

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

**Agenda Item 2**

**CX/FICS 00/2  
October 2000**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS**

**Ninth Session**

**Perth, Australia, 11 – 15 December 2000**

#### **MATTERS REFERRED FROM OTHER CODEX COMMITTEES**

##### **GUIDELINES FOR GENERIC OFFICIAL CERTIFICATE FORMATS AND THE PRODUCTION AND ISSUANCE OF CERTIFICATES**

1. The 47<sup>th</sup> Session of the Executive Committee adopted the proposed draft Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates at Step 5 and advanced the document to Step 6.<sup>1</sup>
2. At the 4<sup>th</sup> Session (March 2000) of the Codex Committee on Milk and Milk Products (CCMMP), the Committee agreed<sup>2</sup> in principle to a further discussion paper on the possible elaboration of a model export certificate for milk products. As an initial step, the Codex Secretariat would issue a circular letter, developed in collaboration with the New Zealand Secretariat of the CCMMP and the Australian Secretariat of the CCFICS, to request information that would assist in the development of a discussion paper. Information would be sought on the approach thought most appropriate for the elaboration of model export certificates for milk products, including objectives and scope; specific definitions required; and general principles and criteria.
3. The CCMMP further agreed that a drafting group led by Switzerland would prepare a discussion paper for consideration at the next session of the Committee taking into consideration written comments submitted at the current meeting, information received in response to the circular letter, and other information from relevant general subject committees as appropriate. It was proposed that the discussion paper would include a suggested framework.
4. At the 24<sup>th</sup> Session (June 2000) of the Codex Committee on Fish and Fishery Products (CCFFP), the Committee noted<sup>3</sup> that the Codex Committee on Food Import and Export Inspection and Certification Systems had forwarded to Step 5 the proposed draft General Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates, which would provide useful guidance in the current work on fishery products. However, the CCFICS would not be working on the establishment of model certificates covering the requirements for specific commodities.
5. The CCFFP noted that the document had not been circulated for comments due to time constraints and agreed that it should be circulated at Step 3 for comments. Governments were invited to provide comments, especially on the Attestation section and the certification requirements, to allow the Delegations of Norway and Canada, with the assistance of interested countries, to revise the text for consideration by the next session if necessary.

<sup>1</sup> ALINORM 01/3, para. 49 and App. IV

<sup>2</sup> ALINORM 01/11, paras. 129-130

<sup>3</sup> ALINORM 01/18, paras. 136-140 and App. VIII

**Secretariat Note:** The draft Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates will be discussed under Agenda Item 3, document CX/FICS 00/3. Comments submitted at Step 6 in response to CL 2000/15-GEN are reproduced in document CX/FICS 00/3-Add.1.

#### **GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS**

6. The 47<sup>th</sup> Session of the Executive Committee approved<sup>4</sup> the elaboration of proposed draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems as new work. In taking this decision, the CCEXEC “indicated that the document should emphasize system requirements”.

**Secretariat Note:** The proposed draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems are scheduled for discussion under Agenda Item 7, document CX/FICS 00/7.

#### **CONSIDERATION OF NEW WORK PROPOSALS AT STEP 1 OF THE PROCEDURE**

7. In considering proposals for new work, the 47<sup>th</sup> Session of the Executive Committee made<sup>5</sup> a general observation that justification for new work in terms of the Criteria for the Establishment of Work Priorities<sup>6</sup> should be well documented when making such proposals. It also noted the practice in some Committees of developing discussion papers or positions papers that explored the merits of proceeding with new work proposals, and encouraged this practice provided that it was not being used as a substitute for taking decisions.

#### **GUIDANCE ON THE APPLICATION OF ISO 9001 AND ISO 9002 IN THE FOOD AND DRINK INDUSTRY (ISO/DIS 15161)**

8. The 47<sup>th</sup> Session of the Executive Committee noted<sup>7</sup> that the above work was being undertaken by International Organization for Standardization (ISO) with inputs from the Codex Secretariat and the Secretariat of the Committee on Food Import and Export Inspection and Certification Systems and expressed its appreciation of the cooperation. It also supported the approach of providing guidance for the integration of HACCP principles into ISO 9000 quality management texts for the food industry as a means of assisting the food industry, especially small and medium sized businesses, in applying HACCP effectively. It requested that this work be reported to the Committee on Food Hygiene and the Committee on Food Import and Export Inspection and Certification Systems to ensure appropriate coordination.

**Secretariat Note:** The Committee might wish to take account of the above ISO document when considering the proposed draft Guidelines for the Utilization and Promotion of Quality Assurance Systems to Meet Requirements in Relation to Food under Agenda Item 5 (CX/FICS 00/5).

