

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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**Agenda Item 3**

**CX/FICS 00/3**

**November 1999**

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

#### **Eighth Session**

**Adelaide, Australia, 21 – 25 February 2000**

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

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 15 January 2000** to: Digby Gascoine, Director, Policy and International Division, Australian Quarantine and Inspection Service, GPO Box 858, Canberra ACT, 2601 (fax: 61.2.6272.3103), or by e-mail to Codex Australia at [codex.contact@affa.gov.au](mailto:codex.contact@affa.gov.au), with a copy to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy.

#### BACKGROUND

1. At its fourth session in February 1996, the CCFICS agreed to a proposal by the Government of Mexico to consider the development of guidelines for food import control systems.<sup>1</sup> During 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, which contained several options for the Committee to consider<sup>2</sup>. The Committee agreed to request the Codex Alimentarius Commission to confirm the appropriateness of the 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 based on Option 3 of the initial discussion paper.<sup>3</sup> The 22<sup>nd</sup> Session of the Commission requested Mexico, in collaboration with the Secretariat, to revise its discussion paper on the development of guidelines for food import control systems for consideration at the next session of CCFICS.<sup>4</sup>

2. The 6<sup>th</sup> Session of the CCFICS decided<sup>5</sup> to request the approval of the 45<sup>th</sup> Session of the Executive Committee to proceed in the elaboration of proposed draft Guidelines/Recommendations for Food Import Control

<sup>1</sup> ALINORM 97/30, para. 31

<sup>2</sup> CX/FICS 97/9

<sup>3</sup> ALINORM 97/30A, paras. 40-44

<sup>4</sup> ALINORM 97/37, para. 142

<sup>5</sup> ALINORM 99/30 para. 36

Systems. The Executive Committee approved the elaboration of the Guidelines, noting that 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”.<sup>6</sup>

3. At the 7<sup>th</sup> meeting of the CCFICS, Mexico presented a revised document incorporating a set of principles and guidance for implementation of each principle. The Committee agreed that the proposed draft guidelines should be restructured and redrafted prior to being circulated for comment at Step 3. The Committee requested that Mexico and the Secretariat co-ordinate a drafting group consisting of Australia, Canada, France, Germany, Japan, Netherlands, South Africa and the USA to undertake this revision.<sup>7</sup>

#### **CURRENT STATUS**

4. The revised proposed draft *Guidelines/Recommendations for Food Import Control Systems* (see Annex 1) specifies the elements, administration and management of the system and provides guidance on implementation of an imported food control system. The intent is that the proposed draft *Guidelines for Food Import Control Systems* complement other Codex texts and references [e.g., *FAO Manual of Food Quality Control; Imported Food Inspection* (1993); *WHO Manual for Inspection of Imported Food* (1992)].

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<sup>6</sup> ALINORM 99/3, Appendix 3

<sup>7</sup> ALINORM 99/30A, para. 53

**PROPOSED DRAFT GUIDELINES/RECOMMENDATIONS FOR  
FOOD IMPORT CONTROL SYSTEMS**

**At Step 3**

**1. INTRODUCTION**

1. For many countries, their sources of food have increasingly become global in nature. While, the development of a global food market provide consumers with a wide variety of food and “out of season” foods all the year around, it also gives rise to new issues that need to be considered. The potential for the occurrence of food safety problems is of critical importance. Rapid and efficient transport systems can spread food contamination and foodborne illness more widely than previously. Consequently, the increase in international food trade has been accompanied by the implementation of food safety programs specifically aimed at imported food. Additionally, differences in requirements for areas such as product hold and test, and documentation, may hinder the facilitation of trade. Management of food import control systems should be consistent with international norms such as the *Principles for Food Import and Export Inspection and Certification*<sup>1</sup>. While the adoption of internationally harmonized science-based food safety standards such those of the Codex Alimentarius can enhance the safety of imported foods, the development of specific guidelines for the proper operation of food import control systems can help to significantly facilitate trade.

**2. SCOPE**

2. This document provides a framework for the development and operation of an import control system consistent with *Principles for Food Import and Export Inspection and Certification*. It is intended to assist countries in the application of requirements and bring about transparency thereby protecting consumers and facilitating trade in foodstuffs.

3. It is the responsibility of producers, exporters and importers to comply with requirements established by the importing country's food control system. The appropriate level of protection achieved as a result of the application of the control measures or requirements should be the same.

**3. DEFINITIONS<sup>2</sup>**

*Appropriate level of protection* [to be developed]

*Audit*\*\* is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.

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

<sup>2</sup> Definitions from CAC/GL 26-1997 *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification systems are marked \*\**

*Certification\*\** 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.

*Equivalence\*\** is the capability of different inspection and certification systems to meet the same objectives.

*Inspection\*\** 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.

*Legislation\*\** includes acts, regulations, requirements or procedures, issued by public authorities, related to foods and covering the protection of public health, the protection of consumers and conditions of fair trading.

