

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.

Section I: Basic texts and definitions

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

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- 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.

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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

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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.

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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

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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:

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- 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.

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- 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

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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.

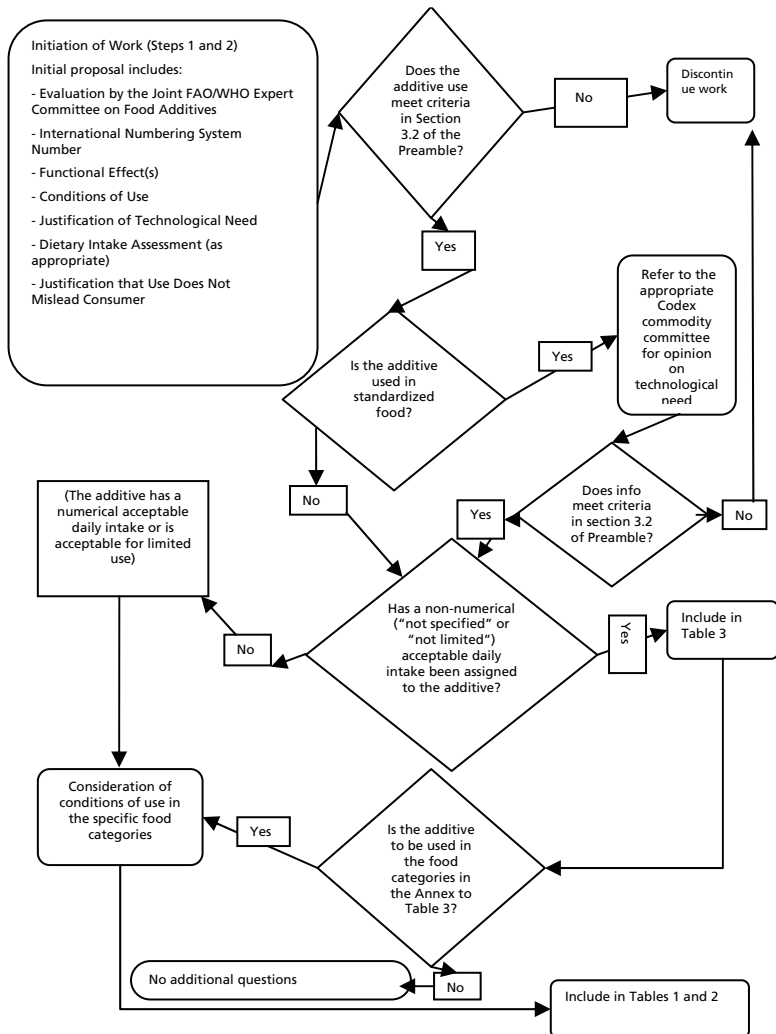
4. When establishing the acceptable maximum level of use for an additive in a specified food category, the Committee on Food Additives considers the technological justification for the proposed level and the exposure assessment in accordance with Sections 3.1 and 3.2 of the Preamble of the General Standard 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. $RSD_R \leq 2 \cdot PRSD_R$			
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 μ g/kg	80 – 110
	0.000001	10^{-8}	10 μ g/kg	60 – 115
0.0000001	10^{-9}	1 μ g/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 RSD_{SR} 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: $ML = 0.1 \text{ mg/kg}$, $C_{ML} = 10^{-7}$:

$$0.1 \pm 3 \cdot S_R = 0.1 \pm 3 \cdot \frac{0.1 \cdot 2 \cdot (0.000001)^{-0.1505}}{100} = 0.1 \pm 0.07 \text{ mg/kg}$$

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: $ML = 0.01 \text{ mg/kg}$ (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: Matrix/provision: ML:	Lead
	Juice
	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.

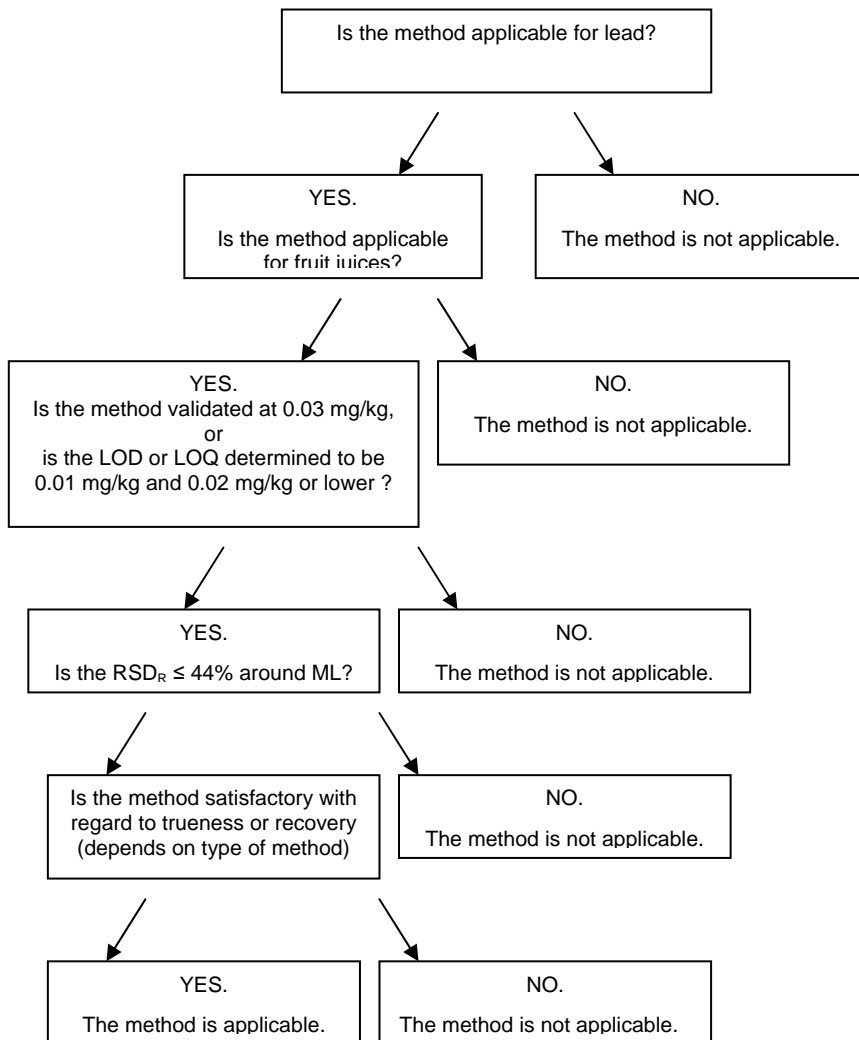
2.1 How to elucidate a method's compliance with the criteria.

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):

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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.