

Codex standards and food safety

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Abstract

The Codex Alimentarius Commission is an inter-governmental organization founded in 1962 by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to implement the Joint FAO/WHO Food Standards Programme. Its primary objective is to protect the health of consumers, to ensure fair practices in international food trade, and to promote coordination of all food standards work undertaken by international governmental and non-governmental organizations; and it is charged with the elaboration of international food standards and other recommendations.

The Codex Alimentarius Commission has met every other year since 1979, alternately in Rome and Geneva, the most recent being held in July 2001 in Geneva. There are several subsidiary bodies; those dealing with issues applicable to all foods, those elaborating standards for individual foods or food groups, and those discussing issues of regional concern.

The Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization states in Article 3.1 that its members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist. In the case of food safety, the Agreement refers specifically to Codex standards and other recommendations. Standards and other recommendations elaborated by the Codex Committees on Food Hygiene, on Food Additives and Contaminants, on Pesticide Residues, and on Residues of Veterinary Drugs in Foods and adopted by the Codex Alimentarius Commission all fall into this category.

Standards and other recommendations relating to food safety are prepared by the relevant Codex committees following an eight-step elaboration procedure and become valid only when the Codex Alimentarius Commission adopts them as Codex final texts. The Codex Alimentarius Commission has been promoting the application and integration of risk analysis in its work in relation to food safety since 1993. In support of this, expert consultations were convened jointly by FAO and WHO to develop a scientific and conceptual framework of risk analysis. The Joint FAO/WHO Expert Committee on Food Additives and the Joint FAO/WHO Meeting on Pesticide Residues, independent from the Codex system, provide scientific and technical advice to the Codex committees dealing with food additives and contaminants, and residues of veterinary drugs and pesticides. Another joint FAO/WHO expert body conducts risk assessment of microbiological hazards in food. These expert committees serve as risk assessors, while the Codex Alimentarius Commission and those committees mentioned above act as risk managers.

Introduction

THE Codex Alimentarius Commission is an inter-governmental organization founded in 1962 by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to implement the Joint FAO/WHO Food Standards Programme. Its primary objective is to protect the health of consumers, to ensure fair practices in international food trade, and to promote coordination of all

food standards work undertaken by international governmental and non-governmental organizations. It is charged with the elaboration of international standards and other recommendations, such as codes of practice and guidelines, for foods moving in bulk in international trade. Since the establishment of the World Trade Organization (WTO) on 1 January 1995 as a result of the Uruguay Round negotiations (1986–1994), the Codex Alimentarius Commission and its activities and recommendations have gained more importance and attracted more attention than before 1995. One of the WTO Agreements, the Agreement on the Application of Sanitary and Phytosanitary Measures

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(SPS Agreement) explicitly refers to Codex standards, and stipulates that member governments of WTO shall base their food safety measures on Codex standards, guidelines or recommendations, where they exist (Article 3.1). In addition, in the area of food safety, the SPS Agreement also urges the member governments of WTO to play a full part, within the limits of their resources, in the Codex Alimentarius Commission and its subsidiary bodies to promote the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary measures (Article 3.4).

Participation in Codex meetings

Members

Membership is open to all member nations and associate member nations of FAO and WHO. The current membership stands at 168. Each member of the Commission shall have one representative, who may be accompanied by one or more alternate representatives and advisors. Each member is responsible for appointing these representatives, alternates and advisors for representing its country at sessions of the Commission and its subsidiary bodies; and establishing Codex Contact Point to act as a link between the Codex secretariat and related agencies within its territory.

Observers

Any member nation and any associate member of FAO or WHO which is not a member of the Commission but has a special interest in the work of the Commission, may, upon request communicated to the Director-General of FAO or WHO, attend sessions of the Commission and its subsidiary bodies as an observer. Nations which, while not member nations or associate members of FAO or WHO, are members of the United Nations, may, upon their request and subject to the provisions of FAO and WHO relating to the granting of observer status to nations, be invited to attend, in an observer capacity, sessions of the Commission and of its subsidiary bodies. Subject to the approval by FAO or WHO, the Director-General of FAO or WHO may invite intergovernmental and international non-governmental organizations to attend, as observers, sessions of the Commission and of its subsidiary bodies. International non-governmental organizations wishing to obtain an observer status in the Commission shall submit information following instructions in the 'Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission' adopted by the Commission in its 23rd Session in 1999.

