Food and Agriculture Organization of the United Nations

World Health Organization

CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

CODEX ALIMENTARIUS COMMISSION PROCEDURAL MANUAL

JOINT FAO/WHO
FOOD STANDARDS PROGRAMME

THIRTIETH EDITION

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Food and Agriculture Organization of the United Nations
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Foreword

At its Second Session held in Geneva in 1964, the Codex Alimentarius Commission (hereinafter "Commission") received a revised report from the Working Party on the Rules of Procedure and Related Matters. The report recommended to the Commission that "the Statutes of the Commission, the statement on the purpose and scope of Codex … the revised Rules of Procedure, and the Procedure for the elaboration of world-wide and regional standards … should for the convenience of Members be available in a single document or handbook which should be revised and re-issued whenever necessary".

At the Eleventh Session of the Executive Committee of the Codex Alimentarius Commission, held in Rome on 19 February 1968, the Joint FAO/WHO Codex Secretariat (hereinafter "Codex Secretariat") advised that "budgetary provision had been made for the publication of the procedural handbook which had been requested by the Commission at its second session. It was hoped to issue this simultaneously with the report of the fifth session and it would be distributed free of charge".

The first edition of the *Codex Alimentarius Commission Procedural Manual* (hereinafter "*Codex Procedural Manual*") was subsequently published in July 1968. The introduction reads that the *Codex Procedural Manual* "was prepared at the request of Members of the Codex Alimentarius Commission to assist their representatives in attending Codex sessions".

The 30th edition

The 30th edition of the *Codex Procedural Manual* continues to work towards a harmonization of language, particularly around synonymous terminology, thus setting precedent for Codex's other written materials.

New in this edition

This edition contains the following changes to Section 4.6: Risk analysis principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), as adopted by the 47th Session of the Commission, held in November 2024:

- a revision of Annex C: Approach for the extrapolation of maximum residue limits for veterinary drugs to one or more species;
- the inclusion of Annex D: Criteria and procedures for the establishment of action levels for residues of veterinary drugs in food of animal origin resulting from unavoidable and unintentional veterinary drug carryover in non-target animal feed; and
- a consequential amendment to paragraph 133, Establishment of priority list.

This edition also contains a change in Section 5.1: Table of committees, document references and terms of reference, where, following the decision by the Commission to reactivate the Codex Committee on Cereals, Pulses and Legumes (CCCPL), this committee was moved from "commodity committees (adjourned *sine die*)" to "commodity committees (active)".

Finally, editorial changes have been made to more consistently apply abbreviations and provide more accurate cross-referencing by numbering subsections.

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Abbreviations

ADI	acceptable daily intake
AGISAR	Advisory Group on Integrated Surveillance of Antimicrobial Resistance
ALOP	appropriate level of protection
ARfD	acute reference doses
CAS	chemical abstracts service
CCCF	Codex Committee on Contaminants in Foods
CCFA	Codex Committee on Food Additives
CCFFP	Codex Committee on Fish and Fishery Products
CCFH	Codex Committee on Food Hygiene
CCFICS	Codex Committee on Food Import and Export Inspection and Certification Systems
CCFL	Codex Committee on Food Labelling
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
CCP	Codex contact point
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
CRD	conference room document
CRM	certified reference materials
CWBC	committees working by correspondence
CXL	Codex maximum residue level
ELISA	enzyme-linked immunosorbent assay
EWG	electronic working group
FAO	Food and Agriculture Organization of the United Nations
FSO	food safety objective
GAP	good agricultural practice
GDP	gross domestic product
GEMS	global environment monitoring system
GMP	good manufacturing practice
GSFA	*General standard for food additives*

HACCP	hazard analysis critical control point
HR	highest residues
IDF	International Dairy Federation
IEDI	international estimated daily intake
IESTI	international estimate of short-term intake
INGO	international non-governmental organization
INS	international system number
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JEMNU	Joint Expert Meeting on Nutrition
JEMRA	Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOD	limit of detection
LOQ	limit of quantification
MC	microbiological criteria
ML	maximum level
MRL	maximum residue limit
MRM	microbiological risk management
PCR	polymerase chain reaction
PO	performance objective
PWG	physical working group
RAC	raw agriculture commodity
STMR	supervised trial median residues
TRIPS	trade-related aspects of intellectual property
UNECE	United Nations Economic Commission for Europe
WHO	World Health Organization
WOAH	World Organisation for Animal Health
WTO	World Trade Organization

Introduction

The *Codex Alimentarius Commission Procedural Manual* (hereinafter "*Codex Procedural Manual*") describes the legal foundations and practical functioning of the Codex Alimentarius Commission (hereinafter "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 1 **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 2 **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 3 **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 4 **Risk analysis**
Contains general and specific texts on risk analysis for application in the framework of the Commission and its subsidiary bodies dealing with the protection of consumers' health and to the joint FAO/WHO expert bodies and consultations.

Section 5 **Subsidiary bodies of the Codex Alimentarius Commission**
Lists the Commission's subsidiary bodies with their terms of reference.

Section 6 **Membership**
Lists the core functions of the Codex contact points and also includes a link to the Codex website with up-to-date information on Codex contact points and membership of the Commission.

Section 7 **Relations with other organizations**
Outlines the principles and guidelines governing the relations between the Commission and international intergovernmental and non-governmental organizations.

Appendix **General decisions of the Codex Alimentarius 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.

Section

1

Basic texts and definitions

1.1 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 of the United Nations (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; and

e. amending published standards, as appropriate, in light of developments.

Article 2
Membership of the Commission is open to all Members and Associate Members of FAO and WHO 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 Members 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 Members 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.

1.2 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 Members 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 practices 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,[i] shall take into account only the intervention of the party which has the right to vote.[ii]

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i The word 'decisions' should be understood to mean both voting and situations where a decision is taken by consensus.

ii 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.

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.
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 staff 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; and

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-governmental 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 geographical 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 geographical 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 subcommittees from among its Members as it may deem necessary to enable it to exercise its functions as effectively as possible. Such subcommittees 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 subcommittee. Consideration should be given to an appropriate geographical balance in the membership of subcommittees.
5. The Chairperson and Vice-Chairpersons of the Commission shall be respectively the Chairperson and Vice-Chairpersons of the Executive Committee.
6. Sessions of the Executive Committee may be convened as often as necessary by the Directors-General of FAO and WHO, in consultation with the Chairperson. The Executive Committee shall normally meet immediately prior to each session of the Commission.
7. The Executive Committee shall report to the Commission.

RULE VI – Sessions

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

RULE VII – Agenda

1. The Directors-General of FAO and WHO, after consultation with the Chairperson of the Commission or with the Executive Committee, shall prepare a provisional agenda for each session of the Commission.
2. The first item on the provisional agenda shall be the adoption of the agenda.
3. Any Member of the Commission may request the Directors-General of FAO or WHO to include specific items in the provisional agenda.
4. The provisional agenda shall be circulated by the Directors-General of FAO or WHO to all Members of the Commission at least two months before the opening of the session.
5. Any Member of the Commission, and the Directors-General of FAO and WHO, may, after the dispatch of the provisional agenda, propose the inclusion of specific items in the agenda with respect to matters of an urgent nature. These items shall be placed on a supplementary list, which, if time permits before the opening of the session, shall be dispatched by the Directors-General of FAO and WHO to all Members of the Commission, failing which the supplementary list shall be communicated to the Chairperson for submission to the Commission.
6. No items included in the agenda by the governing bodies or the Directors-General of FAO and WHO shall be deleted therefrom. After the agenda has been adopted, the Commission may, by a two-thirds majority of the votes cast, amend the agenda by the deletion, addition, or modification of any other item.
7. Documents to be submitted to the Commission at any session shall be furnished by the Directors-General of FAO and WHO to all Members of the Commission, to the other eligible nations attending the session as Observers and to the non-member nations and international organizations invited as Observers thereto, in principle at least two months prior to the session at which they are to be discussed.

RULE VIII – Voting and procedures

1. Subject to the provisions of paragraph 3 of this rule, each Member of the Commission shall have one vote. An alternate or adviser shall not have the right to vote except where substituting for the representative.
2. Except as otherwise provided in these rules, decisions of the Commission shall be taken by a majority of the votes cast.
3. At the request of a majority of the Members of the Commission constituting a given region or a group of countries that a standard be elaborated, the standard concerned shall be elaborated as a standard primarily intended for that region or group of countries. When a vote is taken on the elaboration, amendment or adoption of a draft standard primarily intended for a region or group of countries, only Members belonging to that region or group of countries may take part in the voting. The adoption of the standard may, however, take place only after submission of the draft text to all Members of the Commission for comments. The provisions of this paragraph shall not prejudice the elaboration or adoption of a corresponding standard with a different territorial scope.

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

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

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

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

RULE IX – Observers

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

2. Nations which, while not Members 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 of 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 of 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 (INGO) 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 INGOs. 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 INGOs 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 Members 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; and
      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; and

   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 they shall 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

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.

1.3 General principles of the Codex Alimentarius

Purpose of the Codex Alimentarius

The Codex Alimentarius is a collection of internationally adopted food standards and related texts[iii] 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

The Codex Alimentarius includes standards for all the principal 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.

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

Nature of Codex standards

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. 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

The 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 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.

1.4 Definitions for the purposes of the Codex Alimentarius

For the purposes of the Codex Alimentarius:

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

Codex maximum limit for pesticide residues (MRL) is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Commission to be legally permitted in or on food commodities and animal feeds. MRLs are based on good agricultural practice (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 Joint FAO/WHO Meeting on Pesticide Residues (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 acceptable daily intake (ADI), should indicate that foods complying with Codex MRLs are safe for human consumption.

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 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 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.

Contaminant means any substance not intentionally added to food or feed for food-producing animals, which is present in such food or feed 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 feed, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs, and other extraneous matter.

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 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.

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.

GAP in the use of pesticides 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 authorized 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.

Good manufacturing practice in the use of food additives means that:

a. 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.

b. 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.

c. 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.

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.

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.

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.

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.

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

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.

Section

2

Elaboration of Codex standards and related texts

2.6 Format for Codex commodity standards

Adopted in 1969. Amended in 2007, 2008, 2010, 2011, 2016 and 2021.

2.7 Guidelines for the inclusion of specific provisions in Codex standards and related texts

2.8 Guidelines on the elaboration and/or revision of codes of hygienic practice for specific commodities.

Adopted in 1997.

2.9 Procedure for the inclusion of additional species in Codex standards for fish and fishery products

Adopted in 2013

2.10 Principles for the establishment of Codex methods of analysis

Adopted in 1964. Amended in 1969, 1979, 2001, 2003, 2004, 2008, 2009, 2013 and 2017.

2.11 Principles for the establishment or selection of Codex sampling procedures

Adopted in 1993. Amended in 2007.

2.12 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.

2.13 Provisions on the use of proprietary methods in Codex standards.

Adopted 2012.

2.1 Procedures for the elaboration of Codex standards and related texts

Introduction

The full procedure[iv] 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 decision, based on a strategic planning process (see Part 1: Strategic planning process).

2. An ongoing 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: Critical review).

3. The Commission decides, taking into account the outcome of the ongoing 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 Joint FAO/WHO Codex Secretariat (hereinafter "Codex 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: Uniform procedure for the elaboration of Codex standards and related texts of this section.

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: Uniform accelerated procedure for the elaboration of Codex standards and related texts of this section.

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.

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

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 section).

Part 1
Strategic planning process

10. Taking into account Section 2.3: 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.

11. 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

12. 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:

a) the purposes and the scope of the standard;

b) its relevance and timeliness;

c) the main aspects to be covered;

d) an assessment against Section 2.3: Criteria for the establishment of work priorities;

e) relevance to the Codex strategic objectives;

f) information on the relation between the proposal and other existing Codex documents as well as other ongoing work;[v]

g) identification of any requirement for and availability of expert scientific advice;

h) identification of any need for technical input to the standard from external bodies so that this can be planned for; and

i) the proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

v Countries could seek the assistance of the Codex Secretariat to provide information on other ongoing work in Codex.

13. 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.

14. The critical review includes:

a) examination of proposals for development/revision of standards, taking into account Section 2.3: Criteria for the establishment of work priorities, the strategic plan of the Commission and the required supporting work of independent risk assessment,

b) identifying the standard setting needs of developing countries;

c) advice on the need for coordination of work between relevant Codex subsidiary bodies;

d) 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

e) 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 prioritization of that advice.

15. 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 for food additives* (CXS 192-1995) (GSFA),[vi,1] the *General standard on contaminants and toxins in food and feed* (CXS 193-1995),[vii,2] the Food categorisation system and the *Class names and the International Numbering System for food additives* (CXG 36-1989),[3] shall follow the procedures established by the committees concerned and endorsed by the Commission.

Monitoring progress of standards development

16. 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.

17. 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.

18. 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.

19. 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:

a) monitoring of progress in developing standards and advising what corrective action should be taken;

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vi Including related methods of analysis and sampling plans.
vii See note vi above.

b) examining proposed standards from Codex committees, before they are submitted to the Commission for adoption:

i) for consistency with the mandate of Codex, the decisions of the Commission, and existing Codex texts;

ii) to ensure that the requirements of the endorsement procedure have been fulfilled, where appropriate;

iii) for format and presentation; and

iv) 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 worldwide Codex standard and also decides which subsidiary body or other body should undertake the work. A decision to elaborate a worldwide 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 Commission.

Step 2 The Codex Secretariat arranges for the preparation of a proposed draft standard. In the case of maximum limits for residues of pesticides or veterinary drugs, the Codex 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 Codex 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 Codex 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 Codex Secretariat to the Executive Committee for critical review and to the Commission with a view to its adoption as a draft standard.[viii] 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.

viii 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 Codex 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.

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 Codex 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 Codex 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 Codex 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.

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.[ix] 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 Codex 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 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 Codex Secretariat distributes the recommendations of the IDF.

ix 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 updating of existing standards.

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

Part 5
Subsequent procedure concerning publication of Codex standards

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

21. The above-mentioned publications will constitute the Codex Alimentarius.

Part 6
Subsequent procedure concerning publication and possible extension of territorial application of the standard

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

23. 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 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 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 on 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.

Part 7
Guide to the procedure for the amendment and revision of Codex standards and related texts

24. The procedure for amending or revising a Codex standard is laid down in paragraph 8 of Section 2.1: Procedures 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.

25. 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.

26. 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:

a) correction of an error;

b) insertion of an explanatory footnote; and

c) updating of references consequential to the adoption, amendment or revision of Codex standards and other texts of general applicability, including the provisions in the *Codex Procedural Manual.*

27. 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.

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

29. 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.

30. 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 Codex 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 Codex Secretariat in good time (not less than three months) before the session of the Commission at which they are to be considered. The proposal should be accompanied by a project document (see Part 2 of the elaboration procedures) unless the Executive Committee or the Commission decides otherwise. However, if the amendment proposed is of an editorial nature, the preparation of a project document is not required.

31. Taking into account the outcome of the ongoing 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:

a) 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).

b) 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).

c) 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.

32. Where Codex subsidiary bodies have been abolished or dissolved, or Codex committees have been adjourned *sine die*, the Codex 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 Codex Secretariat should prepare proposed amendments for consideration and adoption by the Commission. If the need for amendments of a substantive nature is identified, the Codex 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.

2.2 Criteria for the establishment of subsidiary bodies of the Codex Alimentarius Commission

33. When there is a proposal for the elaboration of a standard, code of practice or related text in an area not covered by the terms of reference of any existing subsidiary body,[x] 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 Section 2.3: Criteria for the establishment of work priorities.

34. 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:

Terms of reference

a) 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.

b) The terms of reference shall clearly state the objective(s) to be achieved by the establishment of the ad hoc intergovernmental task force.

c) 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.

Reporting

35. The ad hoc intergovernmental task force shall report to the 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.

Operating expenses

36. 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.

Host government arrangements

37. 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.[xi]

x The Commission may wish to consider extending the terms of reference of an appropriate existing body to accommodate the proposal.

xi This may involve host government arrangements with one or more Members of the Commission.

Working procedures

38. Ad hoc intergovernmental task forces shall be open to all Members of the Commission and Section 1.2: Rules of procedure of the Codex Alimentarius Commission and Section 2.1: Procedures for the elaboration of Codex standards and related texts shall apply *mutatis mutandis* to ad hoc intergovernmental task forces.

Dissolution

39. 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.

2.3 Criteria for the establishment of work priorities

40. 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.

41. 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

42. 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).

d) Amenability of the subject of the proposal to standardization.

e) Consideration of the global magnitude of the problem or issue.

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 standardization.

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).

2.4 Guideline on the application of the criteria for the establishment of work priorities (criteria applicable to commodities)

43. These guidelines provide guidance on the application of the criteria, including the information that needs to be examined by the Executive Committee while performing the critical review, in accordance with points (a) through (g) in the "Criteria applicable to commodities" for the establishment of work priorities.

44. In principle, an evidence-based approach that addresses multiple factors shall be taken when the Executive Committee examines proposals of new work to develop or revise commodity standards. Therefore, project proposals (project documents) for commodity standards should contain information indicated below.

Volume of production and consumption in individual countries and volume and pattern of trade between countries

45. Information should be provided on:

a) Volume of production and consumption in individual countries expressed in monetary terms, tonnes, proportion of gross domestic product (GDP)[xii] etc.

b) Volume and patterns of trade, including trends in trade volume and patterns, expressed in monetary terms, tonnes, proportion of GDP[xiii] etc.:

i. between countries;

ii. in intraregional trade, i.e. between or among countries of a region; and

iii. in interregional trade, i.e. between or among regions.

c) Credible sources or citations of information and/or references in order to support credibility of the above information, if possible.

Note: When proposing to develop a regional standard, the coordinating committee concerned should fully take into account paragraph (4) of the terms of reference of FAO/WHO coordinating committees (in Section 5) and provide well-documented and objective evidence that there is significant intraregional trade, and that there is no significant trade, between or within other regions. This requirement will help to avoid the development of more than one standard for the same (or similar) product in different regions.

xii Information on the volume or percentage of trade (import/export) in the commodity may be useful to demonstrate that trade in the commodity represents a significant proportion of the domestic economy of the relevant country or countries.

xiii See note xii above.

46. In case there is substantial production and trade of a regional commodity in countries outside the region, the Executive Committee should recommend to the concerned commodity committee to consider elaborating a global standard taking into account its work programme.

Diversification of national legislation and apparent resultant or potential impediments to international trade

47. Information should be provided on existence of diverse national legislation that may lead to potential or actual impediments to international trade. Evidence of impediments may be provided as quantitative information on volume and/or frequency of rejection of consignments, as expressed, for example, as absolute numbers or as rates of rejection.

International or regional market potential

48. Information should be provided on:

a) international and/or regional market potential; and, where necessary;

b) potential of regional products to enter international trade, including an analysis of current production trends as well as market potential in the foreseeable future.

Amenability of the commodity to standardization

49. Information should be provided on:

a) which quality factors are essential for the identity of the product e.g. definition, composition, etc.; and

b) characteristics of the commodity (e.g. differences in definition, composition, and other quality factors that may vary across countries and regions) that would have to be accommodated in the standard.

Coverage of the main consumer protection and trade issues by existing or proposed general standards

50. Information should be provided on whether there are overlaps or gaps with existing standards. If gaps or overlaps are identified, the new work proposal should explain why revision of the existing standard is not sufficient to meet the need for a standard.

Note: This information is required in order to identify whether there are gaps between the proposed new work and existing standards or standards under elaboration. This analysis is necessary to avoid the elaboration of new standards when revision of existing standards, or of certain provisions in existing standards, would adequately address the concern.

51. If overlaps are identified, it may be possible to propose that new work should be started, while suggesting that existing standards should also be considered for revision to avoid inconsistency or overlap.

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

52. Commodity standards should preferably be developed in a generic manner to cover the relevant products concerned. Information should be provided on the rationale for the need to develop separate standards indicating whether raw, semi-processed, or processed.

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

53. Information should be provided on activities that have been already undertaken by other relevant international organizations, including an analysis of areas of potential complementarities, gaps, duplication, or conflict with the above activities.

Note: Even when standards exist outside Codex, a rationale for new work in Codex should be provided, based on information presented in the above analysis.

2.5 Relations between commodity committees and general subject committees

54. Codex committees may seek the advice and guidance of general subject committees responsible for matters applicable to all foods on any points coming within their province, in accrdance 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 insofar as they elaborate commodity standards) and general subject committees during the elaboration of Codex commodity standards.

55. Codex general subject committees which include the Codex Committees on Food Labelling (CCFL); Food Additives (CCFA); Contaminants in Foods (CCCF); Pesticides Residues (CCPR); Residues of Veterinary Drugs in Foods (CCRVDF); Food Hygiene (CCFH); Methods of Analysis and Sampling (CCMAS); Nutrition and Foods for Special Dietary Uses (CCNFSDU); and Food Import and Export Inspection and Certification Systems (CCFICS) may establish general provisions on matters within their terms of reference. These general provisions should only be incorporated into commodity standards by reference unless there is a need for doing otherwise (see Section 2.6: Format for Codex commodity standards).

56. 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 general standards, codes or guidelines shall be referred to the responsible general subject committees at the most suitable and earliest time in Section 2.1: Procedures 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

57. Commodity committees shall refer any exemptions from, or additions to, the reference to the *General standard for the labelling of pre-packaged foods* (CXS 1-1985)[4] and, where applicable, the *General standard for the labelling on non-retail containers of food* (CXS 346-2021),[5] indicated in Section 2.6: Format for Codex commodity standards to CCFL for endorsement.

58. In respect of date marking (Section 4.7 of the *General standard for the labelling of pre-packaged 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 CCFL.

Food additives

59. Commodity committees shall examine the GSFA with a view towards incorporating a reference to the general standard. All proposals for additions or amendments to the GSFA in order to establish a reference to the GSFA shall be referred to CCFA. CCFA shall consider such proposals for endorsement. Revisions of a substantive nature that are endorsed by CCFA will be referred back to the commodity committee in order to achieve consensus between both committees at an early stage of the step procedure.

60. Should the commodity committee consider that a general reference to the GSFA does not serve its purpose, a proposal should be prepared and forwarded to CCFA for consideration and endorsement. The commodity committee shall provide a justification for why a general reference to the GSFA would not be appropriate in light of the criteria for the use of food additives established in the preamble of the GSFA, in particular Section 3.

61. All provisions in respect of food additives (including processing aids) contained in commodity standards should be referred to CCFA, preferably before the standards have been advanced to Step 5 of Section 2.1: Procedures for the elaboration of Codex standards and related texts 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.

62. All provisions in respect of food additives contained in commodity standards will require endorsement by CCFA, on the basis of technological justification submitted by the commodity committees and on the recommendations of JECFA 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 GSFA.

63. When forwarding a food additive section of a commodity standard for endorsement by CCFA, the Codex Secretariat should prepare a report to the committee that includes the international system number (INS), the ADI assigned by JECFA, technological justification, proposed level, and whether the additive was previously endorsed by CCFA.

64. 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 CCFA for endorsement and inclusion in the GSFA. When CCFA 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 CCFA decides to amend the provision.

65. When no active commodity committee exists, proposals for new additive provisions or amendment of existing provisions for inclusion in the GSFA should be forwarded directly by Codex Members to CCFA.

Contaminants in foods

66. Commodity committees shall examine the *General standard for contaminants and toxins in food and feed* with a view towards incorporating a reference to the general standard.

67. 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 CCCF 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.

68. 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.

69. All proposals should be referred to CCCF, preferably before the advancement of the draft commodity standards concerned to Step 5 of Section 2.1: Procedures for the elaboration of Codex standards and related texts 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.

70. CCCF 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

71. Commodity committees shall examine the provisions on residue limits of pesticides and of veterinary drugs adopted by the Commission with a view towards incorporating a general reference as indicated in the section on contaminants in Section 2.6: Format for Codex commodity standards.

72. Should the commodity committee consider that the general reference above does not serve its purpose, a proposal should be prepared and forwarded to CCPR or CCRVDF as appropriate, for consideration of new work or revision of the adopted residue limits.

Food hygiene

73. Commodity committees should examine the provisions on food hygiene adopted by the Commission, with a view towards incorporating a general reference as indicated in Section 2.6: Format for Codex commodity standards on food hygiene in the commodity committees shall refer any exemptions from, or additions to, the general reference above to CCFH for endorsement.

Methods of analysis and sampling

Normal practice

74. 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 CCMAS at Step 4, to ensure governments can comment at the earliest possible stage in the development of the standard. A commodity committee should, whenever possible, provide information to CCMAS 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 CCMAS 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.

75. 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.

76. At Step 4, commodity committees should discuss and report to CCMAS on matters connected with:

a) provisions in Codex standards which require analytical or statistical procedure;

b) provisions for which elaboration of specific methods of analysis or sampling are required;

c) provisions which are defined by the use of defining methods (Type I);

d) all proposals to the extent possible should be supported by appropriate documentation; especially for tentative methods (Type IV); and

e) any request for advice or assistance.

77. CCMAS 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.

78. When necessary, CCMASshould try to ensure elaboration and collaborative testing of methods by other recognized bodies with expertise in the field of analysis.

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

80. In addition, CCMAS 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

81. When CCMAS 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

82. Methods of analysis included in the *List of Codex specifications for food additives* (CXA 6-2021)[6] for the purpose of verifying the criteria of purity and identity of the food additive, need not be referred to CCMAS for endorsement. CCFA is responsible for carrying out the steps of the procedure.

Methods of analysis of pesticide residues and veterinary drugs in food

83. The methods for determining the levels of pesticide residues and veterinary drug residues in food need not be referred to CCMAS for endorsement. CCPR and CCRVDF are responsible for carrying out the steps of the procedure.

Microbiological methods of analysis and sampling

84. 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 CCFH at the most suitable time during Steps 3, 4 and 5 of Section 2.1: Procedures for the elaboration of Codex standards and related texts, which will ensure that government comments on the methods of analysis and sampling are available to CCFH. The procedure to be followed will be as in the normal practice described above, substituting CCFH for CCMAS. Microbiological methods of analysis and sampling elaborated by CCFH for inclusion in Codex commodity standards for the purpose of verifying hygiene provisions need not be referred to CCMAS for endorsement.

Food import and export inspection and certification systems

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

2.6 Format for Codex commodity standards

Introduction

86. The format is intended for use as a guide by the subsidiary bodies of the 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 are required 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

87. Provisions of general standards, codes or guidelines shall only be incorporated into commodity standards by reference unless there is a need for doing otherwise.

Notes on the headings

Name of the standard

88. 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

89. 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

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

Essential composition and quality factors

91. 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

92. This section should contain a general reference to the corresponding sections of the GSFA which should take the following form:

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

93. Exceptions from, or in addition to, the GSFA 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 Section 2.5: 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."*

94. This section should contain the following reference to the *Guidelines for the use of flavourings* (CXG 66-2008),[7] as appropriate:

> *"The flavourings used in products covered by this standard should comply with the Guidelines for the use of flavourings (CXG 66-2008)."*

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

Contaminants

96. 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 General standard for contaminants and toxins in food and feed (CXS 193-1995)."*

97. 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

98. This section should contain the following general reference to the *General principles of food hygiene* (CXC 1-1969)[8] and the *Principles and Guidelines for the establishment and application of microbiological criteria related to foods* (CXG 21-1997)[9]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 General principles of food hygiene (CXC 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 and guidelines for the establishment and application of microbiological criteria related to foods (CXG 21-1997)."*

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

Weights and measures

100. 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 International System of Units (SI). In the case of standards which include provisions for the sale of products in standardized amounts, e.g. multiples of 100 grams, SI 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

101. 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*.

102. 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.

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

a) a statement that the product shall be labelled in accordance with the *General standard for the labelling of pre-packaged foods*;

b) the specified name of the food; and

c) date marking and storage instructions (only if the exemption foreseen in Section 4.7.1 of the general standard is applied).

104. Where the scope of the standard is not limited to pre-packaged foods, a provision for the labelling of non-retail containers may be included as follows:

"*The labelling of non-retail containers should be in accordance with the General standard for the labelling of non-retail containers of foods (CXS 346-2021).*"

105. 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.

106. In respect of date marking (Section 4.7 of the *General standard for the labelling of pre-packaged 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

107. This section should contain the following wording:

"For checking the compliance with this standard, the methods of analysis and sampling contained in the Recommended methods of analysis and sampling (CXS 234-1999)[10] *relevant to the provisions in this standard shall be used."*

108. The methods of analysis and sampling considered necessary should be selected in accordance with the guidance given in the section on methods of analysis and sampling in Section 2.5: Relations between commodity committees and general subject committees. Preference should be given to set performance criteria according to the guidance established in the general criteria for the selection of methods of analysis using the criteria approach. If two or more methods have been proved to be equivalent by CCMAS, these could be regarded as alternatives.

2.7 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

109. The GSFA is intended to include food additive provisions for standardized and non-standardized foods in the Codex Alimentarius.

110. The following text describes the data and information that should be submitted to CCFA when requesting the committee to initiate work to add or revise food additive provisions in the GSFA. The decisions required to establish acceptance or rejection of new proposals are also elaborated.

