

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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## Agenda Item 4

CX/FICS 99/4  
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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION  
AND CERTIFICATION SYSTEMS  
Seventh Session  
Melbourne, Australia, 22 - 26 February 1999**

**Proposed Draft Guidelines/Recommendations  
For Food Import Control Systems**

## BACKGROUND

1. It is recognized that food import control systems need to be properly designed to ensure product safety while at the same time facilitating trade including the prompt entry of products that meet requirements. Specifying the critical elements of a system, the appropriate level of activity of the elements of a system, and how the various elements interact is important. Food import control systems have a significant impact on consumer protection and on the ease of movement of food in international commerce consistent with international obligations.
2. In combination with the existing *Principles for Food Import and Export Inspection and Certification*<sup>1</sup> and the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Inspection and Certification Systems*<sup>2</sup>, a specific set of guidelines for the proper operation of food import control systems would be of significant value in assuring that internationally traded foods are safe and can readily enter their intended country of import.
3. At its fourth session in February 1996, CCFICS adopted a proposal by the Government of Mexico to consider the possible development of guidelines for food import control systems. During the course of the following year, the Codex Secretariat and Mexico conducted a survey of the food import control systems of several countries and presented a report to CCFICS at its fifth session that contained several options for the Committee to consider<sup>3</sup>. The Committee agreed to request the Codex Alimentarius Commission to confirm the appropriateness of development of guidelines for food import control systems and invited Mexico, with the assistance of the United States, to develop a further discussion paper on the subject focused on Option 3 of the initial discussion paper<sup>4</sup>. The Commission<sup>5</sup>, at its twenty-second Session requested Mexico, in collaboration with the

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<sup>1</sup> CAC/GL 20-1995

<sup>2</sup> CAC/GL 26-1997

<sup>3</sup> CX/FICS 97/9

<sup>4</sup> ALINORM 97/30<sup>a</sup> paragraph 40-44

Secretariat, to revise its discussion paper of guidelines for food import control systems for consideration at the next session of CCFICS.

The intent is that the proposed *Guidelines for Food Import Control Systems* complement other Codex texts and certain other existing references [e.g., *FAO Manual of Food Quality Control; Imported Food Inspection* (1993); *WHO Manual for Inspection of Imported Food* (1992)]. The proposed guidelines would provide guidance for countries in the specific operation of food import control programs with reference made to other texts for more specific detailed operational requirements.

4. The 6<sup>th</sup> CCFICS<sup>6</sup> decided to request the approval of the Executive Committee to proceed in the elaboration of proposed draft Guidelines/Recommendations for Food Import Control Systems. The Executive Committee<sup>7</sup> approved the elaboration of the Guidelines with the understanding that “careful attention should be given to the nature of the output of this work, especially as to the status of the final text”, i.e., as a “guideline” or “recommendation”).

The paper at Attachment I presents a revised set of *Guidelines for Food Import Control Systems* that incorporates a set of operating principles for such systems and implementing guidance for each principle. Attached as an Annex is relevant literature that provides practical information on how to set up and operate an imported food control system and expand on those operational elements.

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<sup>5</sup> ALINORM 97/37 paragraph 142

<sup>6</sup> ALINORM 99/30 paragraph 36

<sup>7</sup> ALINORM 99/30, appendix 3

## PROPOSED DRAFT GUIDELINES/RECOMMENDATIONS FOR IMPORTED FOOD CONTROL SYSTEMS

### SECTION 1. SCOPE

1. Food import control systems need to be properly designed to ensure product safety while at the same time facilitating trade, including the prompt entry of products that meet requirements. Specifying the critical elements of a system, their appropriate level of activity, and how the various elements should interact is important. It is significant to recognize that World Trade Organization (WTO) disciplines, including risk based program design, should be a basis for guidance in the design and operation of a food import control system. Also the availability of sufficient national resources to ensure safe product without unnecessarily restricting trade is essential for an effective food import control system. This document provides a framework for the development of import inspection system consistent with *the Principles for Food Import and Export Inspection and Certification*<sup>8</sup>. It is intended to assist countries in the application of requirements and the determination of equivalence, thereby protecting consumers and facilitating trade in foodstuffs.
2. It is the responsibility of the country's government to establish a food import control system which provides assurance to consumers that imported products are being inspected to be in full compliance with established requirements. Further it is the responsibility of producers, exporters and importers to comply with requirements established by the importing country's food control system.

### SECTION 2. DEFINITIONS

3. *Audit*<sup>9</sup> is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.
4. *Certification*<sup>10</sup> is the procedure by which official certification bodies and officially recognized bodies provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products.
5. *Equivalence*<sup>11</sup> is the capability of different inspection and certification systems to meet the same objectives.
6. *Inspection*<sup>12</sup> is the examination of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify that they conform to requirements.