Expenses

Expenses incurred in connection with attendance at sessions of the Commission and its subsidiary bodies and travel of delegations of the members of the Commission and of observers shall be borne by the governments or organizations concerned.

Official languages

Currently, English, French, Spanish, Arabic and Chinese are the official languages of the Commission. However, in most of the subsidiary bodies, only English, French and Spanish are used due to financial limitations.

Structure of the Codex Alimentarius Commission

THE Codex Alimentarius Commission meets every other year, alternately in Rome and Geneva. Its major tasks are: to consider draft Codex standards and related texts for final adoption; to review the programme of work; to review the budget; and to consider any other matters relevant to its work. Its operations follow the Rules of Procedures of the Codex Alimentarius Commission contained in the *Codex Alimentarius Commission Procedural Manual* (12th edition, FAO, 2001).

The management organs of the Commission are the Executive Committee and the secretariat of the Commission. The Executive Committee consists of 11 members: chair and three vice-chairs of the Commission, and seven elected regional representatives. Six regional coordinators attend as observers. The Executive Committee meets every year and considers the future work for the Commission. It takes decisions on behalf of the Commission when there is no meeting of the Commission in that year. The Codex secretariat, located at the headquarters of FAO in Rome, provides administrative support to the Commission including the preparation of working documents, serves as a link to the Codex Contact Points of member countries, and coordinates work with that of other organizations.

Codex has many subsidiary bodies, as shown in Figure 1: six regional committees, nine general subject committees, eleven commodity committees, and three *ad hoc* intergovernmental task forces. The Codex Committee on Nutrition and Foods for Special Dietary Uses acts as a general subject committee when it considers nutritional issues and as a commodity committee when it elaborates standards and related texts on foods for special dietary uses. Task forces have a limited timeframe: all currently existing task forces were established at the 23rd Session of the Commission in 1999 and are expected to give final reports to the 26th Session of the Commission in 2003.