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

Initiation of work

Revision

112. The food additive provisions of the GSFA may be revised by CCFA after requests submitted by Codex committees, Codex Members, or the Commission. Information to support amendment of the GSFA shall be provided by the proposing body. Supporting information provided to CCFA should include, as appropriate:

a) specifications for the food additive;

b) a summary of the JECFA safety evaluation of the food additive;

c) the food categories or subcategories in which the additive is intended to be used; and

d) an indication of the technological need/justification for the additive, referencing one or more of the general principles for the use of food additives in Section 3 of the GSFA.

113. Maximum use levels for the food additive in the specified food categories:

a) For additives with a numerical ADI, a numerical maximum use level for each specified use although for certain cases, a level of good manufacturing practice (GMP) may be appropriate.

b) 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.

c) 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.

114. 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 GSFA or an exposure assessment, that this level meets the safety requirements enumerated in Section 3.1 of the GSFA.

115. A reasoned statement that consumers will not be misled by the use of the additive.

116. CCFA shall consider all amendments to the GSFA proposed by Codex committees, Codex Members, or the Commission.

Review

117. The food additive provisions for the GSFA shall be reviewed by CCFA 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.

118. If JECFA changes an ADI to a temporary ADI, the food additive provisions of the GSFA may remain unchanged until the ADI has been withdrawn or the full status has been restored by JECFA.

119. If JECFA withdraws an ADI, the food additive provisions of the GSFA shall be amended by removing all provision for the use of the additive.

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

a. **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.

b. **Functional effect of the food additive**

- The functional class list used in *Class names and the international numbering system for food additives* (CXG 36-1989)[3] should be used.

c. **Proposed use of the food additive**

- The appropriate food categories from the food category system (Annex B of the GSFA) 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 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 GSFA, a numerical or 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.

d. **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 GSFA should be included.

e. **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 GSFA, should be included as appropriate.

f. **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*?

121. Section 3.2 of the preamble of the GSFA[1] 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 GSFA. 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 CCFA 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?

122. CCFA 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, CCFA recommends appropriate conditions of use based on proposals of the commodity committee.

123. 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 CCFA for endorsement and, ultimately, incorporation into the GSFA. The development of such food additive lists should be consistent with the principles used in the development of the GSFA. However, the development of food additive lists in commodity standards should be restricted as much as possible. For example, an additive may be listed in a commodity standard if it is needed to achieve a technical effect that is not achievable by the use of other additives of the same functional class. Additives may also be listed in a commodity standard if there is a need, based on a safety assessment, to limit the use of the additive. Justification for such exceptions should be provided by the Codex commodity committees to CCFA for consideration.

124. If the Codex commodity committee has been adjourned, CCFA may revise the food additive provisions in commodity standards under the purview of the adjourned committee, as necessary.

125. CCFA 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 GSFA. These revisions, once adopted by the Commission, would be incorporated into the GSFA.

Has a non-numerical ("not specified" or "not limited") ADI been assigned?

126. 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 GSFA. 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 GSFA. These proposals are considered by CCFA according to the criteria described in the section "**Consideration of conditions of use in the specific food categories**", below.

127. 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 GSFA. These proposals are considered by the 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

128. CCFA identifies and recommends appropriate food categories and use levels for inclusion in Tables 1 and 2 of the GSFA. 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 GSFA:

a) 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).

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

c) 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 GMP. However, exceptions, as noted under "**Initiation of work**", shall also be taken into account by CCFA on a case-by-case basis.

d) When establishing the acceptable maximum level of use for an additive in a specified food category, CCFA 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 GSFA.

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 CCFA, 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.

e) To resolve questions related to dietary exposure of food additives, CCFA may request JECFA to perform exposure assessments for the additives based on the acceptable maximum use levels under consideration by CCFA.

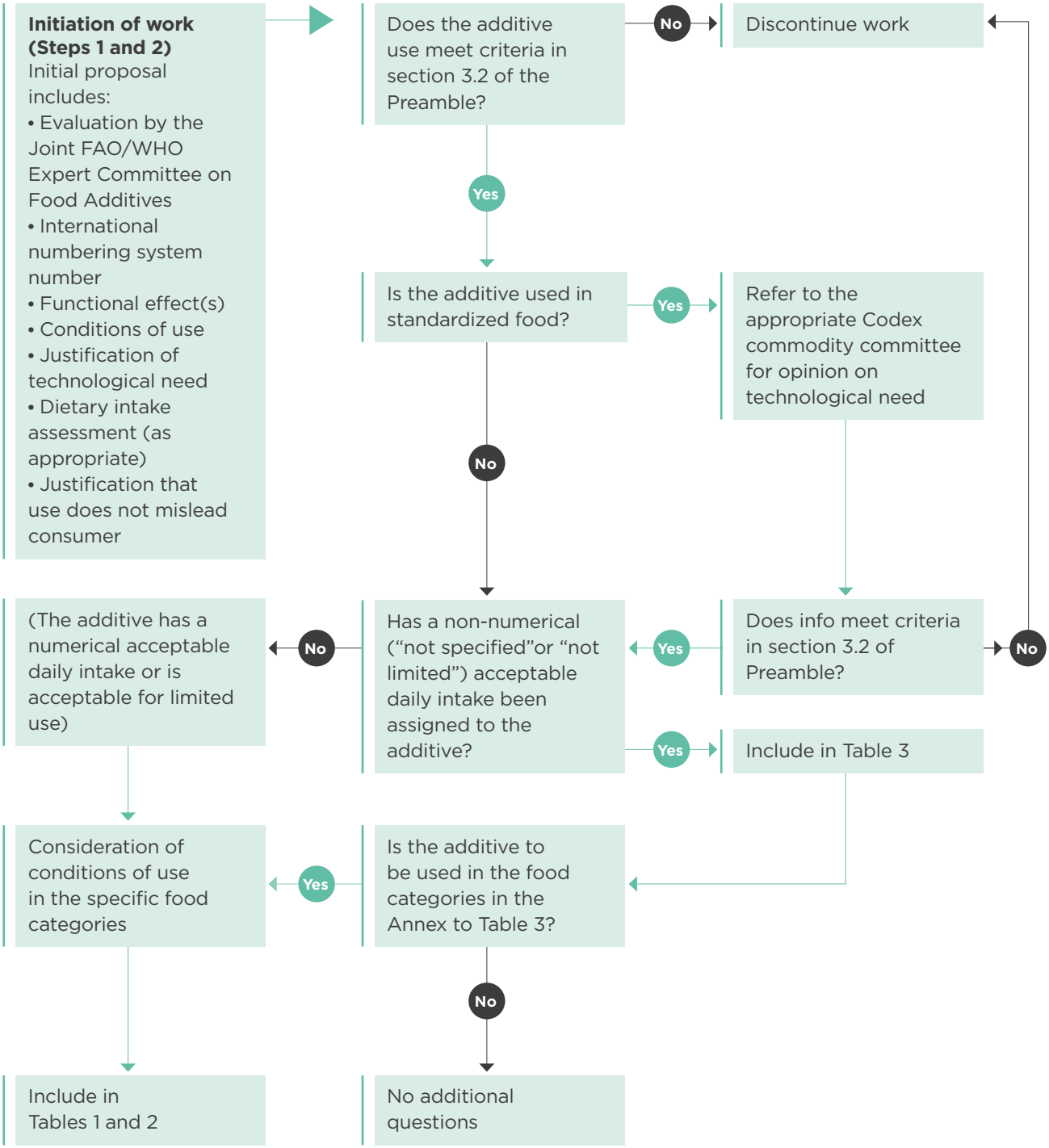
f) Acceptable maximum use levels are established as described in the previous sections and the food additive provisions are entered in the GSFA. Each use level represents the highest acceptable maximum use level in the broadest food category for which the use is technologically justified. To the extent 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 GSFA. In this regard:

i. 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 subcategories of the broad food category that are already listed in the GSFA, 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).

ii. If the new use of a food additive is for a broader food category and at a lower maximum use level than for the subcategories of the broad food category that already exist in the GSFA, then the provisions listed in the GSFA are determined according to the hierarchy of the food category system. The highest maximum use level in each food subcategory, whether from an existing provision or from the new use in the broader food category, is entered into the GSFA. 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).

iii. If the new use of a food additive, together with the already-listed provisions in the GSFA, represents use in all of the subcategories of a broader food category at the same maximum use level, then the use in the broader food category will be listed in the GSFA. The already-listed provisions in the subcategories 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).

Figure 1 **Diagram of procedure for consideration of the entry and review of food additives in the *General standard for food additives***



2.8 Guidelines on the elaboration and/or revision of codes of hygienic practice for specific commodities

129. 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.

130. 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.

131. The *General principles of food hygiene* (including the Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) System) and the *Principles and guidelines for the establishment and application of microbiological criteria related to foods* are the base documents in the field of food hygiene.

132. All 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.

133. Provisions in 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.

134. The above considerations should also apply to codes of practice which contain provisions relating to food hygiene.

2.9 Procedure for the inclusion of additional species in Codex standards for fish and fishery products

Preamble

135. Any Member can make a proposal to revise an existing standard to include an additional species. In accordance with Section 2.3: Criteria for the establishment of work priorities and on the basis of a project document submitted by the proposing Member, the Committee on Fish and Fishery products (CCFFP) may decide to forward to the Commission a proposal for new work. When there is a proposal to start new work on including additional species, CCFFP initiates the inclusion procedure as described below to facilitate its work.

Scope

136. This procedure for inclusion applies to the relevant standards falling within the mandate of CCFFP. The aim of the procedure is to enable new species to be included in the existing standards following a simple and harmonized approach. This procedure does not apply to species currently included in a standard or species dedicated for the non-food industry.

Responsibilities and division of committee decisions

137. The division of labour is the following:

Proposing Member

a) Develops a project document according to the *Codex Procedural Manual*.

b) Provides information on the candidate species pursuant to paragraph 150 (Description) and paragraph 152 (Economic data).

138. If sensory evaluation is required by the committee, it:

a) proposes three species, the most representative of the market to be compared with the candidate species; and

b) proposes three laboratories for sensory evaluation (see paragraph 155: Principles of the sensory evaluation procedure).

Committee

139. Reviews the information listed in paragraph 149: Information required.

140. The information provided by the proposing Member should enable the committee to decide whether the relevant standard must be revised by checking that:

a) the taxonomic relationship of the candidate species is established;

b) the candidate species is described with sufficient precision; and

c) economic potential is clearly demonstrated.

141. Decides to transmit to the Commission a proposal for new work, and at the same time, considers whether or not to establish a working group to coordinate the process and present recommendations to the committee for consideration.

a) If the committee is of the view that the information submitted at this stage is sufficient to allow the inclusion of the candidate species, the committee may agree with the inclusion without further assessment being required. In this case, the committee forwards the draft amendment of the standard to the Commission for its adoption.

b) However, where the committee is in doubt as to whether the candidate species should be included in a processed product standard based on the above information, the committee may decide to form a working group to oversee sensory evaluation of the product(s) of the candidate species.

142. Decides which are the laboratories selected to perform the sensory evaluation and designates the leading laboratory in charge of coordinating the assessment and preparing the final report.

143. Decides which are the species selected to be compared with the candidate species.

144. Reviews the report of the working group on sensory evaluation.

145. Decides if the candidate species is adequate for inclusion in the relevant standard.

146. Transmits the proposed amendment of the standard to the Commission for its adoption.

Working group

147. The working group performs the following functions:

a) reviews the documentation provided by the proposing Member(s);

b) oversees the sensory evaluation;

c) examines the laboratory report on the sensory evaluation; and

d) informs the committee if the candidate species satisfy the requirements for inclusion in the relevant standard.

148. If a working group is not established, then the tasks of the working group will be conducted by the committee.

Information required

149. A Member(s) willing to propose the inclusion of a new species into a standard should, when submitting the proposal, provide the following information to the committee.

Candidate species description

150. To be valid, the information provided should originate from an appropriate recognized institute(s) or credible sources, e.g. literature databases.

151. Species description should include, in order to allow the identification of the products (both as whole fish and commercially processed products):

a) the scientific name, either from credible source e.g. FISHBASE[xiv] or catalogue of fishes, or if appropriate by attestation from an appropriate recognized institution;

b) morphological and anatomical characteristics (including illustrative material as appropriate);

c) taxonomic position of the candidate species in relation to all the species listed in the relevant Codex standard, presented in the form of a dendrogram or a list; the reference of the database(s) used for taxonomic classification (for example FAO database) or bibliographic references; and

d) where appropriate, depending on the product, specific DNA and/or electrophoretic protein profile sequence from international database(s).

Economic data of the candidate species

152. Resources

a) Location of the main capture grounds on the FAO map "Major Fishing Areas for Statistical Purposes".[xv]

b) Yearly catches or the aquaculture production of the candidate species, preferably for the past five years if data are available.

c) Estimate of volume of stocks present in the natural environment if available.

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xiv https://www.fishbase.se/search.php
xv See FAO Fisheries Department Fishing Maps

Processing technology and marketing

153. Data on processed products of the candidate species:

a) types of marketed products;

b) trade names used;

c) main processing treatment(s) e.g. canning, marinating, smoking; and

d) annual production (preferably for the past five years if data are available).

154. Data on international trade of food products derived from the species (yearly quantity and values preferably for the past five years if data are available).

Principles of the sensory evaluation procedure

155. The sensory evaluation procedure has to be carried out by three laboratories with relevant proven expertise in sensory evaluation of fish and fishery products. Ideally, the three laboratories should be chosen from different Codex regions, preferably excluding the proposing Member(s). The proposing Member(s) may at this stage of the procedure suggest the three laboratories that can carry out independent verification. The committee may decide to choose other laboratories than those suggested. These three laboratories have to be accepted by the committee as suitable for the task. The laboratories will be chosen from countries where the products are mainly consumed, when possible. The committee has to designate one of the three laboratories as the leading laboratory, which will coordinate the tasks. The proposing Member proposes the three species to be compared with candidate species.

156. The performance of the tests should conform to the *Guidelines for the sensory evaluation of fish and shellfish in laboratories* (CXG 31-1999).[11]

157. In addition, the three laboratories shall use the same protocol including:

a) the sensory evaluation method;

b) the species to be compared (candidate species and at least three species currently included in the description section of the pertinent standard);

c) the sampling protocol (e.g. number of samples, sampling period, kind of products); and

d) the criteria and parameters to evaluate the results.

Report of the sensory evaluation of the candidate species

158. The leading laboratory shall provide a report with the results of the sensory evaluation from the designated laboratories.

159. The report on the sensory evaluation should make clear whether whole fish or processed products from the candidate species are or are not significantly different from products covered by the relevant standard.

160. The working group reviews the laboratory report and presents recommendations to the committee for consideration regarding the inclusion of the candidate species.

Final committee decision

161. When the committee has decided to conduct a sensory evaluation, it should decide, on the basis of the working group recommendations, whether the candidate species is suitable for inclusion in the relevant standard.

162. If affirmative, the committee forwards the proposed draft amendment of the standard to the Commission for its adoption.

2.10 Principles for the establishment of Codex methods of analysis

Purpose of Codex methods of analysis

163. 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*

Defining methods (Type I)

164. 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.

Reference methods (Type II)

165. 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.

Alternative approved methods (Type III)

166. Definition: A Type III method is one which meets the criteria required by CCMAS for methods that may be used for control, inspection, or regulatory purposes. **Example**: Volhard Method or Mohr Method for chlorides.

Tentative method (Type IV)

167. 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 Committee on Methods of Analysis and Sampling have not yet been determined. **Example**: chlorine by X ray fluorescence, estimation of synthetic colours in foods.

General criteria for the selection of methods of analysis

168. Official methods of analysis elaborated by international organizations involved with a food or group of foods should be preferred.

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

a) selectivity;

b) accuracy;

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

d) limit of detection;

e) sensitivity;

f) practicability and applicability under normal laboratory conditions; and

g) other criteria which may be selected as required.

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

171. All proposed methods of analysis must have direct pertinence to the Codex standard to which they are directed.

172. 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

173. 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, paragraphs 164 to 167 above, together with other appropriate criteria, e.g. recovery factors.

General criteria for the selection of single-laboratory validated methods of analysis

174. 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:

a) The method is validated according to an internationally recognized protocol (e.g. those referenced in the harmonized International Union of Pure and Applied Chemistry (IUPAC) *Guidelines for single-laboratory validation of methods of analysis*).[12]

b) The use of the method is embedded in a quality system in compliance with the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) standard 17025: *Standard or principles of good laboratory practice*.[13]

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

a) regular participation in proficiency schemes, where available;

b) calibration using certified reference materials, where applicable;

c) recovery studies performed at the expected concentration of the analytes; and

d) verification of result with other validated method where available.

Working instructions for the implementation of the criteria approach in Codex

176. 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.

177. 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 CCMAS to "convert" that method into appropriate criteria. The criteria will then be considered by 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 1: These criteria are applicable to fully validated methods except for methods such as PCR and ELISA, which require other set of criteria.

Note 2: The approaches described for developing method performance criteria are intended for single-analyte provisions. The approaches described may not be suitable for provisions involving sum of components. There are numerous ways in which methods and limits that involve a sum of components can be converted into method performance criteria, but this should be undertaken with care on a case-by-case basis.

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

179. 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 CCMAS may establish appropriate criteria as above.

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

a 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.

b 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

Recommendations for establishing numeric values for method criteria

180. 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.

The applicability

181. 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 ≥ 10^{-7}, the minimum applicable range should be: ML ± 3sR
- For ML < 10^{-7}, the minimum applicable range should be: ML ± 2sR

182. 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 two corresponds to a confidence level of approximately 95 percent, and a coverage factor of three corresponds to a confidence level about 99 percent. As 99 percent is often used as an action level in control charts, a coverage factor of three 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 two is recommended, as a coverage factor of three 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:

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

184. For concentration ratios ≥ 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})

185. By rearranging the equation with respect of sR, the following equation is obtained:

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

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

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

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}):

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

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

186. For concentration ratios < 10^{-7}, the Thompson theory is applied, i.e. $PRSD_R$ = 22% and hence $_{SR}$ = 0.22 · ML

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

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

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

Table 2 **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.

Limit of detection (LOD) and limit of quantification (LOQ)

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

188. The numeric value for the 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.

189. The numeric value for the 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.

The method precision, derived from collaborative method performance studies

190. 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 ($PRSD_R$)

191. 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 percent:

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

192. The numeric values for the precision given in Table 3 are also based on the Horwitz/Thompson equation. For some analyses, using advanced techniques, a better precision can be obtained.

Table 3 **Precision requirement at different concentrations based on the Horwitz/ Thompson equation.**

	Thompson	Horwitz equation ($2C^{-0.1505}$)							
Concentration (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.

Recovery

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

Trueness

194. 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.

Examples on how to establish criteria for a provision

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

According to the *General standard for contaminants and toxins in food and feed*, the ML for lead in fruit juices is 0.05 mg/kg.[2] According to the recommendations for obtaining numeric values for the characteristics based on the ML, the criteria would be those in Table 2.

Table 4 **Recommendation for numeric criteria values for lead in fruit juice**

Applicability:	**Analyte:**	Lead
	Matrix/provision:	Juice
	ML	0.05 mg/kg
Lower level of min. application range		≤ 0.03 mg/–g (= ML - 2sR = 0.–5 mg/kg - 0.44 · 0.05 mg/kg). See Table 1
	LOD	≤ 0.01 mg/kg (= ML · 1/5 = 0.05 mg/kg · 1/5)
	LOQ	≤ 0.02 mg/kg (= ML · 2/5 = 0.05 mg/kg · 2/5)
Precision		For concentration at 0.05 mg/kg, the RSD_R ≤ 44%, See Table 2
Recovery		The method procedure does not include an extraction step and hence recovery is of no relevance.
Trueness		The method procedure does not include an extraction step and hence recovery is of no relevance.

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

196. In Table 5 examples on method criteria are given for certain MLs.

Table 5 **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 (≤ mg/kg)	0.0002	0.002	0.01	0.1	1	10	100	1000
LOQ (≤ mg/kg)	0.0004	0.004	0.02	0.2	2	20	200	2000
RSD_R (≤ %)	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.

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

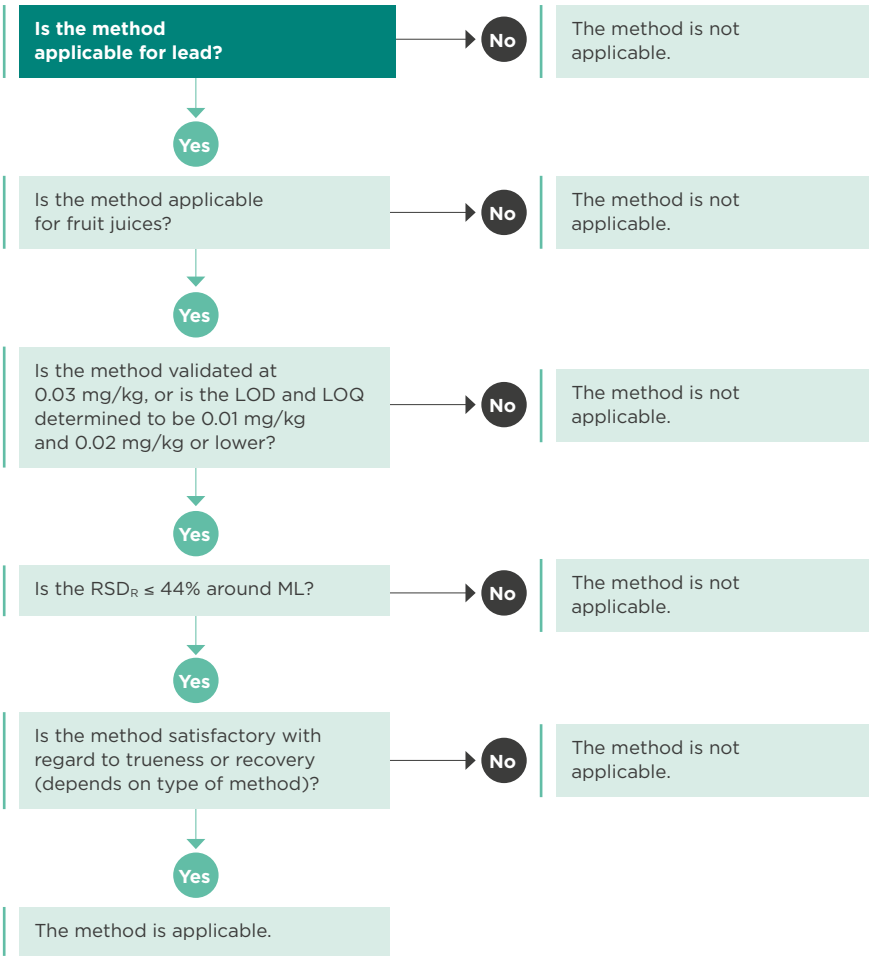
197. To review a method for possible compliance with the established criteria, the method performance characteristics have to be assessed. The result of a method performance study is available in the method and/or published in an international journal.

Example on assessing methods for compliance

198. 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 percent, the RSD_R obtained from the method performance study should then not be higher than 44 percent (corresponding to a 95 percent confidence interval).

199. When assessing a method for compliance, the following steps in Figure 2 should be considered.

Figure 2 **Flow chart for assessing a method for compliance**



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

Table 6 Collaboratively validated methods for analysis of lead

Method No	Applicability	Principle	Assessed level (mg/kg)	LOD (mg/kg)	RSDR (%)	Applicable Yes/No and why
1	All foods	Flame AAS[a]	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[b]	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 RSDR are ok.
8	All foods	ICP-MS[c] after pressure digestion	0.013–2.45	< 0.01	8–47	YES Validation level and RSDR are ok for levels of 0.03 mg/kg and above.

[a] AAS = Atomic absorption spectrometry.
[b] GF-AAS = Graphite furnace atomic absorption spectrometry.
[c] ICP-MS = Inductive coupled plasma – mass spectrometry.

201. Conclusion: Methods No. 3, 7 and 8 are found to be 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 CCMAS

202. When a 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 CCMAS to convert it into suitable generalized analytical characteristics:

a) trueness;

b) applicability (matrix, concentration range and preference given to 'general' methods)

c) limit of detection;

d) limit of quantification;

e) 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;

f) recovery;

g) selectivity;

h) sensitivity; and

i) linearity.

203. These terms are defined in the *Guidelines on analytical terminology* (CXG 72-2009),[14] as are other terms of importance.

204. 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 CCMAS and will be inserted in the appropriate Codex standard.

205. In addition, 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

206. 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.[15]

2.11 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 light of the relevant provision(s) of the applicable Codex standard.

Methods of sampling Types of sampling plans and procedures

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 Sections 3.1 and 4.2 of the *General guidelines on sampling* (CXG 50-2004)[16] may be applied.

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 Sections 3.3 and 4.4 of the *General guidelines on sampling* may be applied.

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 on sampling* may be applied.

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

Sampling methods described in the *General guidelines on sampling* or official methods of sampling elaborated by international organizations involved in a food or a group of foods are preferred. Such official methods may be written using the *General guidelines on sampling* when attracted to Codex standards. When selecting appropriate sampling plans, Table 1 in the *General guidelines on sampling* may be utilized. The appropriate Codex commodity committee should indicate, before it elaborates any sampling plan, or before any plan is endorsed by CCMAS, the following:

a) 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).

b) 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.

c) 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; and

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

d) 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; and

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

General considerations

CCMAS should maintain closest possible relations with all interested organizations working on methods of analysis and sampling.

CCMAS 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.

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

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 CCMAS.

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.

2.12 The use of analytical results: sampling plans, relationship between the analytical results, the measurement uncertainty, recovery factors and provisions in Codex standards

Issues involved

207. 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.

208. 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.

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

210. 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

211. It is recommended that when a commodity committee discusses and agrees on a commodity specification and the analytical methods concerned, it states the following information in the standard:

Sampling plans

212. The appropriate sampling plan, as outlined in the *General guidelines on sampling*, Section 2.1.2 applies. The sampling plan should state:

a) whether the specification applies to every item in a lot, or to the average in a lot, or the proportion non-conforming;

b) the appropriate acceptable quality level to be used; and

c) the acceptance conditions of a lot controlled, in relation to the qualitative/quantitative characteristic determined on the sample.

Measurement uncertainty

213. 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.

Recovery

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

215. 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.

216. 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 a recovery-corrected basis or not.

Significant figures

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

2.13 Provisions on the use of proprietary methods in Codex standards

Definition of a proprietary method of analysis

218. For Codex purposes, a proprietary method of analysis is one that contains protected intellectual property preventing full disclosure of information about the method and/or where the intellectual property owner restricts the use or distribution of the method or materials for its performance such that no alternative source of these would be available. It does not extend to a method which is subject only to copyright.

Requirements

219. Codex committees may occasionally submit methods of analysis which are proprietary, or are based on proprietary aspects, to CCMAS for endorsement. CCMAS encourages the method sponsors to provide data for CCMAS assessment.

a) A proprietary method should not be endorsed if a suitable non-proprietary method of analysis is available which has been or could be endorsed and which has similar or better performance characteristics. This should ensure that no approach is taken such that it appears as if a proprietary method is endorsed by Codex to the detriment of other potential methods; if possible, preference should be given to adopting appropriate method criteria rather than endorsing a specific proprietary method of analysis.

b) Preference should be given to endorsing those methods of analysis where the reagents and/or apparatus are described in the method to the degree that either laboratories or other manufacturers could produce them themselves.

c) Method performance criteria established for proprietary methods are the same as those for non-proprietary methods. Performance criteria should be those stipulated above. If appropriate, information on the effect of manufacturing variability of the proprietary method on the method performance should be provided.

d) After endorsing, any changes that influence performance characteristics must be reported to CCMAS for consideration.

e) A proprietary method should be either fully collaboratively validated or validated and reviewed by an independent third party according to internationally recognized protocols. The results of such studies should be made available for CCMAS. If a proprietary method has not been validated by a full collaborative trial, it may be eligible for adoption into the Codex system as a Codex Type IV method, but not as a Type I, II or III method.

f) While respecting the necessity for reasonable protection of intellectual property, sufficient information should be available to enable reliable use of the method by analysts and to enable evaluation of the performance of the method by CCMAS. In any particular case this may extend beyond performance data, for example to include details of operating principle, at the sole discretion of CCMAS.

g) The supplier or submitter of a proprietary method should demonstrate to CCMAS's satisfaction that the method will be readily available to all interested parties.

h) CCMAS may decline to endorse a proprietary method if restrictions by intellectual property unduly restrict research into determining the method properties, scope of claim and validity or development of improvements to the technology.

220. If suitable non-proprietary methods become available and endorsed, the status of the previously endorsed proprietary method should be reviewed and may be revised.

Section

3

Guidelines for subsidiary bodies

3.1 Guidelines to host governments of Codex committees and ad hoc intergovernmental task forces

Introduction

1. By virtue of Article 7 of the statutes of the Commission and Rule XI.1(b) of its rules of procedure, the Commission has established a number of Codex committees and ad hoc intergovernmental task forces to prepare standards in accordance with Section 2.1: Procedures for the elaboration of Codex standards and related texts to exercise general coordination of its work in specific regions or groups of countries. The rules of procedure of the Commission shall apply, *mutatis mutandis*, to Codex committees, coordinating committees and ad hoc intergovernmental task forces. The guidelines applying to Codex committees, as described in this section, apply also to coordinating committees and to Codex ad hoc intergovernmental task forces.