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<sup>8</sup> CAC/GL-1995

<sup>9</sup> CAC/GL 20-1995

<sup>10</sup> CAC/GL 20-1995

<sup>11</sup> CAC/GL 26-1997

<sup>12</sup> CAC/GL 20-1995

7. *Official accreditation*<sup>13</sup> is the procedure by which a government agency having jurisdiction formally recognizes the competence of an inspection and/or certification body to provide inspection and certification services.
8. *Official inspection systems and official certification systems*<sup>14</sup> are systems administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function or both
9. *Officially recognized inspection systems and officially recognized certification systems*<sup>15</sup> are systems which have been formally approved or recognized by a government agency having jurisdiction.
10. *Requirements*<sup>16</sup> are the criteria set down by the competent authorities relating to trade in foodstuffs covering the protection of public health, the protection of consumers and conditions of fair trading.<sup>4</sup>
11. *Risk analysis*<sup>17</sup> is a process consisting of three components: risk assessment, risk management and risk communication.
12. *Risk assessment*<sup>18</sup> is a scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment and (iv) risk characterization.
13. *Risk management*<sup>19</sup> is the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

### **SECTION 3. TRANSPARENT SYSTEM WITH DOCUMENTED PROCEDURES AND STANDARDS (PRINCIPLE No 1)**

14. The aims and priorities of a Food Import Control System need to be clearly defined. Preferably, policy and planning activities should integrate all food inspection functions undertaken in a country.
15. The government of the importing country should use an official means of communication and publication to disseminate information on the regulations, policies and guidelines applied by the import control systems.
16. The criteria and procedures for evaluation of product conformity should be defined in the regulations, policies and guidelines of the importing country; taking into consideration Codex standards and text as appropriate, using a process based on risk analysis.

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<sup>13</sup> CAC/GL 26-1997

<sup>14</sup> CAC/GL 20-1995

<sup>15</sup> CAC/GL 20-1995

<sup>16</sup> CAC/GL 20-1995

<sup>17</sup> CAC/GL 26-1997

<sup>18</sup> CAC/GL 20-1995

<sup>19</sup> CAC/GL 26-1997

#### **SECTION 4. CLEARLY DEFINED AUTHORITY FOR LEGISLATION, REGULATION AND OFFICIAL INSPECTION SYSTEM (PRINCIPLE No 2)**

17. A sound legislative base enables the official inspection system to regulate food, whether imported or domestic. The importing country should have the legal ability to enforce and take action where non-compliance is detected.
18. The sovereign of a country<sup>20</sup> does not extend to food production controls in other countries, so the legislation should allow development of agreements<sup>21</sup> with supplying countries.
19. The official inspection system responsible for food import control should be clearly and legally defined.
20. When more than one agency is involved in the pre-authorization acceptance of imported foods or their inspection at the port of entry and/or distribution level, responsibilities and authorities should be clearly defined. This includes customs authorities if they have a role in the control of imported foods.
21. If sub-national agencies<sup>22</sup> have responsibilities (including or excluding regulatory decisions) for the control of imports, the division of responsibilities, functions, and competence should be clearly and transparently defined and consistent with priorities and procedures of the central administration.
22. Use of third party organization(s) (private or public) for inspection, test, analysis and certification of conformance need to be based on procedures which guarantee their independence or absence of conflicts of interest, and provide for evaluations which would assess their administrative and technical capability. Such organizations can be third party sampling units, first line or reference analytical laboratories, verification units, or certification organizations. The procedures and/or techniques utilized by the designated authority to determine competency of third party organizations should preferably those of internationally recognized bodies, particularly those of Codex.

#### **SECTION 5. APPLICATION OF RISK ANALYSIS (PRINCIPLE No 3)**

23. Importing countries will manage their systems based on risk analysis in which all available factors will be considered, including: the risk presented by particular foods; the size of imported lot; the target consumer group; the extent and nature of any further processing of the product, the final destination; the country of origin; the history of the product; the compliance history of the processor, shipper and importer; the existence of alert notifications received from other countries, and factors relating to the food safety control system in the exporting country.
24. The frequency of inspection and testing of imported foods should be based on the risk presented by the product. Lot-by-lot inspection should be undertaken when justified by the risk presented by the product considering the history of non-compliance exhibited by the parties involved.

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<sup>20</sup> For the purpose of these guidelines, "country" includes regional economic integration organizations to which a group of countries have transferred competencies as regards food import and export inspection and certification systems and/or the negotiation of agreements with other countries.

<sup>21</sup> ALINORM 99/30 Appendix 2. Section 4 Type of Agreements.