#### **CONSIDERATION OF THE RECOMMENDATIONS AND OTHER MATTERS ARISING FROM THE INTERNATIONAL CONFERENCE ON FOOD TRADE BEYOND 2000**

9. At the 47<sup>th</sup> Session (June 2000) of the Executive Committee,<sup>8</sup> the Representative of FAO introduced the working document describing the outcome of the "International Conference on Food Trade Beyond 2000: Science-based Decisions, Harmonization, Equivalence and Mutual Recognition", which was held in Melbourne, Australia, from 11-15 October 1999. He informed the CCEXEC that the Conference made a large number of recommendations which addressed each one of the issues discussed at the Conference. He referred in particular to the “General Recommendations of the Conference” and to “Other Recommendations” of the Conference that were addressed to, or could be acted upon by, the Codex Alimentarius Commission and/or its subsidiary bodies.

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<sup>4</sup> ALINORM 01/3, para. 43 and App. III

<sup>5</sup> ALINORM 01/3, para. 44

<sup>6</sup> Procedural Manual, 11<sup>th</sup> Edition, 2000, pages 66-67.

<sup>7</sup> ALINORM 01/3, para. 35

<sup>8</sup> ALINORM 01/3, paras. 22-26

10. The Executive Committee noted with satisfaction the Conference's appreciation of the work of the Commission and its fullest support to the current direction of its work. The Executive Committee further noted that the vast majority of the "General Recommendations" were addressed to Member Governments and/or FAO and WHO. It noted that several of these recommendations would need to be considered in the development of the Commission's Medium Term Plan. The Executive Committee noted that most of the "Other Recommendations" were already being addressed by the relevant Codex Committees or by FAO/WHO. Others would need to be examined in relation with the discussion of the Medium Term Plan and/or by the Codex Regional Coordinating Committees.

11. The Executive Committee recognised the need to develop guidelines for determining equivalence of food control systems, covering not only safety but also quality and conformity.

**Secretariat Note:** The report of the Conference on International Food Trade Beyond 2000: Science-Based Decisions, Harmonization, Equivalence and Mutual Recognition (W/X4015E), which was held in Melbourne, Australia from 11-15 October 1999, is available from FAO. The document is also available at:

<http://www.fao.org/docrep/meeting/X4015e.htm> (English)

<http://www.fao.org/docrep/meeting/X4015f.htm> (French)

<http://www.fao.org/docrep/meeting/X4015s.htm> (Spanish)

#### **PREPARATION OF THE MEDIUM TERM PLAN 2003-2007<sup>9</sup>**

12. The 47<sup>th</sup> Session of the Executive Committee noted that the 23rd Session of the Codex Alimentarius Commission had agreed to prepare the subsequent Medium-Term Plan for 2003-2007 to be initiated rapidly for consideration by its Session and that a Circular Letter (CL 2000/3-GEN) had been sent to Member governments subsequently. In view of the very limited response to the Circular Letter, the Executive Committee discussed which elements of the current Medium-Term Plan might be extended into the next period 2003-2007 and considered how the Medium-Term Plan could be developed further in time to be submitted to the Commission.

13. The Executive Committee was of the opinion that the Medium-Term Plans of the Parent Organizations (FAO's Strategic Framework and the Strategic Plan of WHO), the recommendations of FAO Melbourne Conference, and elements of the Chairperson's Action Plan should be incorporated into the Medium-Term Plan. It noted that many studies had been undertaken in the recent past on food standards and particularly food safety issues and therefore agreed to consider issues arising from Cartagena Protocol, WTO/SPS/TBT, EC White Paper of Food Safety, OIE and the OECD reports. It stated that issues regarding food safety and consumer protection would need to be emphasized.

14. The Executive Committee noted the need to complete on-going work included in the current Medium-Term Plan and requested all Codex Committees to assess the progress of their work within this framework so that only a few remaining areas would need to be carried forward to the next period. It also recognized the need for a streamlined coordination between Codex Committees both horizontally and vertically. Better coordination between Regional Coordinating Committees and other Codex Committees was also raised.

15. The Executive Committee also drew attention to the need for the Commission to fulfil its mandate in relation to fair trade practices and product quality.

16. The Executive Committee stressed that the development of the next Medium Term Plan should be based on the premise that certain issues would be concluded by the end of the current planning period. These included development of risk analysis principles, application of precautionary principles or approaches and other legitimate factors in risk management, and principles for microbiological risk assessment. Elements that might be considered for further consideration included guidelines for risk communication, follow-up work on foods derived from biotechnology, traceability, health claims, meat hygiene and inspection. Several Members expressed the view that the Medium Term-Plan should be developed as part of a broader vision of strategic planning.

