May	1998	Spain
22	Madrid	3-6 October	2000	Spain
23	Bratislava	10-13 September	2002	Slovak Republic
24	Bratislava	20-23 September	2004	Slovak Republic
25	Vilnius, Lithuania	15-18 January	2007	Switzerland
26	Warsaw, Poland	7-10 October	2008	Switzerland

CCLAC	FAO/WHO Coordinating Committee for Latin America and the Caribbean			
Membership	Membership of the Committee is open to all Member Nations and Associate Members of FAO and/or WHO which are members of the Codex Alimentarius Commission, within the geographic location of Latin America and the Caribbean.			
Sessions				Coordinator
1	Rome, Italy	25-26 March	1976	Mexico
2	Montevideo	9-15 December	1980	Uruguay
3	Havana	27 March – 2 April	1984	Cuba
4	Havana	17-22 April	1985	Cuba
5	Havana	11-16 February	1987	Cuba
6	San José	20-24 February	1989	Costa Rica
7	San José	1-10 July	1991	Costa Rica
8	Brasília	16-20 March	1993	Brazil
9	Brasília	3-7 April	1995	Brazil
10	Montevideo	25-28 February	1997	Uruguay
11	Montevideo	8-11 December	1998	Uruguay
12	Santo Domingo	13-16 February	2001	Dominican Republic
13	Santo Domingo	9-13 December	2002	Dominican Republic
14	Buenos Aires	29 November – 3 December	2004	Argentina
15	Mar del Plata	13-17 November	2006	Argentina
16	Acapulco	10-14 November	2008	Mexico

CCNEA	FAO/WHO Coordinating Committee for the Near East			
Membership	Membership of the Committee is open to all Member Nations and Associate Members of FAO and/or WHO which are members of the Codex Alimentarius Commission, within the geographic location of the Near East.			
Sessions				Coordinator
1	Cairo	29 January – 1 February	2001	Egypt
2	Cairo	20-23 January	2003	Egypt
3	Amman	7-10 March	2005	Jordan
4	Amman	26 February – 1 March	2007	Jordan
5	Tunis	26-29 January	2009	Tunisia

CCNASWP		FAO/WHO Coordinating Committee for North America and the South West Pacific		
Membership		Membership of the Committee is open to all Member Nations and Associate Members of FAO and/or WHO which are members of the Codex Alimentarius Commission, within the geographic location of North America and the South West Pacific.		
Sessions				Coordinator
1	Honolulu	30 April – 4 May	1990	USA
2	Canberra	2-6 December	1991	Australia
3	Vancouver	31 May – 3 June	1994	Canada
4	Rotorura	30 April – 3 May	1996	New Zealand
5	Seattle	6-9 October	1998	USA
6	Perth	5-8 December	2000	Australia
7	Vancouver	29 October – 1 November	2002	Canada
8	Apia	19-22 October	2004	Samoa
9	Apia	10-13 October	2006	Samoa
10	Nuku'alofa	28-31 October	2008	Tonga

COMMITTEE ESTABLISHED UNDER RULE XI.1(A)

CGECPMMP	Joint FAO/WHO Committee of Government Experts on the Code of Principles Concerning Milk And Milk Products			
Terms of reference	To establish international codes and standards concerning milk and milk products.			
Note	Established by FAO and WHO in 1958 and integrated into the Joint FAO/WHO Food Standards Programme in 1962 as a subsidiary body of the Codex Alimentarius Commission under Rule XI.1(a). Re-named "Codex Committee on Milk and Milk Products" in 1993 and re-established as a subsidiary body under Rule XI.1(b)(i) (see <i>Rules of Procedure</i> in Section I).			
Sessions	1	Rome	18-12 September	1958
	2	Rome	13-17 April	1959
	3	Rome	22-26 February	1960
	4	Rome	6-10 March	1961
	5	Rome	2-6 April	1962
	6	Rome	17-21 June	1963
	7	Rome	4-8 May	1964
	8	Rome	24-29 May	1965
	9	Rome	20-25 June	1966
	10	Rome	25-31 August	1967
	11	Rome	10-15 June	1968
	12	Rome	7-12 July	1969
	13	Rome	15-20 June	1970
	14	Rome	6-11 September	1971
	15	Rome	25-30 September	1972
	16	Rome	10-15 September	1973
	17	Rome	14-19 April	1975
	18	Rome	13-18 September	1976
	19	Rome	12-17 June	1978
	20	Rome	26-30 April	1982
	21	Rome	2-6 June	1986
	22	Rome	5-9 November	1990