<sup>22</sup> "Sub-national authorities" means all levels of government below the national level and includes, for examples, the states of Australia, Mexico and the United States, the provinces of Canada and China, the Landër of Germany, the oblasts of the Russian Federation, the cantons of Switzerland, as well as local and city authorities,

25. Part of the verification and validation of certificates may involve sampling and analysis of certified shipments. This process can form the basis of a point of entry inspection program for food where no certification arrangement exists. As it develops, the program should adopt a risk-managed approach, concentrating on food which is more likely to be a hazard to public health. Controls can be extended as resources allow. Resources will determine priorities. The scope of the program should initially target public health protection of high risk products and place less emphasis on other consumer protection matters.
26. Exporting countries could collect and disseminate epidemiological data on food illness outbreaks, recalls and levels of non-compliance of food produced in the exporting country. Publication on the Internet is encouraged.

**SECTION 6. A FOOD IMPORT CONTROL SYSTEM SHOULD BE CONSISTENTLY IMPLEMENTED AND PROVIDE FOR PARITY WITH DOMESTIC CONTROL (PRINCIPLE No 4)**

27. Countries shall apply the same requirements to imported foods as apply to domestic products.
28. Imports program should be applied consistently and uniformly at each point of entry.
29. Operational details of food import programs include:
- Inspection procedures;
  - Product sampling frequency and methods for sampling and analysis;
  - Use of certificates;
  - Use of product pre-shipment approval.
  - Product, establishment, exporter, or importer registration requirements.
  - Criteria for determining compliance with requirements;
  - Alternatives to decision making;
  - Mechanisms to communicate decisions including report documents;
  - Product disposition including: free entry, entry to sample and verify for conformance, entry of non-conforming product after corrective measures have been taken, rejection and re-exportation, rejection without re-exportation, and destruction.
30. The Food Import Inspection System requires to be fully documented, including a description of its scope and operation, and responsibilities and actions for staff, in order to help every officer involved to know the who, what, how, when and where thing should be done. This enables to maintain a quality service, regardless of changes in personnel or policy. The system should be assessed regularly to ensure principles and objectives are met<sup>23</sup>.
31. The inspection staff is one of the essential elements of the system, therefore is fundamental to have a group of professionals, reliable, well trained and organized staff, with personal qualities and a supporting infrastructure which enable the operating and public relations functions that are required. The inspection system need provide training and maintain an adequate communication system for

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<sup>23</sup> CAC/GL 26 1997 Section 9 deals with assessment and verification and is relevant to imported food inspection systems

the implementation of a consistent import control system throughout the different entry points in the country.

## **SECTION 7. RECOGNITION OF FOOD SAFETY CONTROLS IN THE EXPORTING COUNTRY (PRINCIPLE No 5)**

32. The importing country should be capable of recognizing the established control system and standards in an exporting country where they provides the same level of protection required in the importing country. Acceptance could be through equivalence agreements, certification, or other means of mutual or one way recognition.
33. The development of the equivalence agreement could take as a basis the “*Draft Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems*”<sup>24</sup>. The evaluation could be based on section 9 and related annexes of “*Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems*”<sup>25</sup> and other relevant internationally recognized criteria.
34. Once an Export Inspection and Certification Systems has been accepted, occasional random sampling and analysis of products upon arrival could be required to verify that the system is properly operating.

## **SECTION 8. ADHERENCE TO THE CODEX “CODE OF ETHICS FOR INTERNATIONAL TRADE IN FOOD” (PRINCIPLE No 6)**

35. Those involved in international food trade, and its regulation and control, should adhere to the *Codex Code of Ethics for the International Trade Food*<sup>26</sup>
36. When a food product is rejected by the responsible authority of the importing country, the buyer and the responsible authority of the exporting country should be informed of the reasons for the rejection. The exchange of information should follow the format stipulated in the *Draft Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food*<sup>27</sup>.

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<sup>24</sup> ALINORM 99/30 Appendix 2.

<sup>25</sup> CAC/GL 26-1997

<sup>26</sup> CAC/RPC 20-1979, Rev. 1 (1985)

<sup>27</sup> CAC/GL 25-1997

## RELEVANT LITERATURE

### Imported Food Control

The Food and Agriculture Organization *Manual of Food Quality Control. Imported Food Inspection* (Food and Nutrition Paper 14/15, 1993) details factors and issues to be considered in creating an imported food control system such as alternatives for achieving aims, legal basis and actual inspection options, administrative and technical support and basis for accepting certification systems.

World Health Organization/Western Pacific Regional Center for the Promotion of Environmental Planning and Applied Science (PEPAS): *Manual for the Inspection of Imported Food* (1992) focuses on inspection and sampling procedures in genera and for specific products. It details sampling techniques, equipment and inspection staff responsibilities. Its primary focus is a working (procedural) document for inspection staff.