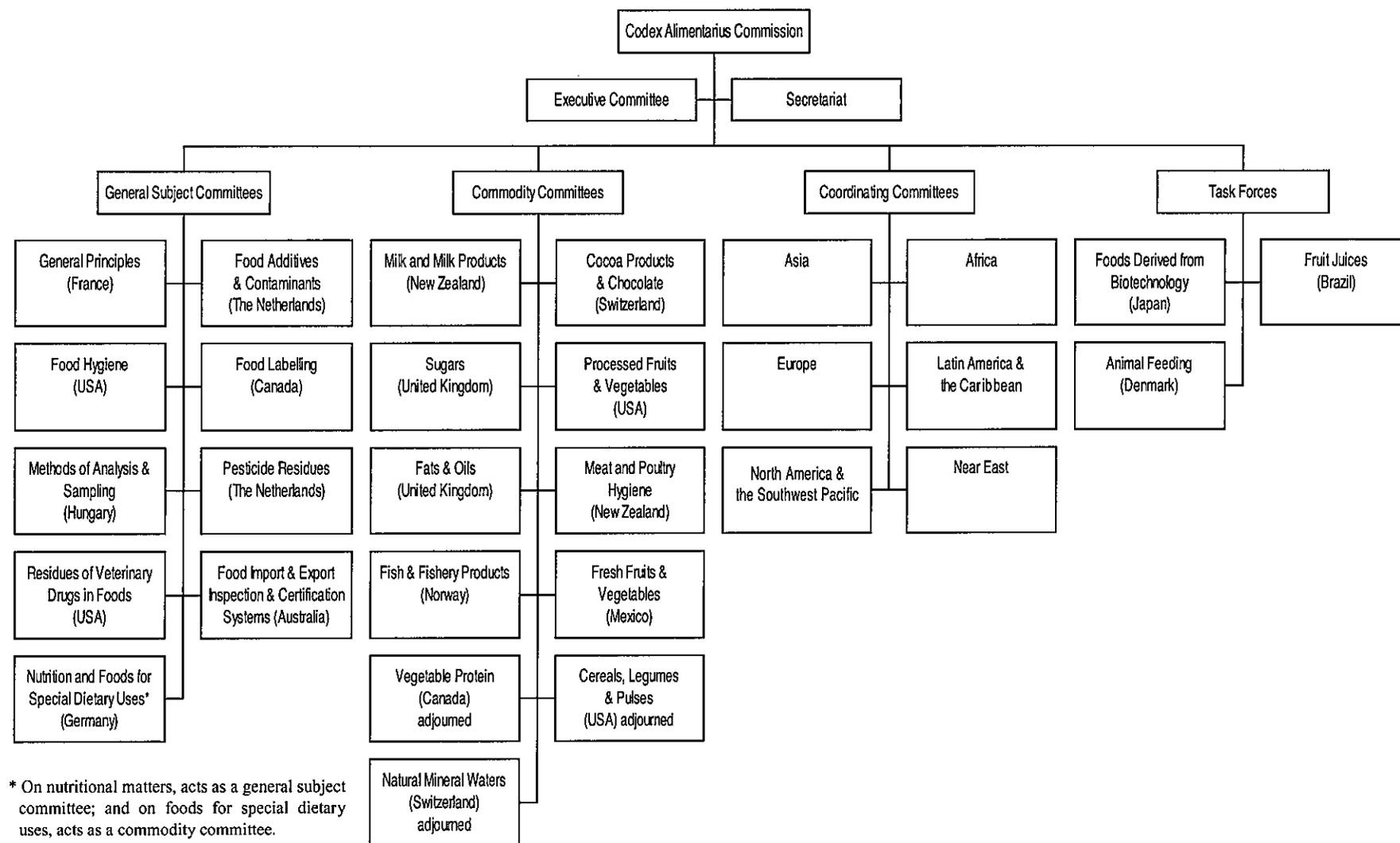


Figure 1. Structure of the Codex Alimentarius Commission

The 19th Session of the Commission in 1991 agreed to focus on horizontal issues and attach significant importance to general subject committees which consider issues applicable to all foods or a large group of foods.

All sessions of the Commission and its subsidiary bodies, except those of the Executive Committee, are held in public i.e. one may listen to and take note of discussions at a Codex session as a member of the public.

Independent and separate from the Codex Alimentarius Commission, there are joint FAO/WHO meetings of individual experts which give scientific advice to the Commission and member countries of FAO and WHO. The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and Joint FAO/WHO Expert Committee on Food Additives (JECFA) are among such expert groups.

Elaboration of Codex standards and other recommendations

THE elaboration of Codex standards and other recommendations follow the eight-step elaboration procedure as stipulated in the 'Procedures for the Elaboration of Codex Standards and Related Texts' contained in the *Procedural Manual*, as shown in Table 1. A decision to initiate the elaboration of a standard can be made only by either the Commission or its Executive Committee on the basis of the 'Criteria for the Establishment of Work Priorities', such as consumer health protection and protection from fraudulent practices, and potential impediments to international trade due to diversification of national legislations. Subsidiary bodies can propose to elaborate a new standard, subject to approval by the Commission or the Executive Committee. In the case of maximum residue limits for pesticides and veterinary drugs, recommendations of JMPR and JECFA are distributed to members and interested international organizations for comments at Step 3 (Table 1).

Subsidiary bodies may propose to the Commission to adopt a proposed draft standard at both Step 5 and Step 8 (Table 1), omitting Steps 6 and 7 when there is consensus in the committee. When elaboration of a Codex standard is a matter of urgency and is not contentious, the proposing committee may propose to follow the five-step accelerated procedure subject to approval by the Commission or the Executive Committee.

The adoption of draft standards and related texts as Codex final texts and the revocation of existing Codex recommendations can be decided only by the Commission itself, while the initiation of work and preliminary adoption can also be done by the Executive Committee.

The revision of existing Codex standards and related texts also follows these elaboration procedures.

Codex standards and other recommendations and the World Trade Organization (WTO)

AMONG all agreements of WTO, the Agreement on the Application of Sanitary and Phytosanitary measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement) have implications to Codex work. The SPS Agreement covers human life and health, including food safety, as well as animal and plant life and health, while the TBT Agreement covers aspects not covered by the SPS Agreement.