Composition of Codex committees

Membership

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

Observers

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

Organization and duties

Chairperson and host country

4. The Codex Alimentarius Commission will designate a Member Nation of the Commission, which has indicated its willingness to accept financial and all other responsibility, as responsible for appointing a chairperson of the committee. In the following, this nation is referred to as host country.

5. The host country is responsible for appointing the chairperson of the committee from among its own nationals. Should this person for any reason be unable to take the chair, the host country shall designate another person to perform the functions of the chairperson for as long as the chairperson is unable to do so.

Rapporteurs

6. A committee may appoint at any session one or more rapporteurs from among the delegates present.

Secretariat

7. A Member Nation to which a Codex committee has been assigned is responsible for providing all conference services including the secretariat. The secretariat should have adequate administrative support staff able to work easily in the languages used at the session and should have at its disposal adequate information technology tools. Interpretation, preferably simultaneous, should be provided from and into all languages used at the session, and if the report of the session is to be adopted in more than one of the working languages of the committee, then the services of a translator should be available. The committee secretariat and the Codex Secretariat are charged with the preparation of the draft report in consultation with the rapporteurs, if any.

Duties and terms of reference

8. The duties of a Codex committee shall include:

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

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

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

d) preparation of draft Codex standards within its terms of reference;

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

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

Sessions

Date and place

9. A host country is consulted by the Directors-General of FAO and WHO before they determine when and where a session of this committee shall be convened. In determining the place of the session, consideration should be given to its accessibility.

Co-hosting arrangements

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

11. The country, different from the host country, in which the session is held is in following referred to as "co-host country".

12. The host country and co-host country should ensure that all arrangements necessary to hold a Codex session in the co-host country are completed in a timely manner so as to not interfere with the time frame for the distribution of the official invitations to the session as mentioned in these guidelines.

Note: Practical information and timelines for co-hosting arrangements can be found on the Codex website at: www.codexalimentarius.org.

Co-chairing

13. The host country may invite the co-host country to appoint an official as a co-chair for the session.

Invitations and provisional agenda

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

15. Invitations should include the following:

a) title of the Codex committee;

b) time and date of opening and date of closing of the session;

c) place of the session;

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

e) if appropriate, information on hotel accommodation; and

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

16. Replies to invitations will normally be requested to be sent to reach the chairperson as early as possible and in any case not less than 30 days before the session. A copy should be sent also to the Secretary of the Commission. It is of the utmost importance that by the date requested a reply to invitations should be sent by all those governments and international organizations which intend to participate.

17. The provisional agenda should state the time, date and place of the meeting and should include the following items:

a) adoption of the agenda;

b) if considered necessary, election of rapporteurs;

c) items relating to subject matter to be discussed, including, where appropriate, the step in the Commission's procedure for the elaboration of standards at which the item is being dealt with at the session. There should also be reference to the committee papers relevant to the item;

d) any other business;

e) consideration of date and place of next session; and

f) adoption of draft report.

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

Organization of work

19. A Codex or coordinating committee may assign specific tasks to countries, groups of countries or to international organizations represented at meetings of the committee and may ask Members and international organizations for views on specific points.

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

21. A Codex or coordinating committee may not set up standing subcommittees, whether open to all Members of the Commission or not, without the specific approval of the Commission.

Preparation and distribution of papers

22. Papers for a session should be made available in the relevant languages through the Codex website at least two months before the opening of the session by the host secretariat in collaboration with the Codex Secretariat

23. Papers for a session prepared by participants must be drafted in one of the working languages of the Commission, which should, if possible, be one of the languages used in the Codex committee concerned. These papers should be sent to the chairperson of the committee, with a copy to the Secretary of the Commission in good time to be included in the distribution of papers for the session.

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

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

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

3.2 Guidelines on the conduct of meetings of Codex committees and ad hoc intergovernmental task forces

Introduction

27. By virtue of Article 7 of the statutes of the Commission and Rule XI.1(b) of its rules of procedure, the Commission has established a number of Codex committees and ad hoc intergovernmental task forces to prepare standards in accordance with Section 2.1: Procedures for the elaboration of Codex standards and related texts to exercise general coordination of its work in specific regions or groups of countries. The rules of procedure of the Commission shall apply, *mutatis mutandis*, to Codex committees, coordinating committees and ad hoc intergovernmental task forces. The guidelines applying to the conduct of meetings of Codex committees as described in this section apply also to those of coordinating committees and to those of coordinating committees and to those of Codex ad hoc intergovernmental task forces.

Conduct of meetings

28. Meetings of Codex and coordinating committees shall be held in public unless the committee decides otherwise. Members responsible for Codex and coordinating committees shall decide who should open meetings on their behalf.

29. Meetings should be conducted in accordance with the rules of procedure of the Commission.

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

xvi See Section 5.1 for references for Codex documents.

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

32. Delegations and delegations from Observer countries who wish their opposition to a decision of the committee to be recorded may do so, whether the decision has been taken by a vote or not, by asking for a statement of their position to be contained in the report of the committee. This statement should not merely use a phrase such as: "The delegation of X reserved its position" but should make clear the extent of the delegation's opposition to a particular decision of the committee and state whether they were simply opposed to the decision or wished for a further opportunity to consider the question.

Reports

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

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

b)If action has to be taken before the next meeting of the committee, the nature of the action, who is to take it and when the action must be completed should be clearly stated.

c) Where matters require attention by other Codex committees, this should be clearly stated.

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

i. standards considered at the session and the steps they have reached;

ii. standards at any step of the procedure, the consideration of which has been postponed or which are held in abeyance and the steps which they have reached; and

iii. new standards proposed for consideration, the probable time of their consideration at Step 2 and the responsibility for drawing up the first draft.

34. The following appendices should be attached to the report:

a) list of participants with full postal addresses; and

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

35. The Codex Secretariat should ensure that, as soon as possible and in any event not later than one month after the end of the session, the final report, as adopted in the languages of the committee, is made available to all Members and Observers of the Commission on the Codex website.

36. Circular letters should be issued, as required, following publication of the meeting report requesting comments on proposed draft or draft standards or related texts at Steps 5, 8 or Step 5 (accelerated), with the indication of the date by which comments or proposed amendments must be received in writing, so as to allow such comments to be considered by the Commission.

Drawing up of Codex standards

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

a) The guidance given in the general principles of the Codex Alimentarius.

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

i. the description of the standard or related text;

ii. a brief description of the scope and purpose(s) of the standard or related text;

iii. references including the step which the standard or related text has reached in the Commission's procedures for the elaboration of standards, together with the date on which the draft was approved; and

iv. matters in the draft standard or related text requiring endorsement or action by other Codex committees.

c) That for standards or any related text for a product which includes a number of subcategories, the committee should give preference to the development of a general standard or related text with specific provisions as necessary for subcategories.

3.3 Guidelines to chairpersons of Codex committees and ad hoc intergovernmental task forces

Introduction

38. By virtue of Article 7 of the statutes of the Commission and Rule XI.1(b) of its rules of procedure, the Commission has established a number of Codex committees and ad hoc intergovernmental task forces to prepare standards in accordance with Section 2.1: Procedures for the elaboration of Codex standards and related texts to exercise general coordination of its work in specific regions or groups of countries. The rules of procedure of the Commission shall apply, *mutatis mutandis*, to Codex committees, coordinating committees and ad hoc intergovernmental task forces. The guidelines applying to the chairpersons of Codex committees as described in this section apply also to those of coordinating committees and to those of Codex ad hoc intergovernmental task forces.

Designation

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

Criteria for the appointment of chairpersons

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

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

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

a) to be a national of the Member Nation responsible for appointing the chairperson of the committee;

b) to have a general knowledge in the fields of the subsidiary body concerned and to be able to understand and analyse technical issues;

c) insofar as possible, to be able to serve in a continuing capacity;

d) to be familiar with the system of Codex and its rules, and to have experience in the work of relevant international, governmental, or non-governmental organizations;

e) to be able to communicate clearly both orally;and in writing in one of the working languages of the Commission;

f) to have demonstrated ability in chairing meetings with objectivity and impartiality, and in facilitating consensus building;

g) to exercise tact and sensitivity to issues of particular importance to Members of the Commission; and

h) not to engage and/or not to have engaged in activities which could give rise to a conflict of interest on any item on the agenda of the committee.

Conduct of meetings

43. The Chairperson should invite observations from members of the committee concerning the provisional agenda and in the light of such observations formally request the committee to adopt the provisional agenda or the amended agenda.

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

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

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

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

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

Consensus[xvii]

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

50. Section 2.1: Procedures for the elaboration of Codex standards and related texts allows for full discussion and exchange of views on the issue under consideration, in order to ensure the transparency of the process and arrive at compromises that would facilitate consensus.

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

52. When working out the means of progressing the work of a committee, the chairperson should consider:

a) the need for timely progress in developing standards;

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

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

53. Where there is opposition to an issue under discussion, the chairperson should ensure that the views of concerned Members be taken into consideration by striving to reconcile conflicting arguments before deciding whether consensus has been reached.

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

a) Ensuring that:

i. the scientific basis is well established on current data including, wherever possible, scientific data and intake and exposure information from the developing countries;

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xvii Reference is made to the measures to facilitate consensus (see Appendix: General decisions of the Codex Alimentarius Commission).

ii. where data from developing countries are not available, an explicit request for collecting and making available such data is made; and

iii. where necessary, further studies are carried out in order to clarify controversial issues.

b) Ensuring that issues are thoroughly discussed at meetings of the committees concerned.

c) Organizing informal meetings of the parties concerned where disagreements arise, provided that the objectives of any such meetings are clearly defined by the committee concerned and that participation is open to all interested delegations and Observers in order to preserve transparency.

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

e) Ensuring that matters are not progressed from step to step until all relevant concerns are taken into account and adequate compromises worked out.[xviii]

f) Facilitating increased involvement and participation of developing countries.

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

a) The committee concerned should clearly state the terms of reference of the facilitator.

b) The facilitator should be experienced in Codex matters but neutral on the matter concerned.

c) All parties participating in the process should agree on the selection of the facilitator.

3.4 Criteria and procedural guidelines for Codex committees and ad hoc intergovernmental task forces working by correspondence

Introduction

56. The criteria and procedural guidelines set out in this section are intended to guide the work and conduct of sessions of Codex committees and ad hoc intergovernmental task forces working by correspondence. The rules of procedure of the Commission apply *mutatis mutandis* to committees working by correspondence, unless otherwise specified in these guidelines.

Definitions

57. Working by correspondence: Describes a working modality that can be assigned by the Commission for the development of an approved new work to a Codex committee or ad hoc intergovernmental task force, which will normally not hold sessions that require the simultaneous presence of participants.

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

58. Committees and ad hoc intergovernmental task forces that are assigned to operate under this modality are defined as committees working by correspondence or (CWBC) in the remainder of this document.

59. Session of a CWBC: After the Commission approves the work, assigns it to the committee, and authorizes the committee to work by correspondence, the chairperson of the committee in consultation with the Codex Secretariat will determine dates for registration of Codex Members and Observers to participate in committee deliberations over a defined period of time that will constitute a "session" of the committee. The duration of the session should be of sufficient length to allow for deliberations on agenda items and report adoption. During a session of a CWBC, participants engage in formal consultations by correspondence.

Codex values

60. An overarching consideration and guiding principle in relation to CWBCs is the need to respect and adhere to the Commission's core values of collaboration, inclusiveness, consensus building, and transparency.

Decision to assign work by correspondence

61. In deciding whether an approved new work should be undertaken by a CWBC, the Executive Committee and the Commission's assessment will take into account the following criteria:

Criteria	Reference
i. Scope, objective, and content	Reference
ii. Nature and complexity of the work and its previous and recent history in Codex (for example, this may include, *inter alia*, the time frame to develop the work)	Meeting reports Project document
iii. Urgency and importance	Project document
iv. Availability of adequate scientific information and/or other supporting information, including any support from expert bodies	Project document
v. Potential for assigning the work to another existing committee, with relevant expertise. This should take into consideration whether the work can reasonably be expected to be completed within a set time frame.	Terms of reference of existing Codex committees

Verification of membership and credentials for participation

62. The status and credentials of participants in sessions of CWBCs are subject to scrutiny and verification by the Codex Secretariat, according to official information provided by CCPs.

63. Before work in a CWBC commences, and before each subsequent session of a CWBC, there shall be a period for registration (opening/closing date) during which Members and Observers may register. After the registration period closes, work of the CWBC will take place among participants (i.e. communication will not be copied to the whole Codex membership) between the starting date and end date of a CWBC session as communicated in the invitation.

Sessions

64. To ensure comparability of sessions of committees and ad hoc intergovernmental task forces meeting with simultaneous presence of participants and those meeting by correspondence, a session of a CWBC is defined as in paragraph 59.

65. The time frames for implementing the workplan, working languages, and tasks for the session of the CWBC including the time frames for preparation of working documents[xix] shall be clearly documented and shall be agreed by Members at the outset of the session of the CWBC.

66. The agenda, working documents, and reports should be published on the Codex website.

67. The work and outputs of the CWBC are subject to critical review by the Executive Committee prior to submission to the Commission.

68. Each session of the CWBC shall be concluded within the time frame prescribed by the Commission.

Languages

69. Use of languages for CWBCs shall be in line with Rule XIV of the rules of procedure of the Commission.[xx]

70. It is the responsibility of the host government to ensure adequate funding for translation of working documents and the reports.

Determining a quorum

71. The quorum shall be calculated on the basis of Rule VI (7) of the rules of procedure of the Commission,[xxi] on the understanding that the majority of Members "attending the session" is construed as those "having registered for the session within the registration period" under paragraphs 62 and 63.

72. The absence of a quorum shall be reported to the Commission for further guidance.

Roles of the chairperson and the Codex Secretariat

The role of the chairperson

73. The guidelines to chairpersons of Codex committees and ad hoc intergovernmental task forces[xxii] apply *mutatis mutandis* to chairpersons of CWBCs.

In particular, chairpersons of CWBCs should ensure that:

a) All communications are open to all participating Members and Observers and are carried out in an open and transparent manner and in accordance with any guidelines or protocols that may be established by the Commission.

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xix See Section 3.1: Guidelines to host governments of Codex committees and ad hoc intergovernmental task forces.
xx See Section 1.2: Rules of procedure of the Codex Alimentarius Commission
xxi See note xx above.
xxii See note xix above.

b) All specific matters raised are fully considered by the CWBC.

c) There is enough time and opportunity for Members and Observers to respond or build on comments made by other Members, much like a plenary conversation in real time.

d) The reports of the CWBC clearly document where there are:

i. significant points of difference either in relation to the content of the work or with respect to the advancement of a standard through the step process.

e) The rules/procedures specified in the *Codex Procedural Manual* are adhered to in the CWBC setting.

74. The chairperson(s) of CWBCs may be supported by one or more co-chairpersons.

The role of the Codex Secretariat

75. The Codex Secretariat shall perform its usual functions in support of the efficient operation of the CWBC, including verification of credentials of participants, preparing and circulating CWBC documents, and providing guidance and support to the chairperson on procedural and other matters relating to the work of the CWBC.

Consensus

76. Chairpersons of CWBCs should make every effort to promote consensus-based decision-making, which may include informal discussions by using virtual technologies, and should also consider implementing measures as described in Section 3.3: Guidelines to chairpersons of Codex committees and ad hoc intergovernmental task forces to facilitate consensus building in the elaboration of standards at the committee stage.

Interpretation of silence

77. Means of communication to signal support or objection shall be explicitly clarified in advance of sessions. It is, however, understood that silence or the absence of specific contrary views or objections shall be taken to mean tacit agreement or no objection to proceed as proposed by the chairperson. This point should be clearly communicated to all participants to avoid any misunderstanding when seeking comment on specific matters under discussion including proposed conclusions on progression of a standard through the step process. Chairpersons should allow sufficient time for response to make sure that silence is not the result of temporary technical problems.

Advancement of standards and related texts

78. In determining the level of consensus when progressing through the step process, chairpersons should typically propose a conclusion for consideration by Members, which may be modified and presented as revised to achieve consensus. The same practice should be followed by CWBCs. For example, a chairperson could propose a conclusion to advance a standard by asking a specific question, such as: "*Is there any objection to advancing the draft standard to Step X?*"

79. CWBCs may use a similar approach, including when determining the level of consensus on more detailed points of discussion, such as text changes.

80. Reservations in the correspondence setting should be treated in the same manner as reservations in a physical meeting (i.e. by specifying the basis or rationale of the delegation's opposition to a decision) and should be recorded in the meeting report upon request.[xxiii]

Options when a CWBC is not able to progress work

81. When a CWBC is not able to progress work, it may recommend alternative working mechanisms to working by correspondence to the Commission, which may include but are not limited to:

a) convening a session that requires the simultaneous presence of all participants;

b) referring the work to another committee (other than the original committee) that has relevant expertise on the topic under consideration; or

c) discontinuing the work.

82. In addition, the chairperson has the opportunity, as part of the critical review process, to report on the status of work and prospects for advancement to the Commission for its consideration.

Voting

83. While the rules of procedure of the Commission provide for voting in situations where all efforts to achieve consensus have failed, CWBCs shall not resort to voting to resolve differences. In this regard, Rule VIII shall not be applicable to CWBCs.

84. Instead, the option of alternative mechanisms (as described above) to resolve differences which cannot be addressed otherwise shall be submitted to the Commission for its consideration.

Reporting to the Commission

85. CWBCs shall report to the Commission. As with reports of physical sessions of Codex committees and ad hoc intergovernmental task forces, reports of CWBCs shall be prepared by the Codex Secretariat in consultation with the chairperson.

86. The conventions and practices that apply to drafting of reports of committees holding physical meetings should also be observed, to the extent relevant, by CWBCs. Reports of CWBCs should be objective and accurately reflect the discussions, conclusions, and recommendations.

87. Members of CWBCs have the right to ask that their positions, including reservations and opposition to a recommendation or decision, be recorded in the report of the CBWC.

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xxiii See note xix above.

88. Members of CWBCs should refrain from raising issues or seeking inclusion of comments that were not relevant to the matters under consideration, and such comments will not be included in the report of the session consistent with the Commission's procedure and practice.

89. The draft report of the CWBC session should be made available to all participants who were registered in the session within one week of the conclusion of the agenda and deliberations. The procedures for review and comments should be clearly communicated to all participants.

90. The Codex Secretariat should circulate the final report, as adopted, in not less than three of the working languages of the Commission, within one month of conclusion of the CWBC session.

3.5 Guidelines on physical working groups

Introduction

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

92. Section 1.2: Rules of procedure of the Codex Alimentarius Commission and the guidelines governing the work of a Codex committee shall apply, *mutatis mutandis*, to the working groups this committee establishes, unless stated otherwise in these guidelines.[xxiv]

93. Section 3.4: Guidelines on physical working groups (hereinafter, "working groups") established by Codex committees as described in these guidelines apply also to those established by regional coordinating committees and by Codex ad hoc intergovernmental task forces.

Composition of working groups

Membership

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

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

Observers

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

xxiv The provisions of the *Guidelines to host governments of Codex committees and ad hoc intergovernmental task forces*, the *Guidelines on the conduct of meetings of Codex committees and ad hoc intergovernmental task forces* and the *Guidelines to chairpersons of Codex committees and ad hoc intergovernmental task forces* are especially relevant in this matter.

Organization and duties

97. A Codex committee may decide that the working groups will be managed by the host government secretariat, or by another Member of the Commission, having volunteered to undertake this responsibility and having been accepted by the committee (hereinafter "the host").

Chairperson

98. The host is responsible for appointing the chairperson of the working group.

99. While selecting of the appointee, the host may consider applying, where relevant, the Codex criteria for the appointment of chairpersons.[xxv]

Secretariat

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

Duties and terms of reference

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

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

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

104. They shall not be binding on the committee.

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

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

Sessions

Date

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

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xxv Reference is made to the *Guidelines to chairpersons of Codex committees and ad hoc intergovernmental task forces*.

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

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

Working group notification and provisional agenda

110. Sessions of a working group shall be convened by the chairperson designated by the host.

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

Organization of work

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

Preparation and distribution of papers

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

114. Papers for the session prepared by the participants should be sent to the host secretariat, in good time.

Conclusions

115. The host secretariat should, as soon as possible after the end of the session of a working group, send a copy of the final conclusions, in the form of either a discussion paper or a working document, and the list of participants, to the Codex Secretariat and to the host country secretariat of the committee.

116. Conclusions of a working group shall be made available electronically to all CCPs and Observers by the Codex Secretariat in time to allow full consideration of the working group's recommendations.

117. The Codex Secretariat should ensure that these conclusions are included in the distribution of papers for the next session of the Codex committee.

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

3.6 Guidelines on electronic working groups

Introduction

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

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

121. Codex committees, when deciding to undertake work between sessions, should give the first priority to considering the establishment of electronic working groups (EWGs).

122. Section 1.2: Rules of procedure of the Codex Alimentarius Commission and the guidelines governing the work of a committee shall apply, *mutatis mutandis*, to the EWGs this committee establishes, unless stated otherwise in these guidelines.[xxvi]

123. The guidelines applying to EWGs established by Codex committees, as described in these guidelines, apply also to those established by regional coordinating committees and by Codex ad hoc intergovernmental task forces.

Composition of electronic working groups

Membership

124. Membership of an EWG is notified to the chairperson of the Codex committee and to the host country secretariat of the committee.

125. When establishing an EWG, a Codex committee should ensure, as far as possible, that the membership is representative of the membership of the Commission.

Observers

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

Organization and procedures

127. Codex committees may decide that the EWG will be managed by the host government secretariat, or by another Member of the Commission, having volunteered to undertake this responsibility and having been accepted by the committee (hereinafter "the host"). The host should be notified of the participants in an electronic working group by Codex Members through their CCPs and by Observer organizations.

xxvi See note xxiv above.

Management

128. The host is responsible for the management of the EWG for which it has been appointed.

129. The business of an EWG is transacted exclusively by electronic means.

Secretariat

130. The host is responsible for providing the secretariat of the EWG with all services needed for its functioning, including suitable information technology equipment, and should meet all the requirements agreed upon by the committee.

Duties and terms of reference

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

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

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

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

135. No decision on behalf of the committee, nor vote, either on point of substance or of procedure, shall take place in EWGs.

Electronic working group notification and programme of work

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

Organization of work

137. Circulation of drafts and calls for comments shall include a request for the names, positions, and email addresses of all the persons willing to contribute to the business of the EWG.

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

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

140. An update on the progress of its work shall be presented by the host at each session of the Codex committee which has established it, indicating the number of countries having submitted contributions electronically. A compilation of these contributions should be made available.

Preparation and distribution of materials

141. Materials should be sent to the host secretariat, in good time.

142. The host is responsible for the distribution of all the materials submitted by a participant during the business of the EWG to all other participants of the EWG.

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

Conclusions

144. As soon as possible after the end of the business of an EWG, the host secretariat should send a copy of the final conclusions, in the form of either a discussion paper or a working document and of the list of participants to the Codex Secretariat and to the host country secretariat of the committee.

145. The conclusions of an EWG and the list of participants shall be distributed to CCPs and Observers by the Codex Secretariat in time to allow full consideration of the EWG's recommendations.

146. The Codex Secretariat should ensure that these conclusions are included in the distribution of papers for the next session of the Codex committee, which has established the EWG.

Section

4

Risk analysis

4.1 Working principles for risk analysis for application in the framework of the Codex Alimentarius

Adopted in 2003.

4.2 Definitions of risk analysis terms related to food safety

Adopted in 1997. Amended in 1999, 2003, 2004 and 2014.

4.3 Risk analysis principles applied by the Committee on Food Additives

Adopted in 2012. Previous Codex Committee on Food Additives and Contaminants text adopted in 2005 and amended in 2007.

4.4 Risk analysis principles applied by the Committee on Contaminants in Foods

Adopted in 2012. Previous Codex Committee on Food Additives and Contaminants text adopted in 2005 and amended in 2007.

4.5 Policy of the Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups

Adopted in 2005. Amended in 2007.

4.6 Risk analysis principles applied by the Committee on Residues of Veterinary Drugs in Foods

Adopted in 2007. Revised in 2012 and 2014. Amended in 2018. Revised in 2021 (to add Annex C) and in 2024 (including adding Annex D).

4.7 Risk assessment policy for residues of veterinary drugs in foods

Adopted in 2007. Revised in 2012.

4.8 Risk analysis principles applied by the Committee on Pesticide Residues

Adopted in 2007. Revised in 2013 (to add Annex C), 2014 and 2015.

4.9 Nutritional risk analysis principles and guidelines for application to the work of the Committee on Nutrition and Foods for Special Dietary Uses

Adopted in 2009. Amended in 2017.

4.10 Risk analysis principles and procedures applied by the Codex Committee on Food Hygiene

Adopted in 2010. Revised in 2012.

4.1 Working principles for risk analysis for application in the framework of the Codex Alimentarius

Scope

1. These principles for risk analysis are intended for application in the framework of the Codex Alimentarius.

2. The objective of these working principles is to provide guidance to the Commission and the Joint FAO/WHO expert bodies and consultations, so that food safety and health aspects of Codex standards and related texts are based on risk analysis.

3. Within the framework of the Commission and its procedures, the responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies (risk managers), while the responsibility for risk assessment lies primarily with the joint FAO/WHO expert bodies and consultations (risk assessors).

Risk analysis – general aspects

4. The risk analysis used in Codex should be:

a) applied consistently;

b) open, transparent, and documented;

c) conducted in accordance with both the Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account and the Statements of principle relating to the role of food safety risk assessment (see Appendix section A1.1); and

d) evaluated and reviewed as appropriate in the light of newly generated scientific data.

5. The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Commission,[xxvii] each component being integral to the overall risk analysis.

6. The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties.[xxviii]

7. Effective communication and consultation with all interested parties should be ensured throughout the risk analysis.

8. The three components of risk analysis should be applied within an overarching framework for management of food related risks to human health.

9. There should be a functional separation of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest.

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xxvii See definitions of risk analysis terms related to food safety

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

However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.

10. When there is evidence that a risk to human health exists, but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.

11. Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assess-ment, and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.

12. The needs and situations of developing countries should be specifically identified and taken into account by the responsible bodies in the different stages of the risk analysis.

Risk assessment policy

13. Determination of risk assessment policy should be included as a specific component of risk management.

14. Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased, and transparent.

15. The mandate given by risk managers to risk assessors should be as clear as possible.

16. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

Risk assessment[xxix]

17. The scope and purpose of the particular risk assessment being carried out should be clearly stated and in accordance with risk assessment policy. The output form and possible alternative outputs of the risk assessment should be defined.

18. Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise, experience, and their independence with regard to the interests involved. The procedures used to select these experts should be documented including a public declaration of any potential conflict of interest. This declaration should also identify and detail their individual expertise, experience and independence. Expert bodies and consultations should ensure effective participation of experts from different parts of the world, including experts from developing countries.

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xxix Reference is made to the *Statements of principle relating to the role of food safety risk assessment:* See Appendix: General decisions of the Codex Alimentarius Commission.

19. Risk assessment should be conducted in accordance with Appendix section A1.2: Statements of principle relating to the role of food safety risk assessment and should incorporate the four steps of the risk assessment, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.

20. Risk assessment should be based on all available scientific data. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.

21. Risk assessment should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.

22. Risk assessment should seek and incorporate relevant data from different parts of the world, including from developing countries. These data should particularly include epidemiological surveillance data, analytical and exposure data. Where relevant data are not available from developing countries, the Commission should request that FAO/WHO initiate time-bound studies for this purpose. The conduct of the risk assessment should not be inappropriately delayed pending receipt of these data; however, the risk assessment should be reconsidered when such data are available.

23. Constraints, uncertainties, and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative but should be quantified to the extent that is scientifically achievable.

24. Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.

25. The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.

26. The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

Risk management

27. While recognizing the dual purposes of the Codex Alimentarius are protecting the health of consumers and ensuring fair practices in the food trade, Codex decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers.

Unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.

28. Risk management should follow a structured approach including preliminary risk management activities,[xxx] evaluation of risk management options, monitoring and review of the decision taken. The decisions should be based on risk assessment, and taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the Criteria for the consideration of the other factors referred to in the second statement of principle (see Appendix section A1.1).

29. The Commission and its subsidiary bodies, acting as risk managers in the context of these working principles, should ensure that the conclusion of the risk assessment is presented before making final proposals or decisions on the available risk management options, in particular in the setting of standards or MLs, bearing in mind the guidance given in paragraph 10.

30. In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.

31. The risk management process should be transparent, consistent, and fully documented. Codex decisions and recommendations on risk management should be documented, and where appropriate clearly identified in individual Codex standards and related texts so as to facilitate a wider understanding of the risk management process by all interested parties.

32. The outcome of the preliminary risk management activities and the risk assessment should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk.

33. Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.