JOINT MEETINGS WITH OTHER ORGANIZATIONS

CXTO	Joint CODEX/IOOC Meeting on the Standardization of Table Olives			
Terms of reference	As approved by the 18th Session of the Commission, the Joint Codex/IOOC meeting was held on an <i>ad hoc</i> basis in order to elaborate a Standard for Table Olives.			
Note	The meeting was not a subsidiary body under any specific rule of the Codex Alimentarius Commission but followed the same procedure as Codex Commodity Committees for the elaboration of Codex standards.			
Sessions	1	Madrid	13-16 December	1971
	2	Madrid	24-27 April	1973

GEQFF	Joint UNECE/ Codex Alimentarius Group of Experts on Standardization of Quick Frozen Foods			
Terms of reference	The Joint UNECE/Codex Alimentarius Group of Experts on the Standardization of Quick Frozen Foods will be responsible for the development of standards for quick frozen foods in accordance with the General Principles of the Codex Alimentarius. The Joint Group will be responsible for general considerations, definitions, a framework of individual standards for quick frozen food products and for the actual elaboration of standards for quick frozen food products not specifically allotted by the Commission to another Codex Committee, such as Fish and Fishery Products, Meat, Processed Meat and Poultry Products. Standards drawn up by Codex commodity committees for quick frozen foods should be in accordance with the general standard laid down by the Joint ECE/Codex Alimentarius Group of Experts on the Standardization of Quick Frozen Foods and should, at an appropriate stage, be referred to it for coordination purposes.			
Notes	The Joint UNECE/Codex Alimentarius groups of experts were not subsidiary bodies under any specific rule of the Codex Alimentarius Commission but followed the same procedure as Codex Commodity Committees for the elaboration of Codex standards. Abolished by the 23 rd Session of the Commission (1999). The work of the Joint Group of Experts was transferred to the Codex Committee on Processed Fruits and Vegetables (see the Terms of Reference of that Committee).			
Sessions	1	Geneva	6-10 September	1965
	2	Geneva	5-9 September	1966
	3	Rome	18-22 September	1967
	4	Geneva	2-6 September	1968
	5	Rome	22-26 September	1969
	6	Rome	27-31 July	1970

GEQFF (cont'd)	7	Geneva	6-10 December	1971
	8	Geneva	30 April – 4 May	1973
	9	Rome	7-11 October	1974
	10	Geneva	6-10 October	1975
	11	Geneva	14-18 March	1977
	12	Rome	30 October – 6 November	1978
	13	Rome	15-19 September	1980

GEFJ	Joint UNECE/ Codex Alimentarius Group of Experts on Standardization of Fruit Juices			
Terms of reference	To elaborate worldwide standards for fruit juices, concentrated fruit juices and nectars.			
Notes	<p>The Joint UNECE/Codex Alimentarius groups of experts were not subsidiary bodies under any specific rule of the Codex Alimentarius Commission but followed the same procedure as Codex Commodity Committees for the elaboration of Codex standards.</p> <p>Abolished by the 23rd Session of the Commission (1999). The work of the Joint Group was transferred to the Codex <i>ad hoc</i> Intergovernmental Task Force on Fruit Juices.</p>			
Sessions	1	Geneva	6-10 April	1964
	2	Geneva	29 March – 2 April	1965
	3	Geneva	21-25 February	1966
	4	Geneva	10-14 April	1967
	5	Rome	25-29 March	1968
	6	Geneva	27-31 October	1969
	7	Rome	20-24 July	1970
	8	Geneva	8-12 March	1971
	9	Rome	20-24 March	1972
	10	Geneva	16-20 July	1973
	11	Rome	14-18 October	1974
	12	Geneva	19-23 July	1976
	13	Geneva	26-30 June	1978
	14	Geneva	9-13 June	1980
	15	Rome	8-12 February	1982
	16	Geneva	30 April – 4 May	1984
	17	Rome	26-30 May	1986
	18	Geneva	16-20 May	1988
	19	Rome	12-16 November	1990

SECTION VI

MEMBERSHIP

- Membership of the Codex Alimentarius Commission as of August 2009.
- Core Functions of Codex Contact Points. (Adopted in 1999)
- Up-to-date information on Codex Contact Points and Membership is available on the Codex website at: <http://www.codexalimentarius.net>.