While the SPS Agreement specifically refers to the Codex Alimentarius Commission, International Office of Epizootics and International Plant Protection Convention as international standard-setting bodies in the area of human, animal and plant health, the TBT Agreement does not name specific standard-setting organizations.

Codex food safety provisions recognized by the SPS Agreement are: maximum residue limits for pesticides and veterinary drugs; maximum levels of food additives in use; maximum levels for contaminants; food hygiene requirements for foods; and methods of analysis and sampling for and labeling of these provisions. Provisions recognized by the TBT Agreement include: food labeling; quality provisions; nutritional requirements; and methods of analysis and sampling for these provisions.

Article 3.1 of the SPS Agreement stipulates that member governments of WTO shall base their sanitary and phytosanitary measures on international standards, guidelines or recommendations established by the three organizations stated above, where they exist. However, Article 3.3 says that members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a member determines to be appropriate in accordance with the relevant provisions of risk assessment.

Food safety

THERE are many Codex committees dealing mostly or partly with food safety issues. These committees are listed in Table 2. Any recommendations, standards, codes of practice, guidelines, or other types of recommendations elaborated by these committees and adopted by the Commission as Codex final texts are regarded as 'international standard' in the SPS Agreement.

The 21st Commission held in 1995 had an extensive discussion on the role of science in Codex decision-making, especially in developing food safety recommendations. After a lengthy and heated debate, it adopted 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', which is contained in an appendix of the *Procedural Manual*. The most contentious point of the debate was the meaning of 'other legitimate factors', e.g. Europe wanted to include animal welfare, while other regions were opposed to its inclusion, stating that animal welfare was outside of the Terms of Reference of the Commission. The 24th Commission in 2001

Table 1. Uniform elaboration procedure for Codex standards and related texts.

Step	Process
1	The Commission decides to elaborate a Codex standard;
2	The secretariat arranges for the preparation of proposed draft standard; and
3	The proposed draft standard is sent to members and interested international organizations for comments.
4	The proposed draft standard is considered by the relevant Codex committee, together with comments submitted.
5	The proposed draft standard is again sent to members and interested international organizations for comments. The Commission or the Executive Committee considers the proposed draft standard and comments for preliminary adoption.
6	The preliminary adopted standard (draft standard) is considered by the relevant Codex committee, together with comments submitted.
7	The draft standard is considered by the relevant Codex committee, together with comments submitted.
8	The draft standard is again sent to members and interested international organizations for comments. The Commission considers the draft standard and comments for final adoption.
Thence Codex standards and related texts	

Table 2. Codex committees dealing with food safety issues.

Codex committees	Food safety issues considered
<i>Committees whose main responsibilities relate to food safety</i>	
Codex Committee on Food Additives and Contaminants	Maximum levels for the use of food additives Maximum levels for contaminants (mycotoxins, heavy metals, other environmental contaminants such as dioxins and PCBs) Codes of practice for the reduction of contaminants in foods Food additive provisions and contaminant provisions contained in individual food standards
Codex Committee on Food Hygiene	Microbiological risk management Codes of hygienic practice Methods of analysis for pathogenic microorganisms
Codex Committee on Pesticide Residues	Maximum residue limits for pesticides in foods and feeds Methods of analysis and sampling for pesticide residues in foods Extraneous maximum residue limits in foods and feeds
Codex Committee on Residues of Veterinary Drugs in Foods	Maximum residue limits for veterinary drugs in foods of animal origin Methods of analysis and sampling for residues of veterinary drugs in foods
Codex Committee on Meat and Poultry Hygiene	Codes of hygienic practice for meat and poultry
<i>Ad Hoc</i> Intergovernmental Task Force on Animal Feeding	Code of practice for good animal feeding
<i>Ad Hoc</i> Intergovernmental Task Force on Foods Derived from Biotechnology	Guidelines for assessing safety of foods derived from biotechnology
<i>Committees whose responsibilities include food safety issues</i>	
Codex Committee on Methods of Analysis and Sampling	Methods of analysis and sampling for contaminants, such as heavy metals, mycotoxins
Codex Committee on Food Labeling	Labeling of allergens Labeling of foods derived from biotechnology
Codex Committee on General Principles	Working principles for risk analysis

agreed with a decision of the Codex Committee on General Principles and adopted eight 'Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle' instead of developing a list of these factors.