34. In order to avoid unjustified trade barriers, risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, the Commission and its subsidiary bodies should seek and take into consideration the potential impact of such measures on trade among its Members and select measures that are no more trade-restrictive than necessary.

35. Risk management should take into account the economic consequences and the feasibility of risk management options. Risk management should also recognize the need for alternative options in the establishment of standards, guidelines, and other recommendations, consistent with the protection of consumers' health.

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

In taking these elements into consideration, the Commission and its subsidiary bodies should give particular attention to the circumstances of developing countries.

36. Risk management should be a continuing process that takes into account all newly-generated data in the evaluation and review of risk management decisions. Food standards and related texts should be reviewed regularly and updated as necessary to reflect new scientific knowledge and other information relevant to risk analysis.

Risk communication

37. Risk communication should:

a) promote awareness and understanding of the specific issues under consideration during the risk analysis,

b) promote consistency and transparency in formulating risk management options/recommendations;

c) provide a sound basis for understanding the risk management decisions proposed;

d) improve the overall effectiveness and efficiency of the risk analysis;

e) strengthen the working relationships among participants;

f) foster public understanding of the process, so as to enhance trust and confidence in the safety of the food supply;

g) promote the appropriate involvement of all interested parties; and

h) exchange information in relation to the concerns of interested parties about the risks associated with food.

38. Risk analysis should include clear, interactive, and documented communication, among risk assessors (Joint FAO/WHO expert bodies and consultations) and risk managers (the Commission and its subsidiary bodies), and reciprocal communication with Members and all interested parties in all aspects of the process.

39. Risk communication should be more than the dissemination of information. Its major function should be to ensure that all information and opinion required for effective risk management is incorporated into the decision-making process.

40. Risk communication involving interested parties should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The need for specific standards or related texts and the procedures followed to determine them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis, and minority opinions expressed in the course of the risk assessment (see paragraph 25).

41. The guidance on risk communication in this document is addressed to all those involved in carrying out risk analysis within the framework of Codex Alimentarius. However, it is also of importance for this work to be made as transparent and accessible as possible to those not directly engaged in the process and other interested parties while respecting legitimate concerns to preserve confidentiality (see paragraph 6).

4.2 Definitions of risk analysis terms related to food safety

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

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

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

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

Hazard characterization
The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical, and physical agents which may be present in food.

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

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

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

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

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

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

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

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

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

Risk estimate
The qualitative and/or quantitative estimation of risk resulting from risk characterization.

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

Risk profile
The description of the food safety problem and its context.

4.3 Risk analysis principles applied by the Codex Committee on Food Additives

Scope

42. This document addresses the application of risk analysis principles by the Codex Committee on Food Additives (CCFA) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). For matters that are not within the terms of reference of JECFA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies or FAO/WHO ad hoc consultations, as approved by the Commission.

43. This document should be read in conjunction with Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius.

CCFA and JECFA

44. CCFA and JECFA recognize that continuous interaction between risk assessors and risk managers is critical to the success of their risk analysis activities.

45. CCFA and JECFA should continue to develop procedures to enhance communication between the two committees.

46. CCFA and JECFA should ensure that their contributions to the risk analysis process involve all interested parties and are fully transparent and thoroughly documented. While respecting legitimate concerns to preserve confidentiality, documentation should be made available, upon request, in a timely manner to all interested parties.

47. JECFA, in consultation with CCFA, should continue to explore developing minimum quality criteria for data requirements necessary for JECFA to perform risk assessments. These criteria are used by CCFA in preparing its priority list for JECFA. The JECFA Secretariat should consider whether these minimum criteria for data have been met when preparing the draft agendas for meetings of JECFA.

CCFA

48. CCFA is primarily responsible for recommending risk management proposals for adoption by the Commission.

49. CCFA shall base its risk management recommendations to the Commission on JECFA's risk assessments, including safety assessments,[xxxi] of food additives.

50. In cases where JECFA has performed a risk assessment and CCFA or the Commission determines that additional scientific guidance is necessary, CCFA or Commission may make a more specific request to JECFA to obtain the scientific guidance necessary for a risk management decision.

51. CCFA's risk management recommendations to the Commission with respect to food additives shall be guided by the principles described in the preamble and relevant annexes of the Codex *General standard for food additives* (CXS 192-1995) (GSFA).[1]

52. CCFA's risk management recommendations to the Commission that involve health and safety aspects of food standards shall be based on JECFA's risk assessments and other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the Criteria for the consideration of the other factors referred to in the second statement of principle (see Appendix section A1.1).

53. CCFA's risk management recommendations to the Commission shall take into account the relevant uncertainties and safety factors described in the risk assessments and the recommendations by JECFA.

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xxxi Safety assessment – an approach that focuses on the scientific understanding and measurement of chemical hazards as well as chemical exposures, and ultimately the risks associated with them. Often used synonymously with risk assessment (EHC 240 – Glossary).

54. CCFA shall endorse maximum use levels only for those additives for which (i) JECFA has established specifications of identity and purity; and (ii) JECFA has completed a risk assessment and established a health-based guidance value.

55. CCFA shall take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending maximum use levels for additives.

56. When establishing its standards, codes of practice, and guidelines, CCFA shall clearly state when it applies any other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the Criteria for the consideration of the other factors referred to in the second statement of principle (see Appendix section A1.1), in addition to JECFA's risk assessment, and specify its reasons for doing so.

57. CCFA's risk communication with JECFA includes prioritizing substances for JECFA review with the view towards obtaining the best available risk assessment for purposes of elaborating safe conditions of use for food additives.

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

a) consumer protection from the point-of-view of health and prevention of unfair trade practices;

b) CCFA's terms of reference;

c) JECFA's terms of reference;

d) the Commission's strategic plan, its relevant plans of work and Section 2.3: Criteria for the establishment of work priorities;

e) the quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;

f) the prospect of completing the work in a reasonable period of time;

g) the diversity of national legislation and any apparent impediments to international trade;

h) the impact on international trade (i.e. magnitude of the problem in international trade);

i) the needs and concerns of developing countries; and

j) work already undertaken by other international organizations.

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

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

61. CCFA requests JECFA to review any methods and guidelines being considered by CCFA for assessing maximum use levels for additives. CCFA makes any such request with a view towards obtaining JECFA's guidance on the limitations, applicability, and appropriate means for implementation of a method or guideline for CCFA's work.

JECFA

62. JECFA is primarily responsible for performing the risk assessments upon which CCFA and ultimately the Commission base their risk management decisions.

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

64. JECFA should strive to provide CCFA with science-based risk assessments that include the four components of risk assessment as defined by Commission and safety assessments that can serve as the basis for CCFA's risk management discussions. For additives, JECFA should continue to use its safety assessment process for establishing acceptable daily intake (ADIs).

65. JECFA should strive to provide CCFA with science-based quantitative risk assessments for food additives in a transparent manner.

66. JECFA should provide CCFA with information on the applicability and any constraints of the risk assessment to the general population to particular subpopulations and should, as far as possible, identify potential risks to populations of potentially enhanced vulnerability (e.g. children, women of childbearing age, the elderly).

67. JECFA should also strive to provide CCFA with specifications of identity and purity essential to assessing risk associated with the use of additives.

68. JECFA should strive to base its risk assessments on global data, including data from developing countries. These data should include epidemiological surveillance data and exposure studies.

69. JECFA is responsible for evaluating exposure to additives.

70. When evaluating intake of additives during its risk assessment, JECFA should take into account regional differences in food consumption patterns.

71. JECFA should communicate to CCFA the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA should provide CCFA with a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment.

72. JECFA should communicate to CCFA the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.

73. JECFA's risk assessment output in response to requests by CCFA is limited to presenting its deliberations and the conclusions of its risk assessments in a complete and transparent manner. JECFA's communication of its risk assessments should not include the consequences of its analyses on trade or other non-public health consequence. Should JECFA include in the risk assessments alternative risk management options, JECFA should ensure that these are consistent with Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius and risk analysis principles applied by CCFA.

74. When establishing the agenda for a JECFA meeting, the JECFA Secretariat works closely with CCFA to ensure that CCFA's risk management priorities are addressed in a timely manner. With respect to food additives, the JECFA Secretariat should normally give first priority to compounds that have been assigned a temporary ADI, or equivalent. Second priority should normally be given to food additives or groups of additives that have previously been evaluated and for which an ADI, or equivalent, has been estimated, and for which new information is available. Third priority should normally be given to food additives that have not been previously evaluated.

75. When establishing the agenda for a JECFA meeting, the JECFA Secretariat should give priority to substances that are known or expected to cause problems in international trade or that present an emergency or imminent public health risk.

4.4 Risk analysis principles applied by the Codex Committee on Contaminants in Foods

Scope

76. This document addresses the applications of risk analysis principles by the Codex Committee on Contaminants in Foods (CCCF) and JECFA. For urgent matters that may pose human health risk and for matters that are not in the terms of reference of JECFA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies, or FAO/WHO ad hoc consultations.

77. This document should be read in conjunction with the Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius.

78. This document also applies to contaminants and toxins in feed in cases where the contaminant in feed can be transferred to food of animal origin and can be relevant for public health. This excludes feed[xxxii] additives, processing aids and agricultural and veterinary chemical residues that are the responsibility of other relevant Codex committees.

General principles of CCCF and JECFA

79. CCCF is primarily responsible for recommending risk management proposals for adoption by the Commission.

80. JECFA is primarily responsible for performing the risk assessments upon which CCCF and ultimately the Commission base their risk management recommendations.

81. CCCF and JECFA recognize that interaction between risk assessors and risk managers is critical to the success of their risk analysis activities. CCCF and JECFA should continue to develop procedures to enhance interaction between the two bodies.

xxxii The term "feed" refers to both "feed (feeding stuffs)" and "feed ingredients" as defined in the *Code of practice on good animal feeding* (CXC 54-2004).[17] For the purposes of these principles, feed refers only to food-producing animals and does not cover feed for pet animals.

82. CCCF and JECFA should ensure that their contributions to the risk analysis process involve all interested parties, are fully transparent and thoroughly documented. While respecting legitimate concerns to preserve confidentiality, documentation should be made available, upon request, in a timely manner to all interested parties.

83. JECFA, in consultation with CCCF, should continue to explore developing minimum quality criteria for data requirements necessary for JECFA to perform risk assessments. These criteria should be used by CCCF in preparing its priority list for JECFA. The JECFA Secretariat should consider whether these minimum requirements for data availability have been met when preparing the draft agendas for meetings of JECFA.

CCCF

Communication with JECFA

84. CCCF's risk communication with JECFA includes prioritizing substances for JECFA assessment with a view to obtaining the best quality risk assessment for contaminants and toxins in food and feed.

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

a) consumer protection from the point-of-view of health and prevention of unfair trade practices;

b) CCCF's terms of reference;

c) JECFA's terms of reference;

d) the Commission's strategic plan, its relevant plans of work and Section 2.3: Criteria for the establishment of work priorities;

e) the quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;

f) the prospect of completing the work in a reasonable period of time;

g) the diversity of national legislation and any apparent impediments to international trade;

h) the impact on international trade (i.e. magnitude of the problem in international trade);

i) the needs and concerns of developing countries; and

j) work already undertaken by other international organizations.

86. When referring substances to JECFA, CCCF shall provide a clearly defined scope for the risk assessment request, background information and explain the reasons for the request when chemicals are nominated for evaluation.

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

88. CCCF may request JECFA to review any methods and guidelines being considered by CCCF for assessing MLs for contaminants and toxins. CCCF would make such request in order to obtain JECFA's guidance on the limitations, applicability and appropriate means for implementation of a particular method or guideline.

89. In cases where JECFA has performed a risk assessment and CCCF and ultimately Commission determines that additional scientific guidance is necessary, CCCF or Commission may make a more specific request to JECFA to obtain the scientific guidance necessary for a decision on a risk management recommendation.

Risk management

90. CCCF's risk management recommendations to the Commission with respect to contaminants and toxins shall be guided by the principles described in the preamble and relevant annexes of the *General standard for contaminants and toxins in food and feed* (CXS 193-1995).[2]

91. CCCF's risk management recommendations to the Commission that involve safety aspects of food and feed standards for human health shall be based on JECFA's risk assessments and shall take into account the relevant uncertainties and safety factors in the risk assessment and recommendations described by JECFA. When establishing its standards, codes of practice, and guidelines, CCCF shall clearly state when it applies any other legitimate factors, in addition to JECFA's risk assessment, in accordance with the Appendix section A1.1: Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account and specify its reasons for doing so.

92. CCCF shall endorse MLs only for those contaminants for which: 1) JECFA or other FAO/WHO expert consultations have performed a quantitative risk assessment; 2) meet the criteria established as a significant contributor to total dietary exposure for consumers (as per Section 4.5: Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups); and 3) the level of the contaminant in food or feed can be determined through appropriate sampling plans and analytical methods, as adopted by Codex. CCCF should take into consideration the analytical capabilities of developing countries unless public health considerations require otherwise.

93. CCCF may also set MLs in order to address and distinguish the justifiable presence of the substances from intentional unauthorized use in food and feed which may give rise to a human health concern.

94. CCCF shall take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending MLs for contaminants and toxins in food and feed.

95. Before finalizing proposals for MLs for contaminants and toxins, CCCF shall seek the scientific advice of JECFA about the validity of the analysis and sampling aspects, about the distribution of concentrations of contaminants and toxins in food or feed and about other relevant technical and scientific aspects, as necessary to provide for a suitable scientific basis for its risk management proposals to Commission.

JECFA

Preparation of risk assessment

96. When establishing the agenda for a JECFA meeting, the JECFA Secretariat works closely with CCCF and the Codex Secretariat to ensure that CCCF's work priorities are addressed in a timely manner. The JECFA Secretariat should give first priority to substances that present an emergency or imminent public health risk and then to substances that are known or expected to cause problems in international trade.

Risk assessment

97. The selection of JECFA experts to participate in any specific meeting should be made after a careful consideration of the necessary scientific competence and experience required for the assessment of the substances on the agenda and independence, taking into account gender and geographical representation to ensure that all regions are represented.

98. JECFA should provide CCCF with science-based risk assessments that include the four components of risk assessment as defined by the Commission. JECFA should determine, to the extent possible, the risks associated with various levels of dietary exposure to contaminants and toxins. Because of the lack of appropriate information, however, this may be possible only on a case-by-case basis.

99. JECFA should strive to base its risk assessments on global data, including data from developing countries. These data should include epidemiological surveillance data and exposure studies.

100. When evaluating dietary exposure to contaminants and toxins during its risk assessment, JECFA should take into account regional differences in food consumption patterns.

Communication with CCCF

101. JECFA should strive to provide CCCF with science-based quantitative risk assessments in a transparent manner.

102. JECFA should provide CCCF with information on the applicability and any constraints, uncertainties, and assumptions of the risk assessment to the general population, to particular subpopulations and should, as far as possible, identify potential risks to populations of potentially enhanced vulnerability (e.g. children, women of childbearing age and the elderly).

103. JECFA should provide to CCCF its scientific views on the validity and the distribution aspects of the available data regarding contaminants and toxins in food and feed, which have been used for exposure assessments, and should give details on the magnitude of the contribution to the exposure from specific foods and feeds as may be relevant for the risk management recommendations of CCCF.

104. JECFA should communicate to CCCF the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA should provide CCCF with a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment.

105. JECFA should communicate to CCCF the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.

106. JECFA's risk assessment output to CCCF is limited to presenting its deliberations and the conclusions of its risk assessments in a complete and transparent manner. JECFA's communication of its risk assessments should not include the consequences of its analyses on trade or other non-public health consequence. Should JECFA include risk assessments of alternative risk management options, JECFA should ensure that these are consistent with Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius.

4.5 Policy of the Codex Committee on Contaminants in Food for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups

Introduction

107. Maximum levels (MLs) do not need to be set for all foods that contain a contaminant or a toxin. The preamble of the *General standard for contaminants and toxins in food and feed* states in Section 1.3.2 that MLs shall only be set for those foods in which the contaminant may be found in amounts that are significant for the total exposure of the consumer. They should be set in such a way that the consumer is adequately protected. Setting standards for foods that contribute little to dietary exposure would mandate enforcement activities that do not contribute significantly to health outcomes.

108. Exposure assessment is one of the four components of risk assessment within the risk analysis framework adopted by Codex as the basis for all standard-setting processes. The estimated contribution of specific foods or food groups to the total dietary exposure to a contaminant as it relates to a quantitative health hazard endpoint (e.g. PMTDI, PTWI)[xxxiii] provides further information needed for the setting of priorities for the risk management of specific foods/food groups. Exposure assessments must be guided by clearly articulated policies elaborated by Codex with the aim of increasing the transparency of risk management decisions.

109. The purpose of this section is to outline steps in contaminant data selection and analysis undertaken by JECFA when requested by CCCF to conduct a dietary exposure assessment.

110. The following components highlight aspects of JECFA's exposure assessment of contaminants and toxins that contribute to ensuring transparency and consistency of science-based risk assessments. Exposure assessments of contaminants and toxins in foods are performed by JECFA at the request of CCCF. CCCF will take this information into account when considering risk management options and making recommendations regarding contaminants and toxins in foods.

xxxiii Provisional maximum tolerable daily intake (PMTDI) and provisional tolerable weekly intake (PTWI) of essential elements.

Estimation of total dietary exposure to a contaminant or toxin from foods/food groups

111. JECFA uses available data from Members and from the global environment monitoring system (GEMS) Food Operating Programme[xxxiv] for analytical laboratories system on contaminant levels in foods and the amount of foods consumed to estimate total dietary exposure to a contaminant or toxin. This is expressed as a percentage of the tolerable intake (e.g. PTDI, PTWI, or other appropriate toxicological reference point). For a carcinogen with no clear threshold, JECFA uses available data on intake combined with data on carcinogenic potency to estimate potential population risks.

112. Median/mean contaminant levels in foods are determined from available analytical data submitted by countries and from other sources. These data are combined with information available for the GEMS/Food consumption cluster diets to generate dietary exposure estimates for regions in the world. JECFA provides an estimate as to which of the GEMS/Food consumption cluster diets are likely to approach or exceed the tolerable intake.

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

114. JECFA performs exposure assessments if requested by CCCF using the GEMS/Food consumption cluster diets and, if needed, available national consumption data to estimate the impact on dietary exposure of proposed alternative MLs to inform CCCF about these risk management options.

Identification of foods/food groups that contribute significantly to total dietary exposure of the contaminant or toxin

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

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

117. The criteria are as follows:

a) foods or food groups for which exposure to the contaminant or toxin contributes approximately 10 percent[xxxv] or more of the tolerable intake (or similar health hazard endpoint) in one of the GEMS/Food consumption cluster diets; or

b) foods or food groups for which exposure to the contaminant or toxin contributes approximately 5 percent or more of the tolerable intake (or similar health hazard endpoint) in two or more of the GEMS/Food consumption cluster diets; or

xxxiv https://extranet.who.int/gemsfood/
xxxv Rounded to the nearest 1/10th of a percent.

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

Generation of distribution curves for concentrations of the contaminant in specific foods/food groups (concurrent with paragraphs 111 to 114), or subsequent step)

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

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

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

Assessment of the impact of agricultural and production practices on contaminant levels in foods/food groups (concurrent with paragraphs 111 to 114, or subsequent step)

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

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

4.6 Risk analysis principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods

Purpose – Scope

123. The purpose of this document is to specify risk analysis principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF). This document should be read in conjunction with Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius.

Parties involved

124. Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius defines the responsibilities of the various parties involved. The responsibility for providing advice on risk management concerning residues of veterinary drugs lies with the Commission and its subsidiary body, CCRVDF, while the responsibility for risk assessment lies primarily with JECFA.

125. CCRVDF shall base its risk management recommendations in relation to maximum residue limits (MRLs) to the Commission on JECFA's risk assessments of veterinary drugs.

126. CCRVDF is primarily responsible for recommending risk management proposals for adoption by the Commission.

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

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

Risk management in CCRVDF

129. Risk management should follow a structured approach including:

a) preliminary risk management activities;

b) evaluation of risk management options; and

c) monitoring and review of decisions taken.

130. The decisions should be based on risk assessment, and take into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for fair practices in food trade, in accordance with the Criteria for the consideration of the other factors referred to in the second statement of principle (see Appendix section A1.1).

Preliminary risk management activities

131. This first phase of risk management covers:

a) establishment of risk assessment policy for the conduct of the risk assessments;

b) identification of a food safety problem;

c) establishment of a preliminary risk profile;

d) ranking of the hazard for risk assessment and risk management priority; and

e) commissioning of the risk assessment.

Risk assessment policy for the conduct of the risk assessment

132. The responsibilities of the CCRVDF and JECFA and their interactions along with core principles and expectations of JECFA evaluations are provided in Section 4.7: Risk assessment policy for residues of veterinary drugs in foods, established by the Commission.

Establishment of priority list

133. CCRVDF identifies, with the assistance of Members, the veterinary drugs that may pose a consumer safety problem and/or have a potential adverse impact on international trade. CCRVDF establishes a priority list for assessment by JECFA, extrapolation of MRLs by CCRVDF in accordance with Annex C and establishment of action levels by CCRVDF in accordance with Annex D.

134. In order to appear on the priority list of veterinary drugs for the establishment of a MRL, the proposed veterinary drug shall meet some or all of the following criteria:

a) a Member has proposed the compound for evaluation (a template for information recommended for consideration in the priority list by CCRVDF has been completed and will be available to the committee);

b) a Member has established good veterinary practices with regard to the compound;

c) the compound has the potential to cause public health and/or international trade problems;

d) the compound is available as a commercial product; and

e) there is a commitment that a dossier will be made available.

135. CCRVDF takes into account the protection of confidential information in accordance with the World Trade Organization (WTO) Agreement on trade-related aspects of intellectual property rights (TRIPS)[18] – Section 7: Protection of Undisclosed Information – Article 39 and makes every effort to encourage the willingness of sponsors to provide data for JECFA assessment.

Establishment of a preliminary risk profile

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

137. Where CCRVDF considers the possible extrapolation of MRLs to other species, this should be clearly identified in the preliminary risk profile. Pre-requisites include:

a) comprehensive data packages or established MRLs for the veterinary drug are available for at least one animal species; and

b) the drug is approved for use in the species for which MRL extrapolation is requested in at least one Member Nation and good veterinary practice has been established.

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

Ranking of the hazard for risk assessment and risk management priority

139. CCRVDF establishes an ad hoc working group open to all its Members and Observers, to make recommendations on the veterinary drugs to include into (or to remove from) the priority list of veterinary drugs for the JECFA assessment. The working group also develops and recommends to CCRVDF the questions to be answered by the JECFA risk assessment. CCRVDF considers these recommendations before agreeing on the priority list, taking into account pending issues. In its report, CCRVDF shall specify the reasons for its choice and the criteria used to establish the order of priority.

140. CCRVDF forwards the agreed priority list of veterinary drugs for the JECFA assessment to the Commission for new work in accordance with Section 2.1: Procedures for the elaboration of Codex standards and related texts.

Commissioning of the risk assessment

141. After approval by the Commission of the priority list of veterinary drugs as new work, CCRVDF forwards it to JECFA with the qualitative preliminary risk profile as well as specific guidance on the CCRVDF risk assessment request. JECFA, WHO and FAO experts then proceed with the assessment of risks related to these veterinary drugs, based on the dossier provided and/or all other available scientific information. CCRVDF may also refer risk management options, with a view towards obtaining JECFA's guidance on the attendant risks and the likely risk reductions associated with each option.

Consideration of the result of the risk assessment

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

When the data are insufficient, JECFA may recommend temporary MRLs on the basis of a temporary ADI using additional safety considerations. If JECFA cannot propose an ADI and/or MRLs due to lack of data, its report should clearly indicate the gaps and a time frame in which data should be submitted. Temporary MRLs may proceed through the step process but should not be advanced to Step 8 for adoption by the Commission until JECFA has completed the evaluation.

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

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

145. CCRVDF may ask JECFA for any additional explanation.

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

147. A delegation may ask JECFA for additional explanation on the scientific concerns, which will be put forward to JECFA by using the concern form (see below).

Using the concern form

148. The concern form is an additional tool for Members to bring scientific concerns to the attention of JECFA concerning its risk assessment.

149. Procedure for the use of the concern form:

a) All concern forms and supporting documentation should be submitted to the JECFA and Codex Secretariats by Members on the proposed MRLs circulated for comments at Step 3 or later in the step procedure, preferably as part of Members comments on the proposed MRLs, or at the latest one month after the CCRVDF session, by using the template recommended in Annex B.

b) Scientific concerns that could not be addressed at the session of the CCRVDF will be described in the concern form and made available for a JECFA review with supporting documentation.

c) Submission of concern form prior to the CCRVDF session might allow the JECFA Secretariat to prepare clarification in response to some concerns during the session.

d) Concerns related to interpretation of the existing data (e.g. review of the ADI) can be submitted without the need for any additional data.

e) If the concern is entered at Step 3 and cannot be addressed at the session, the specific MRLs will not advance beyond Step 5. If the concern is entered at Step 6, the specific MRLs will not advance beyond Step 7.

f) Identical concerns should be considered only once by JECFA.

g) The JECFA Secretariat should schedule the concern for a JECFA review as soon as possible to allow JECFA to respond by the next CCRVDF session.

Evaluation of risk management options

150. CCRVDF shall proceed with a critical evaluation of outcomes of the JECFA risk assessment including the proposals on MRLs and may consider other legitimate factors relevant for health protection and fair-trade practices in the framework of the risk analysis. The Criteria for the consideration of the other factors referred to in the second statement of principle (see Appendix section A1.1) should be taken into account. These other legitimate factors are those agreed during the 12th session of CCRVDF[xxxvi] and subsequent amendments made by this committee.

151. CCRVDF may:

a) recommend the MRLs based on the JECFA assessment;

b) recommend extrapolation of MRLs to one or more other species;[xxxvii]

c) modify the MRLs in consideration of other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade;

d) request JECFA to reconsider the evaluation for the veterinary drug in question;

e) decline to advance the MRLs based on risk management concerns consistent with the risk analysis principles of the Codex Alimentarius and the recommendations provided by JECFA; and

f) develop risk management guidance, as appropriate, for veterinary drugs for which JECFA has not been able to establish an ADI and/or to recommend an MRL, including those with specific human health concern. As a result of this consideration, CCRVDF may refer a range of risk management options to JECFA to obtain guidance on the attendant risks and likely risk reductions.

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

Monitoring and review of the decisions taken

153. Members may ask for the review of decisions taken by the Commission. To this end, veterinary drugs should be proposed for inclusion in the priority list. In particular, review of decisions may be necessary if they pose difficulties in the application of the *Guidelines for the design and implementation of national regulatory food safety assurance programme associated with the use of veterinary drugs in food-producing animals* (CXG 71-2009).[19]

xxxvi ALINORM 01/31, paragraph 11.

xxxvii Approach for the extrapolation of MRLs of veterinary drugs to one or more species is presented in Annex C to these principles.

154. The CCRVDF may request JECFA to review any new scientific knowledge and other information relevant to risk assessment and concerning decisions already taken, including the established MRLs. The CCRVDF should review and update standards or related texts for veterinary drugs in food, as necessary, in the light of new scientific information.

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

Risk communication in the context of risk management

156. In accordance with Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius of the Codex Alimentarius, the CCRVDF, in cooperation with JECFA and the Codex Secretariat, shall ensure that the risk analysis process is fully transparent and thoroughly documented and that results are made available in a timely manner to Members. The CCRVDF recognizes that communication between risk assessors and risk managers is critical to the success of risk analysis activities.

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

ANNEX A

Template for information recommended for consideration in the priority list by the Codex Committee on Residues of Veterinary Drugs in Foods

Administrative information

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

Purpose, scope and rationale

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

Risk profile elements

8. Justification for use
9. Veterinary use pattern, including information on approved uses if available
10. Commodities for which Codex MRLs are required

Risk assessment needs and questions for the risk assessors

11. Specific request to risk assessors

Available information[xxxviii]

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

Timetable

15. Date when data could be submitted to JECFA.

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

ANNEX B
Template for concern form

Submitted by: (name of the delegation)

Date:

Veterinary drug:

Commodity (species and tissues):

MRL (mg/kg):

Present step:

Description of the concern:

Summary of the supporting documentation that will be submitted to JECFA (e.g. toxicology, residue, microbiology, dietary exposure assessment):

ANNEX C
Approach for the extrapolation of maximum residue limits for veterinary drugs to one or more species

General criteria for extrapolation:

1. Extrapolation should take place only between the same tissues/food commodities in the reference and concerned species (e.g. muscle to muscle, fat to fat etc.).

2. Extrapolation of reference species MRLs to a concerned species on a one-to-one basis should be considered only if all of the following are satisfied:

a) The reference and concerned species are related (see "A note on terminology").

b) The marker residue in the reference species is the parent compound only or is the same as the total residues of toxicological concern, or the Codex MRL status in the reference species is 'unnecessary' and there is an expectation that the active substance will be used under the same conditions (i.e. by the same administration routes and at similar doses) in both species. In cases where the active substance is a combination of homologous compounds, the marker residue can be considered the same as the parent if it is a homolog that is a major component of the active substance.

c) The M:T[xxxix] (the marker 'M' to total residues of toxicological concern 'T') established for the reference species can be applied to the concerned species.