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<sup>9</sup> ALINORM 01/3, paras. 36-41

17. The Executive Committee agreed that all these issues and areas should be considered as the basis for building Medium-Term Plan and invited a small group consisting of the Chairperson and the Vice-Chairpersons together with the Secretariat to prepare a draft of the Medium-Term Plan 2003-2007 and develop a strategic statement of the Commission's vision for the future. It also decided to request the opinions of Regional Coordinating Committees. The Executive Committee agreed that the drafts of these documents should be made available for consideration and discussion by the next session of the Commission.

**Secretariat Note:** The results of discussions between the Chairperson and Vice-Chairpersons of the Commission are contained in the Summary Report of a Working Group of the Executive Committee of the Codex Alimentarius Commission (CX/EXEC 00/47/WG.1REP) (under separate cover).

#### **CODEX CODE OF ETHICS FOR INTERNATIONAL TRADE IN FOOD**

18. In view of time constraints, the 15<sup>th</sup> Session of the Codex Committee on General Principles (April 2000) did not consider<sup>10</sup> the Codex Code of Ethics for International Trade in Food section by section but had an exchange of views to identify the areas which needed further clarification.

19. Several delegations stressed the need to clarify the status of the Code in international trade, especially in relation to the SPS and TBT Agreements; in addition the consequences of non-compliance with the provisions of the Code should be addressed.

20. Some delegations pointed out that Codex standards and related texts were usually addressed to governments and that some clarification was needed as to the scope of the Code, especially whether it applied to governments or to producers. It was noted that the Code applied to all those engaged in international trade and that this would apply to all sectors involved in the production, transport and distribution of food, as reflected in Section 7.

21. The Committee agreed to return the proposed draft Code to Step 3 for redrafting by the Secretariat in the light of the comments received and the above discussion, for consideration at the next session.

#### **RISK ANALYSIS: FOOD SAFETY OBJECTIVES**

22. The 15<sup>th</sup> Session (April 2000) of the Codex Committee on General Principles noted<sup>11</sup> that it had agreed at its last session to consider the general aspects of the development and application of "food safety objectives" following discussions at the 7<sup>th</sup> Session of the Codex Committee on Food Import Export Inspection and Certification Systems (CCFICS) and the 45<sup>th</sup> Session of the Executive Committee.

23. The Committee discussed whether there was a need to define "food safety objectives" and how it would proceed to consider the concept in relation to risk analysis specifically. The Committee was of the opinion that the application of "food safety objectives" concept was of a technical nature and it was premature to generalize the concept with a specific definition.

24. The Committee agreed that the concept of "food safety objectives" could be further developed by other relevant Committees in order to identify how it could be applied to specific food safety issues, and that the Committee should continue to oversee the consistency in the definition and application of the concept.

25. The 33<sup>rd</sup> Session of the Codex Committee on Food Hygiene (October 2000) noted<sup>12</sup> that the proposed draft Principles and Guidelines for the Conduct of Microbiological Risk Management had been revised and restructured since its last Session, including that the term food safety objective (FSO) was changed to Microbiological Food Safety Objective (MFSO), although it was noted that this concept needed further development.

26. The CCFH agreed that, where they existed, the definitions used should be those adopted by the Codex Alimentarius Commission. Delegations also identified a number of additional terms which needed to be

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<sup>10</sup> ALINORM 01/33, paras. 96-108

<sup>11</sup> ALINORM 01/33, paras. 63-68

<sup>12</sup> DRAFT Report of the 33<sup>rd</sup> Session of the Codex Committee on Food Hygiene, ALINORM 01/13A, paras. 83-95

defined, including, tolerable level of risk (TLR), microbiological hazard, appropriate level of protection, risk profile, interested parties, stakeholders, risk management policy and acceptable level of risk. The Committee also noted that for terms such as TLR and MFSO, further definition of the concepts was required before the terms could be defined.

27. The CCFH agreed that a Circular Letter would be sent out to request information and views and examples of food safety objectives. The Committee also agreed to return the proposed draft Principles and Guidelines to Step 3 for revision by a drafting group under the direction of France.

**Secretariat Note:** The final report of the 33<sup>rd</sup> Session of the Codex Committee on Food Hygiene, including those paragraphs related to the CCFH discussions on food safety objectives, will soon be available on the Codex Website at [www.codexalimentarius.net](http://www.codexalimentarius.net)

#### **CONSIDERATION OF THE ELABORATION OF STANDARDS, GUIDELINES OR OTHER PRINCIPLES FOR FOODS DERIVED FROM BIOTECHNOLOGY**

28. At the 1<sup>st</sup> Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (March 2000) many delegations and observer organizations identified<sup>13</sup> safety and nutrition assessment of foods derived from biotechnology as the main priority area of the work. While recognizing that the concept of the substantial equivalence was being used in safety assessment, several delegations and observer organizations stressed the need for further review of the concept and its applicability to safety assessment. In addition, the following factors were mentioned by some delegations as potential other legitimate factors: ethical/religious/cultural considerations, consumer concerns/interests, food security, enforcement capacity and environmental risk.