MEMBERSHIP OF THE CODEX ALIMENTARIUS COMMISSION**Member countries and years of accession (as of AUGUST 2009)**

AFRICA		AFRICA	
Angola	1990	Niger	1997
Benin	1974	Nigeria	1969
Botswana	1978	Rwanda	1988
Burkina Faso	2002	Sao Tome and Principe	2009
Burundi	1964	Senegal	1966
Cameroon	1969	Seychelles	1984
Cape Verde	1981	Sierra Leone	1980
Central African Republic	1971	Somalia	2009
Chad	1978	South Africa	1994
Comoros	2009	Swaziland	1972
Congo	1971	Togo	1968
Côte d'Ivoire	1969	Uganda	1964
Democratic Republic of the Congo	1970	United Republic of Tanzania	1972
Djibouti	2009	Zambia	1971
Equatorial Guinea	1988	Zimbabwe	1985
Eritrea	1996		
Ethiopia	1968	ASIA	
Gabon	1972	Afghanistan	2005
Gambia	1971	Bangladesh	1975
Ghana	1966	Bhutan	1999
Guinea	1978	Brunei Darussalam	1997
Guinea-Bissau	1974	Cambodia	1974
Kenya	1969	China	1984
Lesotho	1984	Democratic People's Republic of Korea	1981
Liberia	1971	India	1964
Madagascar	1966	Indonesia	1971
Malawi	1971	Japan	1963
Mali	2003	Lao People's Democratic Republic	1995
Mauritania	1996	Malaysia	1971
Mauritius	1971	Maldives (Republic of)	2008
Morocco	1968	Mongolia	1992
Mozambique	1984		
Namibia	1999		

Member countries and years of accession

ASIA		EUROPE	
Myanmar	1978	Ireland	1963
Nepal	1974	Israel	1963
Pakistan	1970	Italy	1966
Philippines	1968	Kazakhstan	2003
Republic of Korea	1971	Kyrgyzstan	2002
Singapore	1969	Latvia	1993
Sri Lanka	1972	Lithuania	1992
Thailand	1963	Luxembourg	1963
Viet Nam	1989	Malta	1966
		Moldova	1997
EUROPE		Netherlands	1963
Albania	1992	Norway	1963
Armenia	1994	Poland	1963
Austria	1963	Portugal	1963
Belarus	2006	Romania	1969
Belgium	1963	Russian Federation	1993
Bosnia and Herzegovina	2007	Serbia	2006
Bulgaria	1969	Slovakia	1994
Croatia	1994	Slovenia	1993
Cyprus	1971	Spain	1963
Czech Republic	1994	Sweden	1963
Denmark	1963	Switzerland	1963
Estonia	1992	The former Yugoslav	
Finland	1964	Republic of Macedonia	1994
France	1963	Turkey	1963
Georgia	1998	Ukraine	2004
Germany	1963	United Kingdom	1963
Greece	1963	Uzbekistan	2005
Hungary	1968	Member Organization:	
Iceland	1970	European Community	2003

Member countries and years of accession

LATIN AMERICAN AND THE CARIBBEAN		NEAR EAST	
Antigua and Barbuda	1988	Algeria	1970
Argentina	1963	Bahrain	1981
Bahamas	2002	Egypt	1972
Barbados	1970	Iran (Islamic Republic of)	1966
Belize	1992	Iraq	1969
Bolivia	1971	Jordan	1966
Brazil	1968	Kuwait	1964
Chile	1969	Lebanon	1970
Colombia	1969	Libyan Arab Jamahiriya	1972
Costa Rica	1970	Oman	1972
Cuba	1964	Qatar	1971
Dominica	1990	Saudi Arabia	1968
Dominican Republic	1971	Sudan	1968
Ecuador	1970	Syrian Arab Republic	1968
El Salvador	1975	Tunisia	1965
Grenada	1982	United Arab Emirates	1972
Guatemala	1968	Yemen	1988
Guyana	1970		
Haiti	1984	NORTH AMERICA	
Honduras	1988	Canada	1963
Jamaica	1971	United States of America	1963
Mexico	1969	SOUTH WEST PACIFIC	
Nicaragua	1971	Australia	1963
Panama	1972	Cook Islands	1998
Paraguay	1969	Fiji	1971
Peru	1963	Kiribati	1990
Saint Kitts and Nevis	1996	Micronesia, Federated	
Saint Lucia	1987	States of	1993
Saint Vincent and the Grenadines	2004	New Zealand	1963
Suriname	1984	Papua New Guinea	1989
Trinidad and Tobago	1964	Samoa	1974
Uruguay	1970	Solomon Islands	1998
Venezuela	1969	Tonga	1997
		Vanuatu	1997

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.