Specific criteria for extrapolation

3. In order to ensure that the third of the above-mentioned three general criteria is satisfied, the following specific criteria are proposed:

a) Where identical Codex MRLs have been established in at least two related species on the basis of JECFA recommendations or there is good reason to consider extrapolation from just one related species, these Codex MRLs can be extrapolated to other related species (e.g. extrapolate from cattle and sheep to all ruminants).

Explanatory note: *The existence of identical MRLs in two related species provides grounds upon which to base the assumption that metabolism does not vary significantly within the group of related species – i.e. that the M:T established for the reference species can be applied to the concerned species.*

b) Where identical M:T values have been used in JECFA calculations for two related species but the MRLs recommended (by JECFA) differ, the most conservative set of Codex MRLs (i.e. the MRLs from the species associated with the lowest consumer exposure estimate) can be extrapolated to other related species (e.g. where different MRL values have been established for cattle and sheep and extrapolation is considered to goats, the lowest set of MRLs should be used for extrapolation).

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xxxix EHC 240 (1) defines the marker residue as: The parent drug, or any of its metabolites, or a combination of any of these, with a known relationship to the concentration of the total residue in each of the various edible tissues at any time between administration of the drug and the depletion of residues to safe levels. Where 'total residues of toxicological concern' are not defined, 'total residue' may be used where 'total residue' is defined CXA 5-1993 (2): the total residue of a drug in animal derived food consists of the parent drug together with all the metabolites and drug-based products in the food after administration of the drug to food producing animals. The amount of total residues is generally determined by means of a study using the radiolabelled drug and is expressed as the parent drug equivalent in mg/kg of the food.

Explanatory note: *The fact that JECFA considered it appropriate to use identical M:T values in two related species provides grounds upon which to base the assumption that metabolism does not vary significantly within the group of related species – i.e. that the M:T established for the reference species can be applied to the concerned species.*

c) Where the M:T established by JECFA is 1 in all tissues in a single reference species, the same Codex MRLs can be extrapolated to related species.

Explanatory note: *The fact that the M:T is 1 in all tissues/food commodities indicates that the marker residue includes all the compounds of concern. It is considered reasonable to assume that this would also be the case in the concerned species.*

4. Finally, while the above criteria can be used in all cases, the following additional criteria are proposed for fish, milk, eggs and camelids (i.e. extrapolation for fish, eggs and camelids may be based on the above criteria OR based on the additional criteria below):

a) For fish, where the MRL in muscle/fillet recommended by JECFA was established based on the limit of quantification (LOQ) (e.g. twice the LOQ), the Codex MRL can be extrapolated to all bony fish.

Explanatory note: *The fact that the MRL in muscle/fillet is below the LOQ indicates that residues in muscle/fillet are not measurable and so do not make a significant contribution to the intake calculation. Even if there are differences in metabolism between fish species, the possibility that they will be so dramatic as to result in a level of residues in muscle/fillet sufficiently high to significantly impact on overall consumer exposure is considered unrealistic.*

b) For milk and eggs, where the M:T established by JECFA is 1 (in milk or eggs of a reference species), the milk/egg Codex MRL of the reference species can be extrapolated to milk of other ruminants and eggs of other domesticated poultry species, respectively, even if the M:T is not 1 in tissues.

Explanatory note: *For milk and eggs, there may be a concern that the fat content differs between related species. However, if the M:T is 1 in the reference species this indicates that the M:T is not significantly influenced by the fat content.*

For milk, when extrapolation criteria are not met, if the existing risk assessment information indicates that the dietary exposure to residues from all commodities with MRLs in the reference species provides a large margin of safety relative to the Codex health-based guidance value (HBGV), then CCRVDF might conclude that any potential inter-species M:T differences in milk are not expected to result in a risk to human health. In these cases, CCRVDF might consider extrapolating the MRL for milk to additional species.

c) For camelids, extrapolation of MRLs can be supported where the following criteria are satisfied:

A note on terminology

'Reference species' is used to refer to a species in which Codex MRLs have been established based on a scientific evaluation by JECFA.

'Concerned species' is used to refer to a species for which extrapaolation is being considered.

'Related species' means species belonging to the same category of food-producing species of rumainant and non-ruminant mammals,[a] birds or finfish.[b]

'Unrelated species' is used to refer to species belonging to different categories of food-producing species.

a - The category of non-ruminant food-producing mammals is considered to include pigs, horses, and rabbits.

b - Three distinct classes of fish are usually identified: (i) jawless fish (Agnatha), (ii) cartilaginous fish (Chondrichytes) and (iii) finfish. To date, MRL data have been provided only for finfish, and it is these that are predominantly farmed and eaten. Consequently, it is proposed that MRL extrapolations in fish should be limited to this class. Special attention should be paid to harmonizing the terminology used for the edible tissues.

i) Extrapolation should only occur between the same tissues/food commodities in the reference and concerned species (e.g. muscle to muscle, fat to fat, etc.).

ii) The marker residue is the parent compound.

- In cases where the active substance is a combination of homologous compounds, the marker residue can be considered the same as the parent if it is a homolog that is a major component of the active substance.

iii) For meat tissues, extrapolation of reference species MRLs to camelids on a one-to-one basis should be considered if either:

- identical MRLs have been established in at least one ruminant species and one nonruminant mammalian species based on JECFA recommendations, and the M:T ratio used by JECFA was 1 in all tissues for the ruminant and nonruminant species, OR
- based on JECFA recommendations, identical MRLs have been established in at least one ruminant, nonruminant mammalian, and avian species. JECFA used the same M:T ratio for each tissue type for all three species.

iv) Where conditions 2 and 3 are satisfied, extrapolation of an MRL for milk should also be considered in those cases where the M:T ratio used by JECFA was 1 in milk.

Reporting extrapolated MRLs

5. Where CCRVDF agrees to extrapolate MRLs, it should be clear that these MRLs were established by extrapolation rather than on the basis of a substance/species specific JECFA assessment. An appropriate symbol should be included next to the relevant values reported in the MRL database. Moreover, extrapolated MRLs should be reconsidered in case the reference MRLs are modified or new data/information on the active substance in question becomes available.

ANNEX D

Criteria and procedures for the establishment of action levels for residues of veterinary drugs in food of animal origin resulting from unavoidable and unintentional veterinary drug carryover in non-target animal feed

Definitions and terms

Action level: A concentration of residue resulting from unintended and unavoidable carry-over in a feed of a veterinary drug (expressed in mg/kg or µg/kg on a fresh weight basis) in a non-target animal that is recommended by the Codex Alimentarius Commission to be recognized as acceptable in or on a food, above which action should be taken.

Transfer factor (TF): The ratio between the veterinary drug residue in the tissue or commodity of interest (fat/skin, muscle, liver, kidney, milk, or eggs) and the concentration of veterinary drug in animal feed.

Unavoidable and unintended veterinary drug carry-over in a non-target animal feed: The presence of a veterinary drug in a non-target animal feed caused by the previous manufacture of feed using the same equipment after one or more mitigation procedures have been performed (e.g. flushing, sequencing or physical clean-out).

Non-target animal: An animal unintentionally exposed to a veterinary drug not authorized or registered for use in that animal species or production class.

1. Action levels for unavoidable and unintended presence of veterinary drug residues in food products from non-target animals exposed to veterinary drug carry-over in animal feed will be established based on a scientific risk assessment taking into account food safety and whether the best practice has been followed (e.g. Code of Practice on Good Animal Feeding (CXC 54-2004), Good Manufacturing Practices (GMP) and Hazard Analysis and Critical Control Point (HACCP)) to minimize the unavoidable and unintended veterinary drug carry-over in non- target animal feed, to a level that is achievable after having implemented mitigation measures according to the Code of Practice on Good Animal Feeding.

General criteria for the proposed approach

2. Action levels for the unintended and unavoidable carry-over of veterinary drugs in non-target animal feed to food should be based on the 'As Low as Reasonably Achievable' concept and only be derived where the framework of the Code of Practice on Good Animal Feeding, GMPs, and/or HACCP has been used to minimize the veterinary drug carry-over.

3. Action levels should be developed only to cover situations where low-level residues of an approved/registered veterinary drug used according to good veterinary practices are consistently detected by a competent authority in edible commodities from non-target animals and investigations by the competent authority confirm the source to be unintended and unavoidable carry-over of a veterinary drug in animal feed.

4. Action levels for non-target animals should be derived only for veterinary drugs authorized for use in a target class of animals

5. The residues in food resulting from the authorized or registered use of the veterinary drug plus the residues in food resulting from unavoidable and unintended veterinary drug carry-over in animal feed should not result in an exposure that exceeds the established health-based guidance value (HBGV) for the veterinary drug.

6. Action levels should be derived only for residues of veterinary drugs that have adopted (or JECFA recommended) maximum residue limits (MRLs).

- Action levels should not be established for veterinary drugs for which the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was unable to establish an HBGV or recommend MRLs due to specific human health concerns or inadequate toxicological data.

7. Transfer factors (TFs) can be used to estimate the concentration of residues in edible commodities from non-target animals.

8. Action levels in edible commodities may be derived from the transfer factors and concentration of unintended and unavoidable veterinary drugs in non-target animal feed after appropriate mitigation steps have been performed (e.g. flushing, sequencing, or physical clean-out) following the manufacture of feed containing the maximum authorized concentration of the drug for the target class of animals.

9. Analytical methods should be available for the veterinary drug residue in the edible commodity for which action levels are proposed.

Procedure

10. The following four steps should be followed for setting action levels for residues of veterinary drugs detected in foods of animal origin determined to be caused by unavoidable and unintended veterinary drug carry-over in non-target animal feed based on the Guidelines on the Application of Risk Assessment for Feed (CXG 80-2013) and risk assessment approaches.

Step 1. Assess animal dietary exposure assessment.

Step 2. Estimate anticipated residue levels in food commodities of animal origin.

Step 3. Set Action levels.

Step 4. Evaluate human dietary exposure assessment.

11. CCRVDF will perform **Steps 1, 2, and 3**, and then for **Step 4**, CCVRDF may request that JECFA conduct an appropriate exposure assessment based on the proposed action level derived under **Step 3**.

12. CCRVDF will do an initial Theoretical Maximum Daily Intake (TMDI) calculation, and where there are exceedances, can request such an exposure assessment from JECFA under **Step 4**. CCRVDF may:

- provide JECFA with the proposed action level(s) in the applicable commodity(ies) from **Steps 1-3** and any data that might help with conducting an exposure assessment;
- request JECFA to conduct an exposure assessment that considers exposure from the proposed action level(s) and sources of exposure from the authorized use(s) of the veterinary drug.

13. Data such as residue transfer and residue monitoring data from peer-reviewed scientific literature and/or data previously reviewed by regulatory authorities may be used by CCRVDF in setting action levels for residues in food products from non-target animals, where it can be concluded that it

was due to the unavoidable and unintended veterinary drug carry-over in non-target animal feed.

14. Residue monitoring data, including trace-back information from a competent authority, demonstrating that residues are caused by unavoidable and unintended veterinary drug carry-over in non-target animal feed, should be made available to CCRVDF.

15. CCRVDF may consider the following when evaluating the data:

- Does the data demonstrate that unavoidable and unintended carry-over occurs even when mitigation steps are followed (e.g. flushing, sequencing)?
- Does the data demonstrate that unavoidable and unintended carry-over concentrations of the veterinary drug in the feed of non-target animals cause residues in edible commodities from non- target animals?
- Are the data representative of the various formulations of the veterinary drug available globally?
- Are the data representative of feed mixing practices used globally?

16. The details of the four general steps for setting action levels for residues of veterinary drugs detected in foods of animal origin determined to be caused by unavoidable and unintended veterinary drug carry-over in non-target animal feed are discussed below.

Step 1: Assess animal dietary exposure assessment

17. The veterinary drug carry-over present in non-target feed or feed ingredients will be identified.

18. The anticipated exposure levels for non-target animals will be estimated considering:

- **Option 1:** A default hypothetical carry-over of 1% can be applied to the highest authorized dose of the veterinary drug in feed for the target class of animals in situations where:

  i) unintended and unavoidable carry-over has been demonstrated; and

  ii) suitable data is not available to establish with certainty that unintended and unavoidable carry-over would occur at a level higher (or lower) than 1%.

- **Option 2:** The maximum observed concentration of unavoidable and unintended veterinary drug carry-over in non-target feed determined in feed mills operating under routine good manufacturing conditions. Monitoring data where investigations cannot verify GMP is unsuitable for this purpose.

Step 2: Estimate anticipated residue levels in food of animal origin

a) Calculating the Transfer Factors (TFs)

19. The potential transfer of a veterinary drug from feed to food can be estimated by calculating TFs based on suitable feeding studies in which levels of the

veterinary drug in feed are close to the calculated carryover. This concerns both the route of administration and whether it was via capsule, tablet, or solution as this simulates the pharmacokinetics after ingestion of non-target animal feed. In addition, the similarity of the feed should be considered.

20. TF can be calculated as follows:

$$\mathbf{TF} = \frac{\textbf{residue level in food of animal origin (milk, eggs or tissues) (fresh weight) expressed in mg/kg}}{\textbf{level in total feed ration (dry weight) expressed in mg/kg}}$$

Explanatory notes:

a) The highest individual animal tissue residue level will be used in the TF calculations. The average residue will be used if the highest residue is not reported.

b) In the case of residue levels that are below the limit of quantification of the analytical method (LOQ) and above the limit of detection (LOD) of the analytical method, the TF will be reported as LOQ ÷ feed concentration.

c) Residue values less than the LOD of the analytical method will not be used.

d) If there are multiple feeding studies for a particular animal species, studies that fed the veterinary drug at concentrations most representative of the carry-over level should be used preferentially to calculate the TFs.

e) If multiple TFs are derived from drug concentrations in feed close to the carry-over level, the median transfer factor will be used to estimate the anticipated residue levels in edible animal commodities.

f) Survey/monitoring data from national regulatory bodies or reported in the scientific literature may be used to increase confidence in the estimated residue levels in edible tissues resulting from veterinary drug carry-over under good manufacturing practices.

g) TFs should be calculated for one food commodity (e.g. liver) and should not be applied to a different commodity (e.g. eggs).

h) TFs should be calculated for one species and should not be applied to a different species.

Calculating the anticipated veterinary drug residue transfer level

21. Anticipated veterinary drug residue transfer levels in food of animal origin (including muscle, liver, kidney, skin/fat, milk or egg) of non-target animals can be calculated using the TFs, and the level of veterinary drug in the animal's feed estimated either by hypothetical carry-over rates of the highest authorized dose of the veterinary drug in feed for the target-class of animals or the maximum observed carry-over level as measured in non-target feed from feed mills operating under routine good manufacturing conditions. Monitoring data where investigations cannot verify GMP is unsuitable for this purpose.

$$\textbf{Anticipated residue level} = \mathbf{TF} \times \textbf{veterinary drug carry-over level in animals total feed ration (dry weight)}$$

Step 3: Action levels

22. Action levels for food of animal origin from non-target animals can be estimated based on the anticipated residue levels in food of animal origin from animals exposed under practical conditions.

Explanatory notes:

TF based on a relatively high drug concentration in feed might overestimate the residue concentration in food of animal origin caused by unavoidable and unintended veterinary drug carry-over in animal feed. To account for this, the anticipated residue level in food of animal origin from non-target animals can be the lesser of either:

- the concentration estimated by using the TF; or
- the residue concentration determined to be caused by unavoidable and unintended veterinary drug carry-over in animal feed that satisfied bullet point 2 of the General Criteria.

"Action levels should be developed only to cover situations where low-level residues of an approved/registered veterinary drug used according to good veterinary practices are consistently detected by a competent authority in edible commodities from non-target animals, and investigations by the competent authority confirm the source to be unintended and unavoidable carry-over of a veterinary drug in animal feed".

Step 4: Human dietary exposure assessment

23. An estimate of consumer dietary exposure from residues present at action levels in food of animal origin (eggs, milk, meat, edible offal) from non-target animals will be calculated following approaches for both chronic exposure (based on the ADI) and acute exposure (based on the ARfD, when established).

Explanatory notes:

(a) In performing the dietary exposure assessment, exposure to the relevant foods containing residues at the proposed action level(s) and the other sources of dietary exposure from the authorized use(s) of the veterinary drug (e.g. exposure originating from the current Codex MRLs) should be considered.

(b) An estimate of the ratios for marker residues to total residues of toxicological or microbiological concern (M:T) may be required.

(c) Extrapolation of M:T ratios from one species to a related species (i.e. ruminant to ruminant) is likely feasible if:

- identical or very similar M:T ratios exist for tissues/commodities of two related species; and/or
- the M:T ratios in tissues/commodities of one related species = 1.

(d) Dietary exposure estimates based on the intended use of the veterinary drug plus the residues in food resulting from the proposed action level(s) should not exceed the established health-based guidance value (HBGV).

(e) Seek advice from JECFA if the exposure from residues in food resulting from the intended use of the veterinary drug plus the residues in food resulting from the proposed action level(s) exceeds the established health-based guidance value (HBGV).

4.7 Risk assessment policy for residues of veterinary drugs in foods

Role of JECFA

158. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an independent scientific expert body convened by both Directors-General of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on veterinary drug residues in food.

159. This annex applies to the work of JECFA in the context of Codex and in particular as it relates to advice requests from CCRVDF.

a) JECFA provides CCRVDF with science-based risk assessments conducted in accordance with Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius and incorporating the four steps of risk assessment. JECFA should use its risk assessment process for establishing acute reference doses (ARfD) or ADIs and proposing MRLs, and/or responding to other questions from the CCRVDF.

b) JECFA should take into account all available scientific data and assessments in conducting the risk assessment. It should use available quantitative and qualitative information to the greatest extent possible.

c) Constraints, uncertainties, and assumptions that have an impact on the risk assessment should be clearly communicated by JECFA.

d) JECFA should provide CCRVDF with information on the applicability, public health consequences and any constraints of the risk assessment to the general population and to particular subpopulations and, as far as possible, should identify potential risks to specific groups of populations of potentially enhanced vulnerability (e.g. children).

e) Risk assessment should be based on realistic exposure scenarios.

f) When the veterinary drug is used both in veterinary medicine and as a pesticide, a harmonized approach between JECFA and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) should be followed.

g) MRLs, that are compatible with the ADI or ARfD, where appropriate, should be recommended for target animal tissues (e.g. muscle, fat, or fat and skin, kidney, liver), and specific food commodities (e.g. eggs, milk, honey) originating from the target animal species to which a veterinary drug can be administered according to good veterinary practice based on appropriate consumption figures. When requested by CCRVDF, extension of MRLs between species will be considered if appropriate data are available.

h) While considering extrapolation of MRLs:

i. There should be a reasonable expectation that two food-producing species that are biologically/physiologically related will generally exhibit a similar pattern of metabolism, distribution, and depletion of veterinary drug residues (e.g. ruminant to ruminant).

ii. There should be a reasonable probability that a unique metabolite(s) of toxicological concern is unlikely to occur in species in which MRLs are being extrapolated.

iii.JECFA should, when requested, assess different risk management options and present, in its report the implications of these different risk management options for the CCRVDF to consider.

i) When scientific data are insufficient to complete an evaluation, JECFA should indicate the data gaps and propose a time frame in which data should be submitted. JECFA may also recommend guidance according to paragraph 10 of Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius.

Data protection

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

Expression of risk assessment results in terms of MRLs

161. MRLs have to be established for relevant target animal tissues (e.g. muscle, fat, or fat and skin, kidney, liver), and specific food commodities (e.g. eggs, milk, honey) originating from the target animal species to which a veterinary drug can be administered according to good veterinary practice.

162. However, if residue levels in various target tissues are very different, JECFA is requested to consider MRLs for a minimum of two. In this case, the establishment of MRLs for muscle or fat is preferred to enable the verification of the compliance of food of animal origin moving in international trade.

163. When the calculation of MRLs to be compatible with the ADI may be associated with a lengthy withdrawal period, JECFA should clearly describe the situation in its report.

164. JECFA should provide a clear explanation and rationale for its conclusions and recommendations. This is particularly important when no ADI can be established and/or no MRLs can be recommended due to data gaps or because of specific public health concerns, or when JECFA recommends withdrawal of MRLs or ADI.

4.8 Risk analysis principles applied by the Codex Committee on Pesticide Residues

Scope

165. This document addresses the respective applications of risk analysis principles by the Codex Committee on Pesticide Residues (CCPR) as the risk management body and JMPR as the risk assessment body and facilitates the uniform application of Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius. This document should be read in conjunction with the above-mentioned section.

General aspects

Summary of the maximum residue limit (MRL)-setting process.

166. In addressing pesticide residue issues in Codex, providing advice and taking decisions on risk management is the responsibility of the Commission and CCPR, while conducting risk assessment is the responsibility of JMPR.

167. The MRL-setting process begins with a Member or Observer nominating a pesticide for evaluation by JMPR. In considering the nomination, CCPR, in consultation with JMPR joint secretaries may then prioritize and schedule the pesticide for evaluation.

168. The WHO Core Assessment Group considers available data encompassing a wide range of toxicological endpoints with the aim of estimating an ADI and an ARfD where necessary and if sufficient data are available.

169. The FAO Panel of Experts on Pesticide Residues in Food and the Environment considers data on registered use patterns, fate of residues, animal and plant metabolism, analytical methodology and residue data derived from supervised residue trials in order to propose residue definitions and maximum residues levels for the pesticide in food and feed.

170. JMPR risk assessment includes the estimation of both short-term (single day) and long-term dietary exposures and their comparison with the relevant toxicological benchmarks. MRLs in or on food and animal feeds are based on good agricultural practice (GAP) information, taking into consideration information on dietary intakes, and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable.

171. CCPR considers the recommendations of JMPR in the light of information provided in the relevant JMPR reports and monographs. MRL recommendations accepted by CCPR are submitted to the Commission for adoption as Codex MRLs (CXLs). An active periodic review programme complements this process.

172. CCPR and JMPR should ensure that their respective contributions to the risk analysis process result in outputs that are scientifically based, fully transparent, thoroughly documented and available in a timely manner to Members.[20]

Risk assessment policy

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

a) CCPR's terms of reference;

b) JMPR's terms of reference;

c) the Commission's strategic plan; and

d) nomination requirements and criteria for the prioritization and scheduling of pesticides.

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

175. When referring pesticides to JMPR, CCPR may also refer a range of risk management options, with a view to obtaining JMPR's guidance on the attendant risks and the likely risk reductions associated with each option. CCPR shall request JMPR to review any risk assessment policies, methods and guidelines being considered by CCPR for assessing MRL for pesticides.

176. When establishing its standards, CCPR shall clearly state when it applies any considerations based on other legitimate factors[xl] relevant for the health protection of consumers and for the promotion of fair practices in food trade, in addition to JMPR's risk assessment and recommended MRLs and specify its reasons for doing so.

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xl *Statement of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account* (Appendix section A1.1).

177. JMPR applies a transparent, science-based risk assessment process for establishing an ADI and ARfD, where appropriate.

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

179. The JMPR Secretariat shall consider whether these minimum data requirements have been met when preparing the provisional agenda for meetings of JMPR.

MRLs for specific groups

MRLs for foods of animal origin

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

181. If no adequate studies are available, no MRLs will be established for foods of animal origin. MRLs for feeds (and the primary crops) should not be established in the absence of animal transfer data. Where the exposure of livestock to pesticides through feeds leads to residues at the LOQ, MRLs at the LOQ must be established for foods of animal origin. MRLs should be established for groups of foods of animal origin, for example, edible offal (mammalian), if animals are exposed to pesticide residues via animal feed, and for specific foods, for example, cattle kidney, in cases where animals are directly treated with a pesticide.

182. If the recommended MRLs or limits for foods of animal origin resulting from direct treatment of the animal and residues from animal feed do not agree, the higher recommendation will prevail regardless of whether they are recommended by JMPR or JECFA.

MRL for fat-soluble pesticides

183. If a pesticide is determined as "fat soluble" after consideration of the following factors, it is indicated with the text "the residues are fat soluble" in the residue definition:

a) When available, information concerning the partitioning of the residue (as defined) in muscle versus fat or residue in whole milk versus milk fat in the metabolism studies and livestock feeding studies determines the designation of a residue as being "fat soluble".

b) In the absence of useful information on the distribution of residues in muscle and fat or in milk or milk fat, residues with octanol-water partition coefficient (log Pow) > 3 are likely to be "fat soluble".

184. For milk and milk products, two maximum residue levels would be estimated for fat-soluble pesticides, if the data permits; one MRL for whole

milk and one for milk fat. When needed, MRLs for milk products can then be calculated from the two values, by taking into account the fat content and the contribution from the non-fat fraction.

185. For regulation and monitoring of residues of fat-soluble pesticides in milk, where CXLs have been established for both whole milk and milk fat, whole milk should be analysed, and the result should be compared with the CXLs for whole milk.

MRLs for spices

186. MRLs for spices can be established on the basis of monitoring data in accordance with the guidelines established by JMPR.

MRLs for processed or ready-to-eat foods or feeds

187. JMPR evaluates processing studies to derive processing factors used to estimate residue concentrations in processed foods or feeds for dietary risk assessments and, if necessary, recommends MRLs for processed foods or feeds.

188. CCPR:

a) establishes MRLs for important processed foods and feeds moving in international trade;

b) establishes MRLs for processed foods and feeds only if the resulting value is higher than the MRL established for the corresponding raw agriculture commodity (RAC) processing factor > 1.3 (PF > 1.3);

c) continues the practice of establishing MRLs for processed foods and feeds where, due to the nature of the residues during some specific process, significant amounts of relevant metabolites appear or increase; and

d) supports the current JMPR practice of evaluating all processing studies provided and including in each evaluation or review a summary table of all validated processing factors.

MRLs for minor crops

189. Guidance to facilitate the establishment of MRLs for pesticides for minor crops by CCPR is provided in Annex D.

Establishment of extraneous maximum residue limits (EMRLS)

190. The EMRL refers to a pesticide residue or a contaminant arising from environmental sources due to former agricultural uses not from the use of the pesticide directly or indirectly on the food or feed. It is the maximum concentration of a pesticide residue that is recommended by the Commission to be legally permitted or recognized as acceptable in or on a food or animal feed.

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

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

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

194. Because residues gradually decrease, CCPR evaluates every five years, if possible, the existing EMRL, based on the reassessments of JMPR.

Risk assessment

Role of JMPR

195. JMPR consists of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. It is an independent scientific expert body convened by both Directors-General of FAO and WHO according to the rules of both organizations, charged with the task of providing scientific advice on pesticide residues.

196. JMPR is primarily responsible for performing the risk assessments and proposing MRLs upon which CCPR and ultimately the Commission base their risk management decisions. JMPR proposes MRLs based on residue data from GAP/registered uses or in specific cases, such as EMRL and MRL for spices, based on monitoring data.

197. JMPR provides CCPR with science-based risk assessments that include the four components of risk assessment as defined by Commission, namely hazard identification, hazard characterization, exposure assessment and risk characterization that can serve as the basis for CCPR's discussions.

198. JMPR should identify and communicate to CCPR in its assessments any information on the applicability and any constraints of the risk assessment in regard to the general population and to particular subpopulations and shall, as far as possible, identify potential risks to populations of potentially enhanced vulnerability (e.g. children).

199. JMPR communicates to CCPR possible sources of uncertainties in the exposure assessment and/or in the hazard characterization of the pesticide that, if resolved, would allow a refinement of the risk assessment.

Dietary intake

200. JMPR is responsible for evaluating exposure to pesticides. JMPR must strive to base its exposure assessment and hence the dietary risk assessments on global data, including that from developing countries. In addition to global environment monitoring system (GEMS)/Food data, consumption monitoring data and exposure studies may be used. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are based on the available high percentile consumption data as provided by Members and compiled by GEMS/Food.

201. In undertaking dietary exposure risk assessments to assist CCPR, JMPR uses the WHO and FAO guidance documents.[21, 22] JMPR recommends supervised trial median residues (STMRs) and highest residues (HRs) for dietary intake purposes.

202. JMPR establishes the ADI and calculates the international estimated daily intake (IEDI). JMPR also establishes ARfDs, where appropriate, and indicates cases where an ARfD is not necessary. Where an ARfD is set, JMPR calculates the international estimate of short-term intake (IESTI) for the general population and for children (under six years old), following a procedure described by JMPR.

203. JMPR uses the most up-to-date and most refined residue and consumption data available to calculate the IEDI. When the IEDI exceeds the ADI in one or more of the GEMS/Food cluster diets, JMPR flags this situation when recommending maximum residue levels to CCPR. JMPR also indicates relevant data to refine the IEDI.

204. Where the IESTI exceeds the ARfD for a pesticide/food combination, the JMPR report should describe the particular situation that gives rise to that acute intake concern. JMPR shall indicate the possibilities to refine the IESTI.

205. If either IESTI exceeds the ARfD or IEDI exceed ADI, JMPR indicates that the provision of additional data would be necessary to refine these calculations. Members/Observers have the opportunity to supply the new data and shall commit to provide them in accordance with the four-year rule.