The Commission also promotes consumer involvement in relation to food safety standard setting. Member countries have been encouraged to involve consumers both at the national and Codex levels. A number of international consumer organizations have been granted 'observer' status at Codex and have actively participated in many Codex sessions.

Risk analysis

The 19th Commission held in 1991 decided that, in the future, risk analysis should be applied in the elaboration of Codex standards and related texts. FAO and WHO helped the Commission by organizing a number of expert consultations on elements of risk analysis, and provided recommendations to the Commission and member countries of FAO and WHO. The 20th Commission in 1993 considered the first-ever working paper on risk analysis that analyzed the application of risk analysis in the past and contained recommendations to strengthen risk analysis related activities in Codex. The paper also urged those joint FAO/WHO bodies giving scientific advice to the Commission to implement formal risk assessment processes. At the time, there was a general agreement that risk analysis should be applied but there also was a considerable opposition to the paper.

In recent years, risk analysis is on the agendas of many of the Codex committees included in Table 2 and it is now unthinkable that risk assessment aspects and risk management aspects were not considered in setting food safety standard by these committees.

In 1995, the Commission adopted a number of definitions of risk analysis terms related to food safety and the Statements of Principle Relating to the Role of Food Safety Risk Assessment. The Codex Committee on General Principles has been elaborating working principles for risk analysis within the framework of Codex. In the course of the elaboration, a significant amount of time was spent on the discussion on 'precaution'. While most countries agreed that when there were insufficient scientific data, and consequently there was uncertainty in risk assessment, precautionary measures should be taken, there was a sharp split in whether or not to use the term 'precautionary principle' and to what extent precautionary measures could be applied. Since the term 'precautionary principle' has been used within the European Union, European countries wish to include the term in the Codex document. On the other hand, countries of the Americas and Asia, and Australia and New Zealand, were opposed to use of this term. In particular, countries from Latin America

showed great concerns that the term 'precautionary principle' might justify unfair trade barriers.

Article 5.1 of the SPS Agreement states that members of WTO shall ensure that their sanitary and phytosanitary measures are based on an assessment of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations. The Codex Committee on General Principles will start considering working principles for risk analysis for member countries in 2003.

In the framework of risk analysis related to food safety, the Codex Alimentarius Commission, including its subsidiary bodies, is regarded as a risk manager, and scientific advisory bodies as risk assessors. These bodies include those dealing with chemicals in foods and others dealing with pathogenic microorganisms in foods. In those dealing with chemicals, such as JECFA and JMPR, the WHO Panels review toxicological data to allocate acceptable daily intakes (ADI; for those chemicals used intentionally in food production) or provisional tolerable daily (weekly) intakes (PTD(W)I; for those chemicals not intentionally used in food production, i.e. contaminants). In the case of pesticides and veterinary drugs, acute reference doses may be allocated to those chemicals showing adverse health effects as a result of one-day ingestion.

For pesticides and veterinary drugs, the FAO Panels review trial data along with other data, such as metabolism, and recommend residue definitions and maximum residue limits which will further be considered by the relevant Codex committees. These FAO Panels also perform exposure assessments. In the case of contaminants, such as heavy metals and mycotoxins, the Codex Committee on Food Additives and Contaminants estimates maximum levels through work offered by certain member countries. However, it asks JECFA to perform exposure assessment.

The relevant Codex committees are responsible for establishing priority lists of chemicals for which maximum residue limits or maximum levels be elaborated and which therefore need to be evaluated by JMPR and JECFA. They are also responsible for elaborating maximum residue limits or maximum levels to be adopted by the Codex Alimentarius Commission. In elaborating these limits and levels, not only scientific and technical issues but also economic issues, and sometimes even cultural issues, may be considered.

Recently, it has become more important to ensure good risk communication between risk managers (Codex committees) and risk assessors (relevant scientific bodies) as well as to establish risk assessment policy for effective and efficient risk analysis.

Conclusions

AS Codex recommendations have gained importance, especially in international trade of food, and as consumer interests and concerns in food safety have increased significantly in the world in recent years, it is

important for each Codex member to actively and constructively participate in Codex sessions and to promote its work in its country to obtain as wide a range of opinions as possible from its consumers and the industry.