29. Many delegations and observers identified the development of a guideline for the monitoring and traceability of the foods derived from biotechnology as a priority, indicating that these issues were not related only to consumer information but to consumer health protection. Other delegations and observers stated that the concept of “traceability” was new to Codex and required further clarification and explanation including the implications for developing countries. It was also noted that the concept may not be exclusive to foods derived from biotechnology and may need to be considered at a more general level.

30. Regarding key concepts and definitions, many delegations emphasised the need to establish clear definitions on several key words. The definitions of “modern biotechnology” and “substantial equivalence” were identified by many delegations and it was suggested that the Task Force refer to definitions established or to be established by other fora, e.g. the definition on modern biotechnology to be developed by the Codex Committee on Food Labelling.

31. The Task Force recognized that the time frame prescribed in its terms of reference necessitated the prioritization of its work subjects and that a considerable part of the proposed subjects were duly or partly covered by other Codex Committees or other international organizations. The Task Force recalled also that, according to its terms of reference, the Task Force should coordinate and closely collaborate with appropriate Codex Committees and take full account of existing work carried out by other international organizations. It agreed to identify those subjects that were already under discussion by other Codex subsidiary bodies or other international organizations and which therefore would not need to be considered in detail in the priority areas of the work of the Task Force.

32. Taking into account the priorities discussed above, the Task Force decided that it would proceed with the elaboration of two major texts, namely:

- ◆ A set of broad general principles for risk analysis of foods derived from biotechnology including matters such as:
  - Science-based decision-making;
  - Pre-market assessment;
  - Transparency;
  - Post-market monitoring [including traceability]; and
  - Other legitimate factors as appropriate.

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<sup>13</sup> ALINORM 01/34, paras. 13-38

- ◆ Specific guidance on the risk assessment of foods derived from biotechnology including such matters as:
  - Food safety and nutrition;
  - “Substantial equivalence”;
  - Potential long-term health effects; and
  - Non-intentional effects.

33. It was agreed that careful attention should be paid to the development of adequate and appropriate definitions, drawing on definitions already developed and agreed to in other texts (such as the Cartagena Protocol) or by other bodies (such as the Codex Committee on Food Labelling).

34. Concerning the issues of *Traceability* and *Familiarity* raised by several delegations, the Task Force noted that a better understanding of these concepts and their implications was required before they could be included definitively in either of the main texts to be developed. It therefore agreed that discussion papers should be prepared on these issues as soon as possible. In the meantime, any reference to these issues in the main texts under development would remain in square brackets.

#### **CONSIDERATION OF THE REVISED DRAFT CODE OF PRACTICE ON GOOD ANIMAL FEEDING AND MATTERS REGARDING OTHER ASPECTS OF FOOD SAFETY IN ADDITION TO THE CURRENT CODE OF PRACTICE**

35. In discussing the above subject, the 1<sup>st</sup> Session of the Codex Ad Hoc Intergovernmental Task Force on Animal Feeding considered<sup>14</sup> the question of “traceability” in reference to the control of feedingstuffs and the ability to take corrective measures in case of emergency situations or when there was an indication of non-compliance with established standards or procedures. It was noted that this issue was also being debated in other Codex bodies including the Ad Hoc Intergovernmental Codex Task Force on Foods Derived from Biotechnology and that the Codex Committee on Food Import and Export Inspection and Certification Systems had developed a number of relevant Guidelines that could be used.

36. The Task Force agreed that special provisions relating to “traceability” should be included in the Code especially in reference to good manufacturing practices for the production, distribution and use of feedingstuffs. It also proposed that reference may need to be made to other Codex texts and to standards developed by ISO for this purpose. It was suggested that general requirements in relation to traceability might be included in the Code, leaving specific provisions for application to Member governments.

37. The Task Force also agreed that the Code should include provisions for the labelling of feedingstuffs as part of good manufacturing practice and risk management in view of the need for adequate labelling within the framework of traceability. Moreover, it was stressed that labelling should be clear and informative so as to allow the farmer to handle and use feedingstuffs correctly.

38. The Task Force agreed that references should be made to official inspection and control procedures and self regulation (auto control), taking into account recommendations already adopted and published by the Commission. References to HACCP principles should also be included. The Task Force agreed however that specific reference to legislative requirements would not be appropriate for inclusion in the Code.

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<sup>14</sup> ALINORM 01/38, paras. 31-32