206. In these cases, the four-year rule is applied when insufficient data have been submitted to set a new CXL. Members/Observers may provide a commitment to JMPR and CCPR to provide the necessary data for evaluation within four years. The proposed MRL is maintained for a period of no more than four years, pending the evaluation of the additional data. A second period of four years is not granted. If there is no commitment to provide additional information, or no data are supplied despite a commitment being made in relation to the four-year rule, CCPR considers withdrawal of the draft MRL.

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

Risk management

Role of CCPR

208. CCPR is primarily responsible for recommending risk management proposals, such as MRLs, for adoption by the Commission.

209. CCPR shall base its risk management recommendations to the Commission on JMPR's risk assessments of the respective pesticides, considering, where appropriate, other legitimate factors[ii] relevant for health protection of consumers and for the promotion of fair practices in food trade.

210. In cases where JMPR has performed a risk assessment and CCPR or the Commission determines that additional scientific guidance is necessary, CCPR or the Commission may make a specific request to JMPR to provide further scientific guidance necessary for a risk management decision.

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

212. CCPR shall consider only MRLs recommended by JMPR.

213. CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by Members and compiled by GEMS/Food.

214. If no validated methods of analysis are available for enforcing an MRL for a specific pesticide, no MRL will be established by CCPR.

Selection of pesticides for JMPR evaluation

215. Each year CCPR, in cooperation with the JMPR Secretariat, agrees on a schedule of JMPR evaluations in the following year and considers prioritization of other pesticides for future scheduling.

Procedure for the preparation of the schedules and priority lists

216. CCPR submits the schedules and priority lists of pesticides for JMPR evaluation to the Commission for approval each year, as new work, and requests the re-establishment of the EWG on priorities.

217. The EWG on priorities is tasked with preparing a schedule of pesticides for JMPR (evaluations for the following year) for the consideration of CCPR and the maintenance of a priority list of pesticides for future scheduling by CCPR.

218. The schedules and priority lists are provided in the following tables:

a) Table 1 – CCPR proposed schedule and priority lists of pesticides (new pesticides, new uses, and other evaluations).

b) Table 2A – Schedule and priority lists of periodic reviews.

c) Table 2B – Periodic review list (pesticides that have been last evaluated 15 years ago or more, but not yet scheduled or listed, 15-year rule).

d) Table 3 – Record of periodic review.

e) Table 4 – Pesticide/Food combinations for which specific GAP is no longer supported.

219. Each year, the Codex Secretariat issues a letter, one month after the Commission, seeking application for membership of the EWG on priorities.

220. In early September of each year, the EWG Chair will issue a broadcast email to Members/Observers of the EWG requesting nominations for:

a) new pesticides;

b) new uses of pesticides previously reviewed by JMPR;

c) other evaluations to address, for example, review of toxicological endpoint and alternative GAP; and

d) periodic reviews of pesticides for which there are concerns including public health.

221. Nominations for new pesticides and new uses of pesticides previously reviewed by JMPR are submitted by Members/Observers to the EWG Chair and the JMPR Joint Secretariat using the form in the FAO Manual.[23]

222. The nomination form shall provide a clear indication of the availability of data and national evaluations as well as give an indication of the number of crops and residue trials to be evaluated. The request should also indicate the current status of national registrations for the pesticide.

223. Nominations for other evaluations and periodic reviews should be submitted, on concern forms Annex A and Annex B respectively, with accompanying scientific data addressing the relevant concern. For periodic reviews, the request should also provide information on the most recent evaluation, ADI and ARfD.

224. Nominations complying with the requirements are incorporated into a list, prioritized and scheduled according to the criteria specified below:

a) Those received by 30 November are incorporated into the draft agenda paper which is distributed as a circular letter in early January.

b) Members and Observers are allowed two months from the date of distribution to provide comments to the EWG Chair and JMPR Joint Secretariat.

c) On the basis of comments received in response to the circular letter, the EWG Chair incorporates the new nominations into the schedule and priority lists and prepares an agenda paper for CCPR. The schedule seeks to provide a balance of new pesticides, new uses, other evaluations and periodic reviews.

d) Following plenary discussions on MRL recommendations, the EWG Chair revises the schedule and priority list, which is then presented as a conference room document (CRD) for CCPR's consideration. To cover the possibility that a Member/Observer cannot meet the JMPR data call-in deadline for new pesticide evaluations, CCPR will include reserve pesticides.

e) Following plenary discussion on CRD, CCPR will agree on a JMPR evaluation schedule for the following year. The final schedule will take into account available JMPR resources.

f) At this point, the schedule will be closed for the inclusion of additional pesticides. However, with the agreement of the JMPR Secretariat, the inclusion of additional foods or feeds for scheduled pesticides may be accepted.

Nomination requirements and criteria for the prioritization and scheduling of pesticides for evaluation by JMPR

New pesticides

Nomination requirements

225. Before a nomination is accepted the following requirements must be met:

a) an intention to register the pesticide for use in a Member Nation;

b) the foods or feeds proposed for consideration should be traded internationally;

c) there is a commitment by the Member/Observer of the pesticide to provide supporting data for review in response to the JMPR "data call-in";

d) the use of the pesticide is expected to give rise to residues in or on a food or feed moving in international trade;

e) the pesticide has not been already accepted for consideration; and

f) the nomination form has been completed.

Prioritization criteria

226. The following criteria are applied when preparing the schedules and priority lists:

a) the period of time since the pesticide was nominated for evaluation; a pesticide that was nominated first will have higher priority;

b) timing of data availability;

c) commitment by the Member/Observer to provide supporting data for review with a firm date for data submission; and

d) the provision of information on the foods or feeds for which CXL are sought and the number of trials for each food or feed.

Scheduling criteria

227. In order for CCPR to schedule a pesticide for JMPR evaluation in the following year:

a) it must be registered for use in a Member Nation and formulation labels made available by the time of JMPR "data call-in"; and

b) if the use of the pesticide does not give rise to detectable residues in foods and feeds, it will be afforded a lower priority than those listed pesticides for which use does give rise to measurable residues.

New uses of pesticides previously reviewed by JMPR

Nomination requirement

228. At the request of a Member/Observer, pesticides previously evaluated by JMPR may be listed in Table 1 for the inclusion of additional uses.

Prioritization criteria

229. When prioritizing new use evaluations, the EWG on priorities will consider the following criteria:

a) the date the request was received;

b) commitment by the Member/Observer to provide the required data for review in response to the JMPR "data call-in".

Scheduling criteria

230. Scheduling criteria are as specified in the new pesticide section (paragraph 227).

Other evaluations

Nomination requirements

231. Pesticides previously evaluated by JMPR may be listed for further toxicological and/or residue evaluations by JMPR as a result of requests from CCPR or Members when:

a) a Member seeks to obtain a revised MRL for one or more foods or feeds; for example, on the basis of alternative GAP;

b) CCPR requests a clarification or reconsideration of a recommendation from JMPR;

c) new toxicological data becomes available to indicate a significant change in thn ADI or ARfD;

d) a data deficiency is noted by JMPR during a new pesticide evaluation or periodic review and Members/Observers will supply the required information; and

e) CCPR elects to schedule the pesticide under the four-year rule.

232. In this case, the four-year rule is applied when insufficient data have been submitted to confirm or amend an existing CXL. The CXL is recommended for withdrawal. However, Members/Observers may provide a commitment to JMPR and CCPR to provide the necessary data for review within four years. The existing CXL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted.

Prioritization criteria

233. When prioritizing pesticides for other evaluations, the EWG on priorities will consider the following criteria:

a) the date the request was received;

b) commitment by the Member/Observer to provide the required toxicological and/or residue data for review in response to the JMPR "data call-in";

c) whether the data is submitted under the four-year rule for evaluations; and

d) the reason for its submission; for example, a request from CCPR.

Scheduling criteria

234. Scheduling criteria are as specified in the new pesticides section.

Periodic review

235. Pesticides that have not been reviewed toxicologically for more than 15 years and/or not had a significant review of CXL for 15 years will be listed in Table 2B of the schedules and priority lists.

236. Pesticides listed in Table 2B should be considered for scheduling for periodic review when concerns, including public health concerns are identified and nominated for inclusion in Table 2A. The nominating Member should submit the concern form in Annex B and accompanying relevant scientific information substantiating the concern for consideration by the JMPR Secretariat/EWG on priorities.

237. Pesticides listed in Table 2B may be nominated for inclusion in Table 2A and thus considered for scheduling for periodic review on the basis of the availability of data necessary for the review. The nominating Member should submit an inventory and brief explanation of the relevant toxicological and residue data package for consideration by the JMPR Secretariat/EWG on priorities. The Member should inform the EWG on priorities whether all or some CXLs will be supported and should specify each supported and unsupported CXL.

238. Pesticides listed in Table 2B, for which no periodic review has been undertaken for 25 years, will be brought to the attention of CCPR with a view to transfer to Table 2A and subsequent scheduling.

239. Pesticides which have been the subject of a periodic review during the previous 15 years, and thus are not listed in Table 2B, may be considered for transferring to Table 2A where a concern form in Annex B and accompanying scientific information, upon review, demonstrates a public health concern.

Scheduling and prioritization criteria for pesticides listed in Table 2A

240. The EWG on priorities and CCPR will consider the following periodic review criteria:

a) if scientific data concerning the intake and/or toxicity profile of a pesticide indicates some level of public health concern;

b) if no ARfD has been established by Codex or if an established ADI or ARfD are of public health concern and information is available from Members on national registrations and/or the conclusions from national/regional evaluations indicated a public health concern;

c) the availability of current labels (authorized GAP) arising from recent national reviews;

d) CCPR has been advised by a Member that the residues from a pesticide has been responsible for trade disruption;

e) the date the data will be submitted;

f) if there is a closely related pesticide that is a candidate for periodic review that can be evaluated concurrently; and

g) CCPR agrees to schedule the pesticide under the four-year rule.

241. In this case, the four-year rule is applied when insufficient data have been submitted to confirm or amend an existing CXL. The CXL is recommended for withdrawal. However, Members/Observers may provide a commitment to JMPR and CCPR to provide the necessary data for review within four years. The existing CXL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted.

Periodic review procedure

Identify pesticides for periodic review and solicit data commitments

242. Pesticides are listed for periodic review according to the process and procedures described in Section 4.8: Risk analysis principles applied by the Codex Committee on Pesticide Residue (paragraph 215). The process provides Members/Observers a notice of a periodic review.

243. When a pesticide is listed for periodic review, Members/Observers are able to support it, regarding the two following possibilities:

a) Case A: The pesticide is supported by the original sponsor, who is committed to submit a complete data package to meet JMPR's data requirements.

If the original sponsor does not support some uses, Members/Observers may support them.

b) Case B: The pesticide is not supported by the original sponsor; in this case, interested Members/Observers may support the review of the pesticide.

Commitment to support pesticides or existing CXL or new proposed MRL

244. The commitment of Members/Observers to provide data for the periodic review should be addressed to the Chair of the EWG on priorities and the JMPR Joint Secretariat according to the FAO Manual[23] and the considerations of JMPR on pesticides no longer supported by the original sponsor.

245. For Case A and Case B, data should be submitted in accordance with the guidance of JMPR for the respective cases.[21]

a) in cases where some uses are not supported by the manufacturer but are supported by Members/Observers;

b) if the current GAP support the current CXL, justification for it as well as relevant labels are required; and

c) if GAP were modified, supervised residue trial studies conducted according to current GAP, and relevant studies to support new MRL in animal and processed foods are required.

Elaboration Procedure

Utilization of the accelerated procedure for elaboration of MRL (Step 5/8-procedure)

246. In order to accelerate the adoption of a proposed MRL, CCPR can recommend to the Commission to omit Steps 6 and 7 and adopt the proposed MRL at Step 8. This procedure is called "Step 5/8-procedure". The preconditions for utilization of Step 5/8-procedure are:

a) the new proposed MRL is circulated at Step 3;

b) the JMPR report is available electronically by early February; and

c) no intake concerns were identified by JMPR.

247. If a delegation has a concern with advancing a given MRL, a concern form in Annex A must be submitted following the procedure described in the Procedure for submitting concerns and clarifications, later in this section at least one month before the CCPR session.

248. If that concern is addressed at the CCPR session and the JMPR position remains unchanged, CCPR will decide if the MRL will be advanced to Step 5/8-procedure.

249. If the concern cannot be addressed at the CCPR session, the MRL will be advanced to Step 5 at the CCPR session and the concern will be addressed by JMPR according to the procedure described in paragraphs 255-260: Procedure for submitting concerns and clarifications. Any other draft MRLs for the pesticide, satisfying the above conditions, should be advanced to Step 5/8-procedure.

250. The result of the consideration of the concern by JMPR will be considered at the next CCPR session. If the JMPR position remains unchanged, CCPR will decide if the MRL will be advanced to Step 8.

251. If either IEDI exceeds ADI or IESTI exceeds ARfD in one or more cluster diets, or the ARfD is exceeded in one or more foods or feeds, the accelerated procedure shall not be applied and the procedure described in paragraphs 200-207: Dietary intake applies.

Revocation of CXLS

252. CXLs are proposed for revocation in the following scenarios:

a) as a result of the periodic review procedure including CXLs of pesticides that have not been reviewed for more than 25 years and are not supported by any Member/Observer;

b) where new scientific data, following the JMPR risk assessment, indicate that the pesticide use may compromise human health;

c) the pesticide is no longer produced and commercialized, and there is no remaining stock;

d) the pesticide is produced but is not used in food or feed; and

e) there is no international trade of foods or feeds in which the pesticide may have been used.

253. When a pesticide meets one or more of conditions (a–e), its CXL list will be included in the agenda for the next CCPR session for the committee to consider a recommendation to the Commission for revocation of the CXL. Decisions of the Commission on revocation of CXL will take effect a year after the close of the session of the Commission where such decisions were made.

254. If a pesticide meeting the above stated conditions is environmentally persistent, the need for EMRLs to cover international trade should be considered before its CXLs are revoked. A Member/Observer should indicate the need to maintain CXLs for a period not exceeding four years. Within that period, Members/Observers will be requested to provide monitoring data to allow EMRLs to be established. CCPR will make a decision to establish EMLs when JMPR has evaluated monitoring data and all CXLs will be revoked.

Procedure for submitting concerns and clarifications

Concerns with the advancement of an MRL or the evaluation of a pesticide

255. If Members intend to express concerns with advancement of an MRL or the evaluation of a pesticide, they should complete and submit the concern form in Annex A to the Codex and JMPR Secretaries accompanied by scientific data at least one month before the CCPR session.

256. JMPR will evaluate the scientific data provided with the concern form. CCPR will decide whether JMPR should address the concern and schedule it based on JMPR recommendations and workload.

257. When a concern form is not submitted one month prior to the CCPR session, JMPR will consider the concern at a following meeting and CCPR would subsequently decide on the status of the MRL.

258. When considering concerns expressed by Members, CCPR should recognize the position taken by JMPR as the best available scientific opinion (applicable at the international level) until and if a different position is indicated.

259. Science-based concerns based on the same data/information should be considered only once by JMPR in relationship to any specific pesticide, MRL or CXL.

260. If the same information is submitted, JMPR should simply note that this information has already been reviewed and therefore no further review is warranted.

Concerns with public health on previously evaluated pesticides

261. If Members intend to express a public health concern on a previously evaluated pesticide for prioritization, they should complete and submit the form in Annex B along with the accompanying relevant scientific information substantiating the concern to the Chair of EWG on priorities and the JMPR Secretaries, in accordance with paragraph 215: Selection of pesticides for JMPR evaluation based on their potential higher concern regarding public health.

262. JMPR, in consultation with the EWG on priorities, will consider whether the submitted information indicates some level of public health concern and present proposals at the subsequent CCPR session.

263. If the concern in regard to a pesticide is supported by CCPR, the pesticide will be assigned a high priority and scheduled for the next available year.

264. However, if a Member or Observer disagrees with the proposal by the EWG on priorities, it must lodge additional scientific data to the Chair of the EWG on priorities one month before the next CCPR session. At the following CCPR session, the EWG on priorities will report its proposal. CCPR will make its final decision on prioritization.

Request for clarification

265. If Members seek clarification on a pesticide, they must complete the form provided in Annex A and indicate the specific parts of the JMPR evaluation for which they seek clarification. Such requests must be included in the response to relevant Codex circular letters or other Codex papers. JMPR will address such requests for clarification during the next JMPR meeting and provide a response to such requests by the following CCPR session. CCPR will record any responses or changes in decisions made resulting from the request for clarification. Pending JMPR's respond to the request of the clarification, the MRL relevant to the request can proceed through the Codex 5/8 Step process for the elaboration of CXL.

Addressing differences in procedures for risk assessment

266. MRLs should not be prevented from advancement when there is a science-based concern regarding current JMPR risk assessment procedures that JMPR has addressed through the concern form process. However, where differences exist in procedures for risk assessment (i.e. use of variability factor, use of human studies) it is imperative that CCPR/JMPR attempt to address these differences in order to limit them where possible. Appropriate action by CCPR to address these issues may include referring the issue:

a) to JMPR if there is additional or new information, or if CCPR wishes to provide risk management input to JMPR on the conduct of risk assessments;

b) to national governments or regional authorities for input with a discussion and decision at the next CCPR; and/or

c) where justified by its nature, to a scientific consultation if the resources are available. Members recommending any such action by CCPR should provide information supporting their recommendation for the consideration of the committee.

Risk Communication

267. In accordance with Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius, CCPR, in cooperation with JMPR, shall ensure that the risk analysis process is fully transparent and thoroughly documented and that results are made available in a timely manner to Members and Observers.

268. In order to ensure the transparency of the assessment process in JMPR, CCPR provides comments on the guidelines related to assessment procedures being drafted and published by JMPR.

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

270. CCPR and JMPR must continue to develop procedures to enhance communication between the two bodies.

ANNEX A

Form for expressing concerns with advancement of an MRL or request for clarification of concerns

Submitted by:

Date:

Pesticide/Pesticide code number	**Food**/ Food code number	**MRL** (mg/kg)	**Present step**

Is this a request for clarification?

Request for clarification (specific statement of clarification requested)

Is this a concern?

Is this a continuing concern?

Concern (specific statement of reason for concern to the advancement of the proposed MRL)

Do you wish this concern to be noted in the CCPR report?

Data/Information (description of each separate piece of data/information which will be provided to the appropriate JMPR Secretary within one month of the CCPR meeting)

ANNEX B

Form for expressing concerns with public health on a pesticide for prioritization of periodic review

Submitted by:

Date:

Pesticide/Pesticide code number	**Food(s)**/ Food(s) code number	**CXL** (mg/kg)

Is this a concern?

The concern relates to which prioritization criterion/criteria (Specific statement of concern)

Is supporting data being provided?

Data/Information (description of each separate piece of da-ta/information which is attached or will provided to the EWG on priorities and the appropriate JMPR Secretary within one month of the CCPR meeting)

Is this a continuing concern?

Outline ongoing concern and provide supporting data

ANNEX C
Principles and guidance for application of the proportionality concept for estimation of maximum residue limits for pesticides

1. Use of the concept for soil, seed and foliar treatments has been confirmed by analysis of residue data. Active substances confirmed included insecticides, fungicides, herbicides, and plant growth regulators, except desiccants.

2. The proportionality concept can be applied to data from field trials conducted within a rate range of between 0.3x and 4x the GAP rate. This is only valid when quantifiable residues occur in the dataset. Where there are no quantifiable residues, i.e. values are less than the LOQ, they may only be scaled down. It is unacceptable to scale up in this situation.

3. The variation associated with residue values derived using this approach can be considered to be comparable to using data selected according to the ±25 percent rule for application rate.

4. Scaling is only acceptable if the application rate is the only deviation from critical GAP (cGAP). In agreement with JMPR practice, additional use of the ±25 percent rule for other parameters such as PHI is not acceptable. For additional uncertainties introduced, e.g. use of global residue data, these need to be considered on a case-by-case basis so that the overall uncertainty of the residue estimate is not increased.

5. Proportionality cannot be used for post-harvest situations at this time. It is also recommended that the concept is not used for hydroponic situations due to lack of data.

6. Proportionality can be applied for both major and minor crops. The main difference between minor and major crops is the number of trials required by national/regional authorities, which has no direct relevance to the proportionality of residues. If scaling is applied on representative crops, there is no identified concern with extrapolation to other members of an entire crop group or subgroup.

7. Regarding processed commodities, it is assumed that the processing factor is constant within an application rate range and resulting residues in the commodity being processed. Therefore, existing processing factors can also be used for scaled datasets.

8. With respect to exposure assessments, no restrictions appear to be necessary. The approach may be used for distribution of residues in peel and pulp, provided the necessary information for scaling is available from each trial. Scaled datasets for feeds may also be used for dietary burden calculations for livestock.

9. The approach may be used where the dataset is otherwise insufficient to make an MRL recommendation. This is where the concept provides the greatest benefit. The concept has been used by JMPR and different national authorities on a case-by-case basis and in some cases MRLs may be estimated from trials where all of the data (100 percent) has been scaled.

10. Although the concept can be used on large datasets containing 100 percent scaled residue trials, at least 50 percent of trials at GAP may be requested on a case-by-case basis depending for example on the range of scaling factors. In addition, some trials at GAP might be useful as confirmatory data to evaluate the outcome in cases where the uses result in residue levels leading to a significant dietary exposure.

ANNEX D
Guidance to facilitate the establishment of MRLs for pesticides for minor crops

Minimum number of trials for setting MRL on minor crops

1. To assist Members to identify minor crops and facilitate data submission to JMPR, criteria have been developed for use by CCPR and JMPR. This includes the minimum number of trials necessary to support the establishment of MRLs for minor crops. Due to lower importance of minor crops in terms of consumption, a lower number of trials may be needed to set MRLs than required for major crops.

2. Three categories based on consumption levels (percentage of total daily consumption/capita) have been derived:

- Category 1 – No data in FAO Stat and no GEMS/Food cluster data: to be considered on a case-by-case basis.
- Category 2 – < 0.5 percent worldwide and < 0.5 percent in all of the clusters: minimum of four trials.
- Category 3 – < 0.5 percent worldwide and > 0.5 percent in one or more clusters: minimum of five trials.

3. A methodology was defined to assign crops to these categories (Annex 1). It is based on a two-tiered approach, the first tier based on worldwide consumption and the second one on "local" consumption as defined in GEMS/Food clusters.

4. Crops are classified according to worldwide consumption values above and below the threshold criteria:

5. An information document on the application of this guidance is available on the Codex website;[xli] it includes:

a) Crops for which worldwide consumption values are above the threshold of 0.5 percent of the total daily consumption/capita.

b) The three categories of crops for which worldwide consumption values are below this threshold of 0.5 percent.

6. Crops listing was further refined using national consumption data and on the request of Members. Additional criteria were used in specific instances for seasonal high consumption and/or large portion intakes instead of average intakes.

7. The information document and the minimum number of trials may be revised as necessary to take into account the changes in worldwide consumption levels and additional crops entering the Codex classification for food and feed.

8. The number of trials specified is the minimum proposed to set MRLs. However, data submitters should present as many trials as possible corresponding to good agricultural practices. JMPR, based on expert judgement, can determine if trials provided fulfil JMPR requirements and are adequate to establish robust MRLs.

9. Group MRLs and the use of monitoring data are not in the scope of this guidance. These minimum numbers of trials are only relevant to establish MRLs on individual crops.

xli www.codexalimentarius.org

Label

10. When there is no formal label, the data on a minor crop should be accompanied by an official letter from a government agency that states the chemical is being used on the crop and outlines GAP being used by growers in that country.

Global data set

11. Residue trials from different regions of the world might be taken into account for setting MRLs on minor crops. JMPR performs the evaluation of the submitted information and estimates MRLs regardless of whether it represents worldwide use or is limited to a region, therefore Codex MRLs are applicable regardless of the commodity origin.

12. Provided these data are conducted within the required 25 percent variation of the GAP, JMPR is encouraged to accept data from several countries to support the establishment of a Codex MRL. On the other hand, there should also be acceptance of submissions on priority chemicals that are bundled from multiple countries and submitted by just one country that has agreed to take the lead on behalf of others.

Use of proportionality

13. The committee agreed that proportionality principle was applicable to insecticides, fungicides, herbicides and plant growth regulators and that application rate is the only deviation from critical GAP (cGAP).

14. 100 percent scaled data could be used for large data sets and "at least 50 percent of trials at GAP may be requested on a case-by-case basis depending for example on the range of scaling factors", and some trials at GAP might be useful as confirmatory data. However, using 100 percent scaled data may help facilitate setting MRLs for minor crops if the data are regarded as sufficiently robust.

15. The proportionality principle can be used on residue data from different parts of the world provided the overall uncertainty of the residue estimate is not increased.

Extrapolation

16. Extrapolation principles established by CCPR should be used to set crop group MRLs that include minor crops. Manufacturers and Members are encouraged to include minor crops when a compound is scheduled in the priority list. This should allow for additional minor crops to be added to the existing candidate crops and to set MRLs via extrapolations provided that a label supporting GAP is submitted to JMPR.

17. In case a minor crop is a representative commodity for a crop group (or subgroup) and a MRL is intended for the whole group, a sufficient number of trials to cover the total group consumption level should be provided.

ANNEX
to the guidance to facilitate the establishment of MRLs for pesticides for minor crops

Methodology to assign crops into consumption categories

Tier 1 calculation:

1. Tier one ranking was calculated from GEMS/Food cluster diet as follows:

   a) Items from the same origins were grouped together. Basic grouping was proposed to have only one item per crop, if possible, which is more in line with the process of MRL setting and residue trials, for example all commodities containing wheat and wheat extracts were tentatively grouped together.

   b) For each country, consumption data (GEMS/Food five years average: 2002–2007) were compiled in accordance with the predefined list for each group of commodities, the corresponding consumption value were added.

   c) Then, each compiled consumption value was weighed with the corresponding country population and divided by the world population. The resulting sum for each commodity consequently simulates better the relative importance of each commodity in the world and was considered to fit better with the tier one approach.

2. Hence, for each commodity, the following calculation was realized:

$$\%_i = \left(\frac{\sum^c \frac{\text{consumption}_{i,c} \times \text{population}_c}{\text{population}_w}}{\sum^c \frac{\text{total consumption}_c \times \text{population}_c}{\text{population}_w}} \right) \times 100$$

- $\%_i$: percentage of the commodity "i" in worldwide;
- $\text{consumption}_{i,c}$: consumption of the commodity "i" in the corresponding country "c" (g/hab/day);
- $\text{total consumption}_c$: total consumption (including sugars, beverages, and commodities from animal origins, etc.) in the corresponding country "c" (g/hab/day);
- population_c: population in the country "c" (hab);
- population_w: world population (hab).

Tier 2 calculation:

3. Tier 2 focuses on different existing consumption profiles within each cluster. Indeed, a crop considered of minor importance calculated on a world basis could be of relative high importance in a national diet (depending on the quantity and variety of crops or commodities consumed in the country).

4. The clustering system gathers together similarities between diets and gets a good overview of consumption profiles in the world. Nevertheless, in order not to influence excessively the results by a high local consumption inside a cluster, and in addition since a very local consumption is in all likelihood not the commodity the most subjected to international trade and consequently for which a CXL is required, each country consumption was weighted by its population inside its cluster to get a better consumption profile of the cluster. This better takes into account the real number of consumers within each cluster.

5. Hence, for each commodity and each cluster, the following calculation was realized:

$$\%_j = \left(\frac{\sum^c \frac{\text{consumption}_{j,c} \times \text{population}_c}{\text{population}_z}}{\sum^c \frac{\text{total consumption}_c \times \text{population}_c}{\text{population}_z}} \right) \times 100$$

- $\%_j$: percentage of the commodity "j" in the cluster;
- $\text{consumption}_{j,c}$: consumption of the commodity "j" in the corresponding country "c" (g/hab/day);
- $\text{total consumption}_c$: total consumption (including sugars, beverages, and commodities from animal origins, etc.) in the corresponding country "c" (g/hab/day);
- population_c: population in the country "c" (hab);
- population_z: total population in the cluster (hab).

4.9 Nutritional risk analysis principles and guidelines for application to the work of the Codex Committee on Nutrition and Foods for Special Dietary Uses

Background

271. Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius hereinafter "working principles" establishes general guidance on risk analysis to Codex Alimentarius. These working principles were adopted in 2003 and published in this *Codex Procedural Manual*.

272. The objective of the working principles is "to provide guidance to the Commission and the Joint FAO/WHO expert bodies and consultations so that food safety and health aspects of Codex standards and related texts are based on risk analysis". By its reference to health aspects in addition to food safety, the objective provides clearer direction for risk analysis to apply to nutritional matters that are within the mandate of the Commission and its subsidiary bodies.

273. The nutritional risk analysis principles in Section 4.9 are established to guide the Commission and its subsidiary bodies – primarily but not exclusively the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) – in applying nutritional risk analysis to their work. This guidance may be used for the work of other committees since CCNFSDU is also mandated, in accordance with its 4th term of reference: "to consider, amend if necessary, and endorse provisions on nutritional aspects" of foods including those resulting from application of nutritional risk analysis that are developed by other Codex subsidiary bodies.