SECTION VII

RELATIONS WITH OTHER ORGANIZATIONS

- Guidelines on Cooperation between the Codex Alimentarius Commission and International Intergovernmental Organizations in the Elaboration of Standards and Related Texts. (Adopted in 2005)
- Principles concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission. (Adopted in 1999, amended in 2005, 2007)

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 membership⁴² that form the basis for membership in the Codex Alimentarius Commission and equivalent principles of standards-setting⁴³.

Cooperation at the Initial Drafting Stages of a Codex Standard or Related Text⁴⁴

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 organization 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),

⁴² "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.

⁴³ "Equivalent principles of standards-setting" refers to the General Decisions of the Commission set out in the Appendix to the Procedural Manual.

⁴⁴ 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.

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".

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 bodies⁴⁵ on a regular basis. They may also request invitations to participate at specific sessions of the Commission or its subsidiary bodies on an *ad hoc* basis.

4.2 International Non-Governmental Organizations neither having Status with FAO nor Official Relations with WHO

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

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

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

⁴⁵ The term "subsidiary bodies" means any body established under Rule XI of the Commission's Rules of Procedure.

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 Chairperson⁴⁶;
- (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

⁴⁶ 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.

- 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 non-governmental organizations established in accordance with the present Procedures and shall provide a list of organizations granted Observer Status, with an indication of the membership that they represent. He or she shall also report to the Commission the termination of the observer status of any Organization.

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

ANNEX: Information required of International Non-Governmental Organizations requesting “Observer Status”

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

APPENDIX

GENERAL DECISIONS OF THE COMMISSION

- Statements of Principle concerning the Role of Science in the Codex Decision-Making Process and the Extent to which other Factors are Taken into Account. (Adopted in 1995, amended in 2001)
- Statements of Principle Relating to the Role of Food Safety Risk Assessment. (Adopted in 1997)
- Measures to facilitate consensus. (Adopted in 2003)

STATEMENTS OF PRINCIPLE CONCERNING THE ROLE OF SCIENCE IN THE CODEX DECISION-MAKING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT⁴⁷

1. The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.
2. When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.
3. In this regard it is noted that food labelling plays an important role in furthering both of these objectives.
4. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle⁴⁸

- when health and safety matters are concerned, the *Statements of Principle Concerning the Role of Science* and the *Statements of Principle Relating to the Role of Food Safety Risk Assessment* should be followed;
- other legitimate factors relevant for health protection and fair trade practices may be identified in the risk management process, and risk managers should indicate how these factors affect the selection of risk management options and the development of standards, guidelines and related texts;
- consideration of other factors should not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment;
- recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide;⁴⁹
- only those other factors which can be accepted on a worldwide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex;

⁴⁷ Decision of the 21st Session of the Commission, 1995.

⁴⁸ Decision of the 24th Session of the Commission, 2001.

⁴⁹ Confusion should be avoided between justification of national measures under the SPS and TBT Agreements and their validity at the international level.

- the consideration of specific other factors in the development of risk management recommendations of the Codex Alimentarius Commission and its subsidiary bodies should be clearly documented, including the rationale for their integration, on a case-by-case basis;
- the feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries, may be considered; concerns related to economic interests and trade issues in general should be substantiated by quantifiable data;
- the integration of other legitimate factors in risk management should not create unjustified barriers to trade⁵⁰; particular attention should be given to the impact on developing countries of the inclusion of such other factors.

⁵⁰ According to the WTO principles, and taking into account the particular provisions of the SPS and TBT Agreements.

STATEMENTS OF PRINCIPLE RELATING TO THE ROLE OF FOOD SAFETY RISK ASSESSMENT⁵¹

1. Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.
2. Food safety risk assessment should be soundly based on science, should incorporate the four steps of the risk assessment process, and should be documented in a transparent manner.
3. There should be a functional separation of risk assessment and risk management, while recognizing that some interactions are essential for a pragmatic approach.
4. Risk assessment should use available quantitative information to the greatest extent possible and risk characterizations should be presented in a readily understandable and useful form.

⁵¹ Decision of the 22nd Session of the Commission, 1997.

MEASURES TO FACILITATE CONSENSUS⁵²

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

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

⁵² Decision of the 26th Session of the Commission, 2003.

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