Introduction

274. Codex nutritional risk analysis addresses nutrients[xlii] and related substances[xliii] and the risk to health from their inadequate and/or excessive intake. Nutritional risk analysis applies the same general approach as traditional food safety risk analysis to consideration of excessive intakes of nutrients and related substances. However, unlike many constituents of food that are the subject of traditional food safety risk analysis (such as food additives, chemical (pesticide and veterinary drug) residues, microbiological pathogens, contaminants, and allergens) nutrients and related substances are biologically essential (in the case of essential nutrients) or in other ways potentially favourable to health. Nutritional risk analysis therefore adds a new dimension to traditional risk analysis by also considering risks directly posed by inadequate intakes.

275. Th nutritional risk analysis principles and guidelines for application to the work of CCNFSDU hereinafter "nutritional risk analysis principles" are subsidiary to and should be read in conjunction with the working principles.

276. The nutritional risk analysis principles are framed within the three-component structure of the working principles, but with an added initial step to formally recognize problem formulation as an important preliminary risk management activity.

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xlii **Nutrient** is defined by *General Principles for the Addition of Essential Nutrients to Foods* (CXG 9-1987)[24] to mean: any substance normally consumed as a constituent of food: which provides energy; or which is needed for growth and development and maintenance of healthy life; or a deficit of which will cause characteristic biochemical or physiological changes to occur. **Essential nutrient** means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life, and which cannot be synthesized in adequate amounts by the body.

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

Scope and application

277. Nutritional risk analysis considers the risk of adverse health effects from inadequate and/or excessive intakes of nutrients and related substances, and the predicted reduction in risk from proposed management strategies. In situations that address inadequate intakes, such a reduction in risk through addressing the inadequacy might be referred to as a nutritional benefit.

278. The food constituents of primary interest in nutritional risk analysis are inherent components of food and/or intentionally added to food and are identified as:

a) nutrients that may reduce the risk of inadequacy and those that may increase the risk of adverse health effects; and/or

b) related substances that may increase the risk of adverse health effects at excessive intake and may also reduce the risk of other adverse health effects at lower intake.

279. When favourable effects of the nutrient or related substance of primary interest are being assessed, consideration should be given to whether the food matrix could increase the risk of an adverse health effect.

280. Where appropriate, the application of quantitative nutritional risk assessment may guide decision-making on quantitative content provisions for nutrients and related substances in certain Codex texts.

281. Nutritional risk assessment should be as quantitative as possible, although a qualitative risk-based approach drawing on the principles of nutritional risk analysis could assist the development of Codex texts in such situations as:

a) formulating general principles related to nutritional composition (e.g. principles for the addition of nutrients to foods);

b) formulating general principles for assessing or managing risks related to foods for which a nutrition or health claim has been requested;

c) managing risks by labelling advice in relation to consumption of foods of certain nutrient-related[xliv] compositions, including foods for special dietary use; and

d) advising on risk-risk analysis (e.g. risk associated with significantly reduced or entirely avoided consumption of a nutritious, staple food in response to a dietary hazard such as a contaminant present in that food).

Definitions

282. Section 4.2: Definitions of risk analysis terms related to food safety in this *Codex Procedural Manual* provide suitable generic definitions of risk analysis, risk assessment, risk management, risk communication and risk assessment policy. When applied in a nutritional risk analysis context, these high-level risk analysis terms should be prefaced by 'nutritional' and their existing definitions appropriately adapted by replacement of relevant existing terms and definitions with those listed below.

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xliv For the purpose of these nutritional risk analysis principles, the descriptive term 'nutrient-related' refers to one or more nutrients and/or related substances, as the case may be.

283. However, other definitions of risk analysis terms related to food safety have been modified to reference inadequate intake as a nutritional risk factor. Some new terms also have been defined to provide further clarity. The modified or newly developed subsidiary definitions are as follows:

Adverse health effect[25] – A change in the morphology, physiology, growth, development, reproduction or lifespan of an organism, system, or (sub) population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences.

Bioavailability[26] – The proportion of the ingested nutrient or related substance that is absorbed and utilized through normal metabolic pathways. Bioavailability is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, food processing/preparation, and host-related intestinal and systemic factors.

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

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

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

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

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

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

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

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

Nutrient-related risk characterization – The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on nutrient-related hazard identification, nutrient-related hazard characterization and intake assessment.

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

Principles for nutritional risk analysis

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

Preliminary nutritional risk management activities

285. Preliminary nutritional risk management activities should have regard to the particular sections in the working principles titled general aspects of risk analysis, and risk assessment policy.

Nutritional problem formulation

286. Nutritional problem formulation is necessary to identify the purpose of a nutritional risk assessment and is a key component of preliminary nutritional risk management activity because it fosters interactions between risk managers and risk assessors to help ensure common understanding of the problem and the purpose of the risk assessment.

287. Such considerations should include whether a nutritional risk assessment is needed, and if so:

a) the priority it should be accorded;

b) who should conduct and be involved in the nutritional risk assessment, nutritional risk management and nutritional risk communication processes;

c) the need for development of nutritional risk assessment policy;

d) how the nutritional risk assessment will provide the information necessary to support the nutritional risk management decision;

e) whether data are available to embark on an evaluation of nutritional risks;

f) what level of resources are available; and

g) the timeline for completing the assessment.

288. Specific information to be gathered for nutritional problem formulation may include:

a) a detailed inventory of prior knowledge;

b) identification of the (sub)populations to be the focus for the risk assessment, geographical areas or consumer settings to be covered;

c) relevant source(s) of intake; and

d) the health endpoints to be considered.

Nutritional risk assessment

289. The risk management section of Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius is generally applicable to nutritional risk assessment. Additional nutritional risk assessment principles to consider within the Codex framework are identified below.

Nutrient-related hazard identification and hazard characterization

290. These two steps are often globally relevant because they are based on available scientific and medical literature that contribute data from diverse population groups. This global relevance for characterization of hazard does not, however, preclude the possibility of a (sub)population-specific hazard.

291. Nutritional risk assessment should take into consideration the nutrient-related hazard(s) posed by both inadequate and excessive intakes. This may include consideration of hazard(s) posed by excessive intakes of accompanying risk-increasing nutrients in the food vehicle(s) under consideration.

292. Nutrient-related hazard identification and characterization should recognize current methodological differences in assessment of nutritional risk of inadequate and excessive intakes, and scientific advances in these methodologies.

293. Nutrient-related hazard characterization should take into account homeostatic mechanisms for essential nutrients, and limitations in the capacity for homeostatic adaptations. It may also take into account bioavailability including factors affecting the bioavailability of nutrients and related substances such as different chemical forms.

294. Nutrient reference standards that may be used to characterize nutrient-related hazard(s) related to adequacy include measures of average requirement. Some globally applicable nutrient reference standards for average requirement have been published by FAO/WHO. Official regional and national nutrient reference standards are also available and have been periodically updated to reflect scientific advances. These are more likely to relate to nutrients than to related substances.

295. Nutrient reference standards that may be used to characterize nutrient-related hazard(s) related to excessive intakes include upper levels of intake. Some globally applicable reference standards of upper level of intake have been published by FAO/WHO. In addition, the establishment of international upper levels of intake and highest observed intake that build on recommendations may be considered in the future. Some periodically updated nutrient reference standards are available from regional and national authorities. For some related substances, such standards developed from a systematic review of the evidence are available only in the peer-reviewed scientific literature.

296. The assessment of inadequate and excessive levels of intake of particular nutrients and related substances should take into account the availability of all such scientifically-determined reference sources, as appropriate. When using such reference standards for nutrient and related substances in nutritional risk assessment, the basis for their derivation should be explicitly described.

Nutrient-related intake assessment and risk characterization

297. These two steps are generally specific to the (sub)population(s) under consideration for risk assessment. The populations relevant to Codex consideration are populations at large in Codex Member Nations or particular subpopulation groups in these countries defined according to physiological parameters such as age or state of health.

298. Nutrient-related intake assessment and risk characterization should be applied within a total diet context. Where feasible, it would typically involve the evaluation of the distribution of habitual total daily intakes for the target population(s). This approach recognizes that nutrient-related risks are often associated with total intakes from multiple dietary sources, including fortified foods, food supplements,[xlv] and in the case of certain minerals, water. It may also take into account the bioavailability and stability of nutrients and related substances in the foods consumed.

Nutritional risk management

299. The risk management section of Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius is generally applicable to nutritional risk management. Additional nutritional risk management principles to consider within the Codex framework are identified below.

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

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

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

Nutritional risk communication

303. The risk communication section of Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius is generally applicable to nutritional risk communication.

Selection of risk assessor by CCNFSDU

304. Consistent with their important role in providing scientific advice to the Commission and its subsidiary bodies, FAO and/or WHO, including the FAO/WHO Joint Expert Meeting on Nutrition (JEMNU), are acknowledged as the primary source of nutritional risk assessment advice to Codex Alimentarius. This acknowledgement, however, does not preclude the possible consideration of recommendations arising from other internationally-recognized expert bodies, as approved by the Commission.

305. All requests for risk assessment advice should be accompanied by terms of reference and where appropriate risk assessment policy to provide guidance to the risk assessor. These parameters should be established by CCNFSDU.

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xlv *Guidelines for Vitamin and Mineral Food Supplements* (CXG 55–2005)[27] define food supplements as sources in concentrated forms of those nutrients or related substances alone or in combinations, marketed in forms such as capsules, tablets, powders solution, etc., that are designed to be taken in measured small unit quantities but are not in a conventional food form and whose purpose is to supplement the intake of nutrients or related substances from the diet.

4.10 Risk analysis principles and procedures applied by the Codex Committee on Food Hygiene

Scope

306. This section addresses the respective applications of risk analysis principles and procedures by the Codex Committee on Food Hygiene (CCFH) as the risk management body and the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) as the risk assessment body. This document should be read in conjunction with Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius to which these principles are supplemental.

Prioritization of proposals for new work

307. The committee prioritizes its proposals for new work at each CCFH meeting, when appropriate. This is usually carried out by the committee after consideration of the recommendations from an ad hoc working group. This ad hoc working group considers the priority of proposals for new work taking into account the current workload of the committee, and in accordance with Section 2.3: Criteria for the establishment of work priorities, and if necessary, additional criteria to be prepared by the committee. If CCFH resources are limited, proposals for new work or existing work may need to be delayed in order to advance higher priority work. A higher priority should be given to proposals for new work needed to control an urgent public health problem.

Preliminary risk management activities

308. CCFH arranges to develop a risk profile for bringing forward newly proposed work. The risk profile is a description of a food safety problem and its context that presents in a concise form, the current state of knowledge related to a food safety issue, describes potential microbiological risk management (MRM) options that have been identified by CCFH, if any, and the food safety policy context that will influence further possible actions. Scientific data may be commissioned from a range of sources so as to support a continuous science and risk-based approach.

309. Members, who wish to make a request for inclusion of a new item in the priority list of future work of CCFH, should prepare a project document in accordance with Section 2.1: Procedures for the elaboration of Codex standards and related texts and provide a preliminary risk profile, based on the template in Annex 1 of the *Principles and guidelines for the conduct of microbiological risk management* (CXG 63-2007).[28] The proposals for new work should indicate the specific nature or outcome of the new work being proposed (e.g. new or revised code of hygienic practice, risk management guidance document). CCFH identifies the priority of all the new topics, submitted for its consideration, based on Section 2.3: Criteria for the establishment of work priorities (*Codex Procedural Manual*). CCFH may also identify areas on which inputs from JEMRA are needed and make an appropriate request to JEMRA.

310. CCFH is responsible for developing the risk management questions to be addressed by JEMRA in its risk assessments and additionally has the responsibility for establishing the general risk assessment policy under which JEMRA will conduct its risk assessments for CCFH.

311. When referring pathogen-commodity combinations to JEMRA, CCFH may also refer a range of MRM options, with a view to obtaining JEMRA's guidance on the attendant risks and the likely risk reductions associated with each option.

Risk assessment

312. CCFH commissions JEMRA, through FAO/WHO, as the body primarily responsible for performing international risk assessments upon which CCFH and the Commission will base MRM options. For matters which cannot be addressed by JEMRA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies, as approved by the Commission.

313. There are instances where progress on the work of the committee will require an international risk assessment or other expert scientific advice. When commissioning such work, the committee should follow the structured approach given in the *Principles and guidelines for the conduct of microbiological risk management* and Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius.

314. In seeking an international risk assessment to be conducted by FAO/WHO (e.g. through JEMRA), CCFH should consider and seek advice on whether:

a) Sufficient scientific knowledge and data to conduct the needed risk assessment are available or obtainable in a timely manner. (An initial evaluation of available knowledge and data will typically be provided within the risk profile).

b) There is a reasonable expectation that a risk assessment will provide results that can assist in reaching risk management recommendations related to control of the microbiological hazard without unduly delaying the adoption of the needed MRM guidance.

c) Risk assessments performed at the regional, national, and multinational levels that can facilitate the conduct of an international risk assessment are available.

315. If the committee decides to request that a microbiological risk assessment or other scientific advice be developed, the committee will forward a specific request to FAO/WHO, the risk profile document, a clear statement of the purpose and scope of the work to be undertaken, any time constraints facing the committee that could impact the work, and in the case of a risk assessment, the specific risk management questions to be addressed by the risk assessors. The committee will, as appropriate, also provide FAO/WHO with information relating to the risk assessment policy for the specific risk assessment work to be undertaken. FAO/WHO will evaluate the request according to their criteria and subsequently inform the committee of its decision on whether or not to carry out such work together with a scope of work to be undertaken. If FAO/WHO respond favourably, the committee will encourage its Members to submit their relevant scientific data. If a decision is made by FAO/WHO not to perform the requested risk assessment, FAO/WHO will inform the committee of this fact and the reasons for not undertaking the work (e.g. lack of data, lack of financial resources).

316. FAO/WHO will ensure that the selection of experts and other procedures follow the principles and procedures in the *Framework for the Provision of scientific advice on food safety and nutrition*[29] and in accordance with the *Principles and guidelines for the conduct of microbiological risk assessment* (CXG 30-1999).[30]

317. JEMRA should:

a) strive to base its risk assessments on relevant data from different parts of the world, including from developing countries;

b) identify and communicate to CCFH in its assessments any information on the applicability and any constraints of the risk assessment to the general population and to particular subpopulations and will, as far as possible, identify potential risks to populations of potentially enhanced vulnerability, e.g. infants, immunocompromised population;

c) communicate to CCFH the magnitude and source of uncertainties in its risk assessments. When communicating this information, JEMRA should provide CCFH with a description of the methodology and procedures by which JEMRA estimated any uncertainty in its risk assessment; and

d) communicate to CCFH the basis for all assumptions and the level of uncertainty in risk assessment outcomes as well as key factors contributing to uncertainty in its risk assessment.

318. FAO/WHO will provide the results of the microbiological risk assessment(s) to the committee in a format and fashion to be determined jointly by the committee and FAO/WHO. As needed, FAO/WHO will provide scientific expertise to the committee, as feasible, to provide guidance on the appropriate interpretation of the risk assessment.

319. Microbiological risk assessments carried out by FAO/WHO (JEMRA) will operate under the framework contained in the *Principles and guidelines for the conduct of microbiological risk assessment*.

Risk management

320. Risk management options may include provisions contained in Codex standards, guidelines, codes of practice or related texts.

321. The MRM options recommended by CCFH to the Commission should be based on the policies stated in the following paragraphs and shall take into account all relevant assumptions and uncertainties described by JEMRA.

322. Elaboration of guidelines or codes of hygienic practice could include microbiological criteria (MC) and/or provide enabling tools/procedures for countries to apply other MRM metrics (e.g. FSO, PO, PC), as outlined in Annex II of the MRM document (CXG 63-2007),[24] to address a food safety risk.

323. In cases where JEMRA has performed a risk assessment and CCFH or the Commission determines that additional scientific guidance is necessary, CCFH or the Commission may make a specific request to JEMRA to provide further scientific guidance necessary for recommending on an appropriate MRM option.

324. CCFH decides, on a case-by-case basis, the need to elaborate guidelines or codes of hygienic practice, and/or to establish a MC, or provide enabling tools/procedures for countries to apply other MRM metrics. In most cases, elaboration of a guideline or a code of hygienic practice is the preferred MRM option and should address food safety concerns in a diverse array of situations that prevail globally. It also provides the necessary flexibility to address/manage the risk to an acceptable level in the most efficient and appropriate manner. Also, for certain products that are intended for consumption by sensitive subpopulations (e.g. infant foods, foods specially meant for the elderly people, pregnant women, immunocompromised persons, etc.), it may be necessary for CCFH to establish MCs and/or provide enabling tools/procedures for countries to apply other MRM metrics.

325. Where appropriate, other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade, may also be considered by CCFH, as described in the Appendix section A1.1: 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. When establishing MRM options, CCFH shall clearly state when it applies any considerations based on other legitimate factors and specify its reasons for doing so.

326. Wherever possible, CCFH should consider establishing MCs for those pathogens – food combinations for which JEMRA is able to provide a quantitative microbiological risk assessment. Recommendations by CCFH should be based on the outcomes of the risk assessment taking into account differences in regional and national food consumption patterns and dietary exposure. The applicable guidance provided in the *Principles and guidelines for the establishment and application of microbiological criteria related to foods* (CXG 21-1997)[9] shall be utilized by CCFH for establishment of MCs.

327. Where MCs are established, methods of analysis and sampling plans shall be provided, including validated reference methods.

Risk communication

328. In accordance with Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius, CCFH, in cooperation with JEMRA, should ensure that the risk analysis process is fully transparent and thoroughly documented and that the results are made available to the Members in a timely manner. CCFH recognizes that communication between risk assessors and risk managers is critical to the success of risk analysis activities. To this end, CCFH and JEMRA should utilize the guidance on interaction provided in paragraphs 330–335.

329. In order to ensure transparency of the risk assessment process in JEMRA, CCFH may provide comments on the guidelines related to assessment procedures being drafted or published by JEMRA.

Interaction between risk manager (CCFH) and risk assessor (JEMRA)

330. CCFH recognizes that an iterative process between risk managers and risk assessors is essential for adequate undertaking of any microbiological risk assessment and development of MRM options. In particular, dialogue between CCFH and JEMRA is desirable to thoroughly assess the feasibility of the risk assessment, to assure that the risk assessment policy is clear, and to ensure that the risk management questions posed by CCFH are appropriate.

331. In certain instances when the subject matter would benefit from additional interaction with other Codex committees, other FAO/WHO expert consultations and/or other specialized international scientific bodies, these should be included into the iterative process.

332. It is essential that communications between CCFH and JEMRA are timely and effective.

333. CCFH is likely to receive questions from JEMRA relating to the requested microbiological risk assessment(s). The questions may include those needed to clarify the scope and application of the risk assessment, the nature of the MRM options to be considered and key assumptions to be made regarding the risk assessment. Likewise, CCFH may pose questions to JEMRA to clarify, expand, or adjust the risk assessment to better address the risk management questions posed or to develop the MRM options.

334. CCFH may recommend to the Commission to discontinue or modify work on an MRM option if the iterative process demonstrates that: (a) completion of an adequate risk assessment is not feasible; or (b) it is not possible to provide appropriate MRM options.

335. CCFH and JEMRA should ensure that their respective contributions to the risk analysis process result in outputs that are scientifically based, fully transparent, thoroughly documented and available in a timely manner to Members.

Section

5

Subsidiary bodies of the Codex Alimentarius Commission

5.1 Table of committees, document references and terms of reference

The session history for the Commission, Executive Committee and all other subsidiary Codex bodies is available at www.codexalimentarius.org on the relevant committee page under COMMITTEES AND TASK FORCES.

5.1 Table of committees, document references and terms of reference

Commission and Executive Committee

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

General subject committees

Acronym	Codex Committee on	Id	Document reference	Host country
CCCF	Contaminants in Foods	CX-735	CX/CF	Netherlands (Kingdom of the)

Terms of reference
(a) to establish or endorse permitted maximum levels (MLs), and where necessary revise existing guidelines levels, for contaminants and naturally-occurring toxicants in food and feed;
(b) to prepare priority lists of contaminants and naturally-occurring toxicants for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives;
(c) to consider and elaborate methods of analysis and sampling for the determination of contaminants and naturally-occurring toxicants in food and feed;
(d) consider and elaborate standards or codes of practice for related subjects; and
(e) to consider other matters assigned to it by the Commission in relation to contaminants and naturally-occurring toxicants in food and feed.

CCFA	Food Additives[a]	CX-711	CX/FA	China

Terms of reference
(a) to establish or endorse acceptable MLs for individual food additives;
(b) to prepare priority lists of food additives for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives;
(c) to assign functional classes to individual food additives;
(d) to recommend specifications of identity and purity for food additives for adoption by the Commission;
(e) to consider methods of analysis for the determination of additives in food; and
(f) to consider and elaborate standards or codes for related subjects such as the labelling of food additives when sold as such.

CCFH	Food Hygiene	CX-712	CX/FH	United States of America

Terms of reference
(a) to draft basic provisions on food hygiene[b] applicable to all food;
(b) to consider, amend if necessary and endorse provisions on hygiene prepared by Codex commodity committees and contained in Codex commodity standards; and
(c) to consider, amend if necessary, and endorse provisions on hygiene prepared by Codex commodity committees and contained in Codex codes of practice unless, in specific cases, the Commission has decided otherwise; or
(d) to draft provisions on hygiene applicable to specific food items or food groups, whether coming within the terms of reference of a Codex commodity committee or not;
(e) to consider specific hygiene problems assigned to it by the Commission;
(f) to suggest and prioritize areas where there is a need for microbiological risk assessment at the international level and to develop questions to be addressed by the risk assessors; and
(g) to consider microbiological risk management matters in relation to food hygiene, including food irradiation and in relation to the risk assessment of FAO and WHO.

Acronym	Codex Committee on	Id	Document reference	Host country
CCFICS	Food Import and Export Certification and Inspection Systems	CX-733	CX/FICS	Australia

Terms of reference
(a) to develop principles and guidelines for food import and export inspection and certification systems with a view to harmonizing methods and procedures which protect the health of consumers, ensure fair practices in the food trade and facilitate international trade in foodstuffs;
(b) to develop principles and guidelines for the application of measures by the competent authorities of exporting and importing countries to provide assurance, where necessary, that foodstuffs comply with requirements, especially statutory health requirements;
(c) to develop guidelines for the utilization, as and when appropriate, of quality assurance systems[c] to ensure that foodstuffs conform with requirements and to promote the recognition of these systems in facilitating trade in food products under bilateral/multilateral arrangements by countries;
(d) to develop guidelines and criteria with respect to format, declarations and language of such official certificates as countries may require with a view towards international harmonization;
(e) to make recommendations for information exchange in relation to food import/export control;
(f) to consult as necessary with other international groups working on matters related to food inspection and certification systems; and
(g) to consider other matters assigned to it by the Commission in relation to food inspection and certification systems.

CCFL	Food Labelling	CX-714	CX/FL	Canada

Terms of reference
(a) to draft provisions on labelling applicable to all foods;
(b) to consider, amend if necessary, and endorse draft specific provisions on labelling prepared by the Codex committees drafting standards, codes of practice and guidelines;
(c) to study specific labelling problems assigned to it by the Commission; and
(d) to study problems associated with the advertisement of food with particular reference to claims and misleading descriptions.

CCGP	General Principles	CX-716	CX/GP	France

Terms of reference
To deal with such procedural and general matters as are referred to it by the Codex Alimentarius Commission, including:
- the review or endorsement of procedural provisions/texts forwarded by other subsidiary bodies for inclusion in the *Codex Procedural Manual* of the Codex Alimentarius Commission; and
- the consideration and recommendation of other amendments to the *Codex Procedural Manual*.

CCMAS	Methods of Analysis and Sampling	CX-715	CX/MAS	Germany 1966–1971 Hungary from 1972

Terms of reference
(a) to define the criteria appropriate to Codex methods of analysis and sampling;
(b) to serve as a coordinating body for Codex with other international groups working in methods of analysis and sampling and quality assurance systems for laboratories;
(c) to specify, on the basis of final recommendations submitted to it by the other bodies referred to in (b) above, reference methods of analysis and sampling appropriate to Codex standards which are generally applicable to a number of foods;
(d) to consider, amend, if necessary, and endorse, as appropriate, methods of analysis and sampling proposed by Codex (commodity) committees, except that methods of analysis and sampling for residues of pesticides or veterinary drugs in food, the assessment of microbiological quality and safety in food, and the assessment of specifications for food additives, do not fall within the terms of reference of this committee;
(e) to elaborate sampling plans and procedures, as may be required;
(f) to consider specific sampling and analysis problems submitted to it by the Commission or any of its committees; and
(g) to define procedures, protocols, guidelines or related texts for the assessment of food laboratory proficiency, as well as quality assurance systems for laboratories.

Acronym	Codex Committee on	Id	Document reference	Host country
CCNFSDU	Nutrition and Foods for Special Dietary Uses	CX-720	CX/NFSDU	Germany

Terms of reference
(a) to study specific nutritional problems assigned to it by the Commission and advise the Commission on general nutrition issues;
(b) to draft general provisions, as appropriate, concerning the nutritional aspects of all foods;
(c) to develop standards, guidelines or related texts for foods for special dietary uses, in cooperation with other committees where necessary; and
(d) to consider, amend if necessary, and endorse provisions on nutritional aspects proposed for inclusion Codex standards, guidelines and related texts.

CCPR	Pesticide Residues	CX-718	CX/PR	Netherlands (Kingdom of the) 1966–2007 China from 2007

Terms of reference
(a) to establish MLs for pesticide residues in specific food items or in groups of food;
(b) to establish MLs for pesticide residues in certain animal feeding stuffs moving in international trade where this is justified for reasons of protection of human health;
(c) to prepare priority lists of pesticides for evaluation by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR);
(d) to consider methods of sampling and analysis for the determination of pesticide residues in food and feed;
(e) to consider other matters in relation to the safety of food and feed containing pesticide residues; and
(f) to establish maximum limits for environmental and industrial contaminants showing chemical or other similarity to pesticides, in specific food items or groups of food.

CCRVDF	Residues of Veterinary Drugs in Foods	CX-730	CX/RVDF	United States of America

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

Commodity committees (active)

Acronym	Codex Committee on	Id	Document reference	Host country
CCCPL	Cereals, Pulses and Legumes	CX-729	CX/CPL	United States of America

Terms of reference
To elaborate worldwide standards and/or codes of practice as appropriate for cereals, pulses, legumes and their products.

CCFFP	Fish and Fishery Products	CX-722	CX/FFP	Norway (working by correspondence only since 2021)

Terms of reference
To elaborate worldwide standards for fresh, frozen (including quick-frozen) or otherwise processed fish, crustaceans and mollusc.

CCFFV	Fresh Fruits and Vegetables[d]	CX-731	CX/FFV	Mexico

Terms of reference
(a) to elaborate worldwide standards and codes of practice as may be appropriate for fresh fruits and vegetables; and
(b) to consult, as necessary, with other international organizations in the standards development process to avoid duplication. (Amended 2014)

Acronym	Codex Committee on	Id	Document reference	Host country
CCFO	Fats and Oils	CX-709	CX/FO	United Kingdom of Great Britain and Northern Ireland 1964–2007 Malaysia from 2007
Terms of reference To elaborate worldwide standards for fats and oils of animal, vegetable and marine origin including margarine and olive oil.				
CCSCH	Spices and Culinary Herbs	CX-736	CX/SCH	India
Terms of reference (a) to elaborate worldwide standards for spices and culinary herbs in their dried and dehydrated state in whole, ground, and cracked or crushed form; and (b) to consult, as necessary, with other international organizations in the standards development process to avoid duplication.				

Commodity committees (adjourned *sine die*)

Acronym	Codex Committee on	Id	Document reference	Host country
CCCPC	Cocoa Products and Chocolate	CX-708	CX/CPC	Switzerland
Terms of reference To elaborate worldwide standards for cocoa products and chocolate.				
CCMH	Meat Hygiene[e]	CX-723	CX/MH	New Zealand
Terms of reference To elaborate worldwide standards and/or codes of practice as may seem appropriate for meat hygiene.				
CCMMP	Milk and Milk Products	CX-729	CX/MMP	New Zealand
Terms of reference To establish international codes and standards concerning milk and milk products.				
CCNMW	Natural Mineral Waters[f]	CX-719	CX/NMW	Switzerland
Terms of reference To elaborate regional standards for natural mineral waters.				
CCPFV	Processed Fruits and Vegetables	CX-713	CX/PFV	United States of America
Terms of reference To elaborate worldwide standards and related texts for all types of processed fruits and vegetables, including but not limited to canned, dried and frozen products as well as fruit and vegetable juices and nectars. (Amended 2011)				
CCS	Sugars	CX-710	CX/S	United Kingdom of Great Britain and Northern Ireland 1964–2011 Colombia 2011–2019 (by correspondence)
Terms of reference To elaborate worldwide standards for all types of sugars and sugar products.				
CCVP	Vegetable Proteins	CX-728	CX/VP	Canada
Terms of reference To elaborate definitions and worldwide standards for vegetable protein products deriving from any member of the plant kingdom as they come into use for human consumption, and to elaborate guidelines on utilization of such vegetable protein products in the food supply system, on nutritional requirements and safety, on labelling and on other aspects as may seem appropriate.				

Commodity committees (abolished)

Acronym	Codex Committee on	Id	Document reference	Host country
CCIE	Edible Ices[g]	CX-724	CX/IE	Sweden
Terms of reference To elaborate worldwide standards as appropriate for all types of edible ices, including mixes and powders used for their manufacture.				
CCM	Meat[h]	CX-717	CX/M	Germany
Terms of reference To elaborate worldwide standards and/or descriptive texts and/or codes of practice as may seem appropriate for the classification, description and grading of carcasses and cuts of beef, veal, mutton, lamb and pork.				
CCPMPP	Processed Meat and Poultry Products[i]	CX-721	CX/PMPP	Denmark
Terms of reference To elaborate worldwide standards for processed meat products, including consumer packaged meat, and for processed poultry meat products.				
CCSB	Soups and Broths[j]	CX-726	CX/SB	Switzerland
Terms of reference To elaborate worldwide standards for soups, broths, bouillons, and consommés.				

Ad hoc Codex intergovernmental task forces (dissolved)

Acronym	Ad hoc Codex intergovernmental task force on	Id	Document reference	Host country
TFAF	Animal Feeding	CX-803	CX/AF	Denmark 2000–2004 Switzerland 2011–2013

2000–2004[k]
Objectives
With the aim of ensuring the safety and quality of foods of animal origin, the task force should develop guidelines or standards as appropriate on good animal feeding practices.

Terms of reference
(a) to complete and extend the work already done by relevant Codex committees on the Draft Code of Practice for Good Animal Feeding;
(b) to address other aspects which are important for food safety, such as problems related to toxic substances, pathogens, microbial resistance, new technologies, storage, control measures, traceability, etc.; and
(c) to take full account of and collaborate with, as appropriate, work carried out by relevant Codex committees, and other relevant international bodies, including FAO, WHO, WOAH and IPPC.

2011–2013[l]
Objectives
With the aim of ensuring the safety of foods of animal origin, the task force should develop science-based guidelines or standards specific to the following terms of reference.

Terms of reference
(a) The development of guidelines, intended for governments on how to apply the existing Codex risk assessment methodologies to the various types of hazards related to contaminants/residues in feed ingredients, including feed additives used in feeding stuffs for food-producing animals. The guideline should include specific science-based risk assessment criteria to apply to feed contaminants/residues. These criteria should be consistent with existing Codex methodologies.
The guidelines should also consider the need to address the establishment of rates of transfer and accumulation from feed to edible tissues in animal-derived products according to the characteristics of the hazard.
The guidelines should be drawn up in such a way as to enable countries to prioritize and assess risks based upon local conditions, use, exposure of animals and the impact, if any, on human health.
(b) Develop a prioritized list of hazards in feed ingredients and feed additives for governmental use. The list should contain hazards of international relevance that are reasonably likely to occur and are thus likely to warrant future attention.

In doing so, due consideration should be given to the prioritized list of hazards as recommended by the FAO/WHO Expert Meeting on Animal Feed Impact on Food Safety. Clear criteria should be used to prioritize the list of hazards and take account of the potential transfer of contaminants/residues in feed to edible animal products (e.g. meat, fish meat, milk, and eggs).

Acronym	Ad hoc Codex intergovernmental task force on	Id	Document reference	Host country
TFAMR	Antimicrobial Resistance	CX-804	CX/AMR	Republic of Korea

2007–2011[m]

Objectives

To develop science-based guidance, taking full account of its risk analysis principles and the work and standards of other relevant international organizations, such as FAO, WHO and WOAH.[n] The intent of this guidance is to assess the risks to human health associated with the presence in food and feed including aquaculture and the transmission through food and feed of antimicrobial resistant microorganisms and antimicrobial resistance genes and to develop appropriate risk management advice based on that assessment to reduce such risk.
The task force should attempt to put into perspective the risk of increase of antimicrobial resistance in human beings and animals, generated by different areas of use of antimicrobials such as veterinary applications, plant protection or food processing.[o]

Terms of reference

To develop guidance on methodology and processes for risk assessment, its application to the antimicrobials used in human and veterinary medicine as provided by FAO/WHO through JEMRA, and in close cooperation with WOAH, with subsequent consideration of risk management options. In this process, work undertaken in this field at national, regional and international levels should be taken into account.

2017–2021[p]

Objectives

To develop science-based guidance on the management of foodborne antimicrobial resistance, taking full account of the WHO Global Action Plan on Antimicrobial Resistance, in particular objectives 3 and 4, the work and standards of relevant international organizations, such as FAO, WHO and WOAH, and the One Health approach, to ensure that Members have the necessary guidance to enable coherent management of antimicrobial resistance along the food chain.

Terms of reference

(i) To review and revise as appropriate the *Code of Practice to minimise and contain antimicrobial resistance* (CAC/CXC 61-2005)[31] to address the entire food chain, in line with the mandate of Codex.
(ii) To consider the development of *Guidance on integrated surveillance of antimicrobial resistance,* taking into account the guidance developed by the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) and relevant WOAH documents.

TFFBT	Foods derived from Biotechnology	CX-802	CX/FBT	Japan

1999–2003[q]

Objectives

To develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology or traits introduced into foods by biotechnology, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair practices in the food trade.

Terms of reference

(a) to elaborate standards, guidelines, or other principles, as appropriate, for foods derived from biotechnology;
(b) to coordinate and closely collaborate, as necessary, with appropriate Codex committees within their mandate as relates to foods derived from biotechnology; and
(c) to take full account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora.

2004–2008[r]

Objectives

To develop standards, guidelines or recommendations, as appropriate, for foods derived from modern biotechnology or traits introduced into foods by modern biotechnology, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair practices in the food trade.

Terms of reference

(a) to elaborate standards, guidelines, or other principles, as appropriate, for foods derived from modern biotechnology, taking account, in particular, of the *Principles for the risk analysis of foods derived from modern biotechnology* (CXG 44-2003);[32]
(b) to coordinate and closely collaborate, as necessary, with appropriate Codex committees within their mandate as relates to foods derived from modern biotechnology; and
(c) to take account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora.

Acronym	Ad hoc Codex intergovernmental task force on	Id	Document reference	Host country
TFFJ	Fruit and Vegetable Juices[s]	CX-801	CX/FJ	Brazil

Terms of reference
The ad hoc task force shall:
(a) revise and consolidate the existing Codex standards and guidelines for fruit and vegetable juices and related products, giving preference to general standards;
(b) revise and update the methods of analysis and sampling for these products; and
(c) complete its work prior to the 28th Session of the Commission (2005).

Acronym	Ad hoc Codex intergovernmental task force on	Id	Document reference	Host country
TFPHQFF	The Processing and Handling of Quick-Frozen Foods[t]	CX-805	CX/PHQFF	Thailand

Objectives
To finalize the International Code of Practice for the Processing and Handling of Quick-Frozen Foods.

Terms of reference
To resolve all outstanding issues including quality and safety provisions with a view to the advancement of the Code to Step 8.

FAO/WHO coordinating committees

Membership

Membership of the relevant committee is open to all Members and Associate Members of FAO and/or WHO which are Members of the Codex Alimentarius Commission, within the relevant geographical location.

Terms of reference

1. Defines the problems and needs of the region concerning food standards and food control.
2. Promotes within the committee contacts for the mutual exchange of information on proposed regulatory initiatives and problems arising from food control and stimulates the strengthening of food control infrastructures.
3. Recommends to the Commission the development of worldwide standards for products of interest to the region, including products considered by the committee to have an international market potential in the future.
4. Develops regional standards for food products moving exclusively or almost exclusively in intraregional trade.
5. Draws the attention of the Commission to any aspects of the Commission's work of particular significance to the region.
6. Promotes coordination of all regional food standards work undertaken by international governmental and non-governmental organizations within the region.
7. Exercises a general coordinating role for the region and such other functions as may be entrusted to it by the Commission.
8. Promotes the use of Codex standards and related texts by Members.

Acronym	Est.	FAO/WHO coordinating committee for	Id	Document reference	Coordinators in sequence (present in bold)
CCAFRICA	1974	Africa	CX-707	CX/AFRICA	Ghana, Senegal, Kenya, Togo, Egypt, Nigeria, Zimbabwe, Uganda, Morocco, Ghana (2nd), Cameroon, Kenya (2nd) **Uganda (2nd)**
CCASIA	1978	Asia	CX-727	CX/ASIA	India, Philippines, Thailand, Indonesia, Thailand (2nd), Malaysia, China, Japan, Thailand (3rd), Malaysia (2nd) Republic of Korea, Indonesia (2nd), Japan (2nd), Thailand (4th), India (2nd), China (2nd), **Japan (3rd)**
CCEURO	1965	Europe	CX-706	CX/EURO	Switzerland, Austria, Switzerland (2nd), Austria (2nd), Sweden, Spain, Slovakia, Switzerland (3rd), Poland, Netherlands (Kingdom of the), Kazakhstan, **Germany**
CCLAC	1976	Latin America and the Caribbean	CX-725	CX/LAC	Mexico, Uruguay, Cuba, Costa Rica, Brazil, Uruguay (2nd), Dominican Republic, Argentina, Mexico (2nd), Costa Rica (2nd), Chile, Ecuador, **Uruguay (3rd)**
CCNE	2001	The Near East	CX-734	CX/NE	Egypt, Jordan, Tunisia, Lebanon, Iran (Islamic Republic of), Saudi Arabia, **Oman**
CCNASWP	1990	North America and the Southwest Pacific	CX-732	CX/NASWP	United States of America, Australia, Canada, New Zealand, United States of America (2nd), Australia (2nd), Canada (2nd), Samoa, Tonga, Papua New Guinea, Vanuatu, **Fiji**

Committee established under Rule xi.1(a) (renamed and re-established)

Acronym	Name	Id	Document reference
CGECPMMP	Joint FAO/WHO Committee of Government Experts on the Code of Principles concerning Milk and Milk Products[u]	CX-703	CX/CPMMP

Terms of reference
To establish international codes and standards concerning milk and milk products.

Joint meetings with other organizations (abolished)

Acronym	Name	Id	Document reference
CXTO	Joint Codex/IOOC Meeting on the Standardization of Table Olives[v]		CX/TO

Terms of reference
As approved by the 18th Session of the Commission, the Joint Codex/IOOC meeting was held on an ad hoc basis in order to elaborate a standard for table olives.

Acronym	Name	Id	Document reference
GEFJ	Joint UNECE/Codex Alimentarius Groups of Experts on Standardization of Fruit Juices[w]	CX-704	CX/FJ

Terms of reference
To elaborate worldwide standards for fruit juices, concentrated fruit juices and nectars.

Acronym	Name	Id	Document reference
GEQFF	Joint UNECE/Codex Alimentarius Groups of Experts on Standardization Quick-Frozen Foods[x]	CX-705	CX/QFF

Terms of reference
The Joint UNECE/Codex Alimentarius Group of Experts on the Standardization of Quick-Frozen Foods will be responsible for the development of standards for quick-frozen foods in accordance with the general principles of the Codex Alimentarius.

The Joint Group will be responsible for general considerations, definitions, a framework of individual standards for quick-frozen food products and for the actual elaboration of standards for quick-frozen food products not specifically allotted by the Commission to another Codex committee, such as fish and fishery products, meat, processed meat and poultry products. Standards drawn up by Codex commodity committees for quick-frozen foods should be in accordance with the general standard laid down by the Joint UNECE/Codex Alimentarius Group of Experts on the Standardization of Quick-Frozen Foods and should, at an appropriate stage, be referred to it for coordination purposes.

Notes

a Renamed as Codex Committee on Food Additives and Contaminants by the 17th Session of the Commission (1987); renamed again by the 29th Session of the Commission (2006) as Codex Committee on Food Additives, due to the creation of a Committee on Contaminants in Foods (CX-735).

b The term "hygiene" includes, where necessary, microbiological specifications for food and associated methodology.

c Quality assurance means all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality (ISO-8402 Quality - Vocabulary)

d Established by the 17th Session of the Commission (1987) as the Codex Committee on Tropical Fresh Fruits and Vegetables. Its name and terms of reference were amended by the 21st Session of the Commission (1995).

e Established as the Codex Committee on Meat Hygiene by the 8th Session of the Codex Alimentarius Commission (1971). The terms of reference and the name of the Committee were amended by the 24th Session of the Commission (2001) to include poultry, thus, the Codex Committee on Meat and Poultry Hygiene (CCMPH). The specific reference to poultry in the name and terms of reference was removed by the 26th Session of the Commission (2003).

f The committee was established by the Commission as a regional (European) Codex committee but has since been allocated the task of elaborating worldwide standards for natural mineral waters and bottled (packaged) water other than natural mineral water.

g Abolished by the 22nd Session of the Commission (1997).

h Abolished by the 16th Session of the Commission (1985).

i Abolished by the 23rd Session of the Commission (1999).

j Abolished by the 24th Session of the Commission (2001).

k The task force was dissolved by the 27th Session of the Commission (2004) upon completion of its mandate.

l The task force was re-established by the 33rd Session of the Commission (2010). The task force was dissolved by the 36th Session of the Commission (2013) upon completion of its mandate.

m The task force was dissolved by the 34th Session of the Commission (2011) upon completion of its mandate.

n OIE renamed as of May 2023 to World Organisation for Animal Health (WOAH).

o The objectives were modified by the 31st Session of the Commission (2008).

p The task force was dissolved by the 44th Session of the Commission (2021) upon completion of its mandate.

q The task force was dissolved by the 26th Session of the Commission (2003) upon completion of its mandate.

r The task force was re-established by the 27th Session of the Commission (2004). The task force was dissolved by the 31st Session of the Commission (2008) upon completion of its mandate.

s The task force was dissolved by the 28th Session of the Commission (2005) upon completion of its mandate.

t The task force was dissolved by the 31st Session of the Commission (2008) upon completion of its mandate.

u Established by FAO and WHO in 1958 and integrated into the Joint FAO/WHO Food Standards Programme in 1962 as a subsidiary body of the Codex Alimentarius Commission under Rule XI.1(a). Renamed "Codex Committee on Milk and Milk Products" in 1993 and re-established as a subsidiary body under Rule XI.1(b)(i) (see Rules of Procedure of the Codex Alimentarius Commission, Section 1.2.)

v The meeting was not a subsidiary body under any specific rule of the Codex Alimentarius Commission but followed the same procedure as Codex commodity committees for the elaboration of Codex standards.

w The Joint UNECE Codex Alimentarius groups of experts were not subsidiary bodies under any specific rule of the Codex Alimentarius Commission but followed the same procedure as Codex commodity committees for the elaboration of Codex standards. Abolished by the 23rd Session of the Commission (1999). The work of the Joint Group was transferred to the Codex ad hoc intergovernmental task force on fruit juices.

x The Joint UNECE/Codex Alimentarius groups of experts were not subsidiary bodies under any specific rule of the Codex Alimentarius Commission but followed the same procedure as Codex commodity committees for the elaboration of Codex standards. Abolished by the 23rd Session of the Commission (1999). The work of the Joint Group of Experts was transferred to the Codex Committee on Processed Fruits and Vegetables (see the terms of reference of that committee).

Section

6

Membership

6.1 Core functions of Codex contact points

Adopted in 1999.

Up-to-date information on Codex contact points and membership of the Codex Alimentarius Commission is available on the Codex website at: https://www.fao.org/fao-who-codexalimentarius/about-codex/members/en/

6.1 Core functions of Codex contact points

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

Codex contact points (CCPs):

1. Act as the link between the Codex Secretariat and Codex Members.
2. Coordinate all relevant Codex activities within their own countries.
3. Receive all Codex final texts (standards, codes of practice, guidelines, and other advisory texts) and working documents of Codex sessions and ensure that they are circulated to those concerned within their own countries.
4. Send comments on Codex documents or proposals to the Commission or its subsidiary bodies and/or the Codex Secretariat.
5. Work in close cooperation with the national Codex committee, where such a committee has been established. The CCP acts as the liaison point with the food industry, consumers, traders and all other concerned to ensure that the government is provided with an appropriate balance of policy and technical advice upon which to base decisions relating to issues raised in the context of the Codex work.
6. Act as a channel for the exchange of information and coordination of activities with other Codex Members.
7. Receive the invitation to Codex sessions and inform the relevant chairpersons and the Codex Secretariat of the names of participants from their own countries.
8. Maintain a library of Codex final texts.
9. Promote Codex activities throughout their own countries.

Section

7

Relations with other organizations

7.1 Guidelines on cooperation between the Codex Alimentarius Commission and international intergovernmental organizations in the elaboration of standards and related texts

Adopted in 2005.

7.2 Principles concerning the participation of international non-governmental organizations in the work of the Codex Alimentarius Commission

Adopted in 1999. Amended in 2005 and 2007.

7.1 Guidelines on cooperation between the Codex Alimentarius Commission and international intergovernmental organizations in the elaboration of standards and related texts

Member Nations and years of accession

Scope and application

1. These guidelines establish the modalities of cooperation between the Commission and international intergovernmental organizations when elaborating food standards or related texts.

2. These guidelines should be read in conjunction with Section 2.1, Part 3: Uniform procedure for the elaboration of Codex standards and related texts.

Types of cooperation

3. The Commission may undertake the elaboration of any standard or related text in cooperation with another international intergovernmental body or organization.

4. Such cooperation may consist of:

a) cooperation at the initial drafting stages of a Codex standard or related text; and

b) cooperation through mutual exchange of information and participation in meetings.

Cooperating international intergovernmental organization

5. The cooperating international intergovernmental organization shall have observer status with the Commission.

6. The cooperating international inter-governmental organization shall have the same principles of membership[xlvi] that form the basis for membership in the Commission and equivalent principles of standards-setting.[xlvii]

Cooperation at the initial drafting stages of a Codex standard or related text[xlviii]

7. The Commission, or a subsidiary body of the Commission subject to approval by the Commission and taking into account the critical review conducted by the Executive Committee, as appropriate, may entrust the initial drafting of a proposed draft standard or related text to an international intergovernmental organization with competence in the relevant field, in particular one of those referred to in Annex A of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement),[33] on a case-by-case basis, provided that the willingness of the cooperating organization to undertake such work has been ascertained. Such texts shall be circulated at Step 3 (see Part 3: Uniform procedure for the elaboration of Codex standards and related texts in Section 2.1). When appropriate, the international intergovernmental organizations referred to Annex A of the SPS Agreement shall be associated in the drafting of standards or related texts at Step 2 of the elaboration procedure.

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

xlvii "Equivalent principles of standards-setting" refers to the general decisions of the Commission set out in the Appendix to the *Codex Procedural Manual*.

xlviii See also Article 1 of the Statutes of the Codex Alimentarius Commission, Step 2 of the Uniform procedure for the elaboration of Codex standards and related texts, and the terms of reference of the Codex Committee on Fresh Fruits and Vegetables (CCFFV).

The Commission shall entrust the remaining steps to the relevant Codex subsidiary body within the Codex elaboration procedure.

8. The Commission, or a subsidiary body of the Commission, may use, in whole or in part, an international standard or related text developed by an international intergovernmental organization with competence in the relevant field as a basis for preparing a proposed draft standard or related text at Step 2 of the elaboration procedure, subject to concurrence of the cooperating organization. The proposed draft standard or related text shall be circulated at Step 3 (See Part 3: Uniform procedure for the elaboration of Codex standards and related texts. in Section 2.1)

Cooperation through mutual exchange of information and participation in meetings

9. The Commission or a subsidiary body of the Commission may identify an international intergovernmental organization having specific expertise of particular importance to the work of the Commission. Such organization may be encouraged to actively participate in the elaboration of standards by the Commission and its subsidiary bodies.

10. The Commission or a subsidiary body of the Commission may invite a cooperating organization having specific expertise of particular importance to the work of the Commission to report about its relevant work at their sessions on an ad hoc or regular basis.

11. The Commission or a subsidiary body of the Commission may recommend that the Chairperson of the Commission, the chairperson of the subsidiary body, or, if they are not available, a Vice-Chairperson or the Secretary of the Commission, as appropriate, participate in meetings of the cooperating organization, subject to the concurrence of the cooperating organization.

12. The Commission or a subsidiary body of the Commission may recommend that the Chairperson or the Secretary of the Commission forward comments, opinions, or other relevant information of the Commission to the cooperating organization as regards international standard setting work in areas of mutual interest.

13. The Commission may recommend to the Directors-General of FAO and WHO the conclusion of an appropriate arrangement with the executive head of the cooperating organization with a view to agreeing upon specific modalities to facilitate continuing cooperation between the Commission and the cooperating organization, as set out in the paragraphs above.

7.2 Principles concerning the participation of international non-governmental organizations in the work of the Codex Alimentarius Commission

Purpose

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

Types of relationship

15. Only one category of relationship shall be recognized, namely observer status; all other contacts, including working relations, shall be considered to be of an informal character.

Organizations eligible for observer status

16. The following shall be eligible for observer status:

a) INGOs in consultative status, specialized consultative status or liaison status with FAO;

b) INGOs having official relations with WHO; and

c) INGOs that:

i. are international in structure and scope of activity, and representative of the specialized field of interest in which they operate;

ii. are concerned with matters covering a part or all of the Commission's field of activity;

iii. have aims and purposes in conformity with the statutes of the Commission;

iv. have a permanent directing body and secretariat, authorized representatives and systematic procedures and machinery for communicating with their membership in various countries. Their members shall exercise voting rights in relation to their policies or action or shall have other appropriate mechanisms to express their views; and

v. have been established at least three years before they apply for observer status.

17. For the purpose of paragraph (a), INGOs shall be considered "international in structure and scope of activity" if they have members and carry out activities in at least three countries. The Directors-General of FAO and WHO may, upon the advice of the Executive Committee, grant observer status to organizations not meeting this requirement if it is clear from their application that they would make a significant contribution to advancing the purposes of the Commission.

Procedure for obtaining observer status

INGOs having status with FAO and/or official relations with WHO

18. Observer status shall be accorded to those INGOs in consultative status, specialized consultative status or liaison status with FAO or INGOs having official relations with WHO that inform the Secretary of the Commission of their desire to participate in the work of the Commission and/or any or all of the Commission's subsidiary bodies[xlix] on a regular basis. They may also request invitations to participate in specific sessions of the Commission or its subsidiary bodies on an ad hoc basis.

INGOs neither having status with FAO nor official relations with WHO

19. Before any form of formal relationship is established with a non-governmental organization, such organization shall supply the Secretary of the Commission with the information outlined in the annex to these procedures.

20. The Secretary of the Commission will verify the completeness of the information provided by the organization and will also perform an initial assessment of whether the organization appears to meet the requirements indicated in paragraph 16 of these principles. In case of doubt, he or she will consult with the Directors-General of FAO and WHO and may seek further information and clarifications from the organization as appropriate.

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

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

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

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

xlix The term "subsidiary bodies" means any body established under Rule XI of the Commission's rules of procedure.

Privileges and obligations

25. INGOs in observer status shall have the following privileges and obligations:

Privileges of INGOs in observer status

26. An organization in observer status:

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

b) shall be entitled to send an Observer (without the right to vote) to sessions of specified subsidiary bodies, who may be accompanied by advisers; to receive from the secretariats of the subsidiary bodies, in advance of the session, all working documents and discussion papers; to circulate to these bodies its views in writing, without abridgement; and to participate in discussions when invited by the Chairperson;

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

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

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

Obligations of INGOs in observer status

27. An organization in observer status shall undertake:

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

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

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

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

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

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l An invitation to a Codex meeting and representation thereat by an Observer shall not imply the granting to an INGO of a status different from that which it already enjoys.

Review of observer status

28. The Directors-General may terminate observer status if an organization no longer meets the criteria in paragraphs 16 to 18, or for reasons of exceptional nature, in accordance with the procedures set out in this section. Without prejudice to the preceding paragraph, an INGO in observer status which has neither attended any meetings nor provided any written comments during a period of four years shall be deemed not to have sufficient interest to warrant the continuance of such relationship.

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

30. The Secretary shall report to the Commission on the relations between the Commission and INGOs established in accordance with the present procedures and shall provide a list of organizations granted observer status, with an indication of the membership that they represent. He or she shall also report to the Commission the termination of the observer status of any organization.

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

ANNEX
Information required of international non-governmental organizations requesting observer status

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

2. Full postal address, telephone, email, and website addresses as appropriate.

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

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

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

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

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

8. Relations with other international organizations:

a) UN and its organs (indicate consultative status or other relationship, if any); and

b) other international organizations (document substantive activities).

9. Expected contribution to the Joint FAO/WHO Food Standards Programme.

10. Past activities on behalf of, or in relation to, the Commission and the Joint FAO/WHO Food Standards Programme (indicate any relationship by national affiliates with the regional coordinating committees and/or the national CCPs or committees for at least the last three years preceding the application).

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

12. Previous applications for observer status with the Commission, including those made by a Member Organization of the applicant organization. If successful, please indicate why and when observer status was terminated. If unsuccessful, please indicate the reasons given.

13. Languages (English, French or Spanish) in which documentation should be sent to the INGO.

14. Name, function, and address of the person providing the information.

15. Signature and date.

Appendix General decisions of the Codex Alimentarius Commission

A1.1 Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account

Adopted in 1995. Amended in 2001.

A1.2 Statements of principle relating to the role of food safety risk assessment

Adopted in 1997.

A1.3 Measures to facilitate consensus

Adopted in 2003.

A1.1 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[li]

1. The food standards, guidelines, and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.

2. When elaborating and deciding upon food standards, Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.

3. In this regard, it is noted that food labelling plays an important role in furthering both of these objectives.

4. When the situation arises that Members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, Members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

Criteria for the consideration of the other factors referred to in the second statement of principle[lii]

5. Where health and safety matters are concerned, these statements of principle concerning the role of science and the Statements of principle relating to the role of food safety risk assessment (Appendix section A1.2) should be followed.

6. Other legitimate factors relevant for health protection and fair-trade practices may be identified in the risk management process, and risk managers should indicate how these factors affect the selection of risk management options and the development of standards, guidelines, and related texts.

7. Consideration of other factors should not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment.

8. It should be recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide.[liii]

9. Only those other factors which can be accepted on a worldwide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex.

10. The consideration of specific other factors in the development of risk management recommendations of the Codex Alimentarius Commission and its subsidiary bodies should be clearly documented, including the rationale for their integration, on a case-by-case basis.

li Decision of the 21st Session of the Commission, 1995.
lii Decision of the 24th Session of the Commission, 2001.
liii Confusion should be avoided between justification of national measures under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures Agreement (SPS Agreement) and the Technical Barriers to Trade (TBT) Agreement and their validity at the international level.

11. The feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport, and storage, especially in developing countries, may be considered; concerns related to economic interests and trade issues in general should be substantiated by quantifiable data.

12. The integration of other legitimate factors in risk management should not create unjustified barriers to trade;[liv] particular attention should be given to the impact on developing countries of the inclusion of such other factors.

A1.2 Statements of principle relating to the role of food safety risk assessment[lv]

13. Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.

14. Food safety risk assessment should be soundly based on science, should incorporate the four steps of the risk assessment process, and should be documented in a transparent manner.

15. There should be a functional separation of risk assessment and risk management, while recognizing that some interactions are essential for a pragmatic approach.

16. Risk assessment should use available quantitative information to the greatest extent possible and risk characterizations should be presented in a readily understandable and useful form.

A1.3 Measures to facilitate consensus[lvi]

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

    a. Refraining from submitting proposals in the step process where the scientific basis is not well established on current data and, where necessary, carry out further studies in order to clarify controversial issues.

    b. Providing for thorough discussions and documentation of the issues at meetings of the committees concerned.

    c. Organizing informal meetings of the parties concerned where disagreements arise, provided that the objectives of any such meetings are clearly defined by the committee concerned and that participation is open to all interested delegations and Observers in order to preserve transparency.

    d. Redefining, where possible, the scope of the subject matter being considered for the elaboration of standards in order to cut out issues on which consensus could not be reached.

    e. Providing that matters are not progressed from step to step until all relevant concerns are taken into account and adequate compromises worked out.

    f. Emphasizing to committees and their chairpersons that matters should not be passed on to the Commission until such time as consensus has been achieved at the technical level.

    g. Facilitating the increased involvement and participation of developing countries.

liv According to the WTO principles and taking into account the particular provisions of the SPS and TBT agreements.
lv Decision of the 22nd Session of the Commission, 1997.
lvi Decision of the 26th Session of the Commission, 2003.

Notes

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2. FAO and WHO. 1995. *General standard for contaminants and toxins in food and feed*. Codex Alimentarius Standard, No. CXS 193-1995. Codex Alimentarius Commission. Rome.
3. FAO and WHO. 1989. *Class names and the International Numbering System for food additives*. Codex Alimentarius Guideline, No. CXG 36-1989. Codex Alimentarius Commission. Rome.
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