*Memorandum of Understanding (MOU)* [to be developed]

*Mutual Recognition Agreement (MRA)* [to be developed]

*Official accreditation\*\** 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.

*Official inspection systems and official certification systems\*\** are systems administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function or both.

*Officially recognized inspection systems and officially recognized certification systems\*\** are systems which have been formally approved or recognized by a government agency having jurisdiction.

*Requirements\*\** 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.

*Risk analysis\*\** is a process consisting of three components: risk assessment, risk management and risk communication.

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

*Risk communication\*\** is the interactive exchange of information and opinions concerning risk among risk assessors, risk managers, and other interested parties.

*Risk management\*\** 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.

## **4. ELEMENTS OF AN IMPORT FOOD CONTROL SYSTEM**

### **4.1 Aims and priorities**

4. The aims and priorities of an imported food control system should be determined in a consistent and transparent manner so that, when implemented, the system is able to achieve a country's appropriate level of protection against risks to human life and health arising from food safety hazards.

5. The imported food control system, being an integral part of the food inspection program in a country, should ensure that imports are treated in neither a more nor a less favorable manner than domestic products.

6. Food standards (including Codex) contain public health and consumer protection (e.g., prevention of fraud) matters. Public health protection should be assigned a higher priority. Targeting potentially dangerous food, for example microbiological contamination of ready-to-eat food should take precedence over controlling the entry of food that is short weight in terms of its net content statement.
7. The availability of resources may pre-determine the operation of the imported food control system. Where resources are limited, the program may be more focussed to public health protection; for example, the frequency of inspection for non-public health protection matters may be reduced. Where there is limited access to sophisticated facilities such as laboratories and shipment tracking system, the responsible authority can develop certification agreements with export food inspection agencies and thus implement some initial controls.
8. Regardless of the restrictions placed on the system by limited resources, the system should be sufficiently flexible to permit discretionary inspection, which may include sampling and testing of products which, though normally considered low risk, may have a poor history of conformity or may, as a result of new information, be implicated as a public health threat.
9. The processes undertaken in developing the aims and priorities should be consistent with the *Principles for Food Import and Export Certification and Inspection*, particularly in regard to ensuring that measures applied do not result in unjustified barriers to trade. CAC/GL 20-1995 also notes that any changes to import protocols, which may affect trade, should be promptly communicated to trading partners, allowing a reasonable interval between the publication of regulations and their application.

#### 4.2 Legal framework

10. The details of the legislative framework should encompass all aspects of the food inspection scheme. In developing legislation countries should consider the priorities and mechanism required to achieve those aims and construct legislation accordingly. Legislation setting out the requirements for food import control systems can include:
- licensing of importers
  - analysis of samples, including laboratory accreditation and methods of analysis
  - notification to officials of entry or impending entry of consignments of food;
  - obtaining authorization before distribution, sale or dealing with (for example repackaging or processing) food shipments;
  - procedures for hold, hold and test, and release of food and food ingredients;
  - development of procedures to allow delayed inspection where an imported food is to be further processed;
  - recognition of quality systems covering production and transport of food implemented by importers, which deliver at least the same food safety outcomes as the official inspection system;
  - recognition of quality systems operating in exporting countries and particular factories including conducting off shore inspections
11. Legislation may provide the relevant authority powers to:
- appoint authorized officers
  - inspect, sample and detain imported shipments and relevant documents;
  - order destruction, reconditioning, downgrading (e.g. to “unfit for human consumption”), or re export of shipments;
  - implement administrative or punitive sanctions should importers fail to meet requirements;
  - charge fees for clearing shipments and inspection and analysis
12. Controls implemented by a country do not extend to food production controls in other countries, so the legislation should allow development of arrangements with supplying countries, or jurisdictions, to ensure that stages of production, manufacture, importation, processing, storage, transportation, distribution and trade are controlled to no less an extent than that in the importing country. Consistent with *Guidelines for the Design*,

*Operation, Assessment and Accreditation of Food Import and Export Inspection Systems*<sup>3</sup>, Section 9 and Annex, verification of controls implemented by the certifying authority of the export country should be undertaken by the responsible import authority.

13. These arrangements may take the form of Mutual Recognition Agreements or Memorandum of Understanding among others. The legal structure may include acceptance of certification provided by official inspection and certification systems of the supplying country or other officially recognized inspection and certification systems that are considered acceptable in lieu of, or as an adjunct to, inspection upon arrival.

#### **4.3 Regulations and standards**

14. Imported food standards and application of those standards, as reflective of the importing countries appropriate level of protection, cannot be more rigorous than domestic controls. However as the importing country has no jurisdiction over process controls applied to food manufactured in another country, there may be a variation in approach to the compliance monitoring of domestic and imported food. The standards applied to the imported food should not be any more restrictive than standards demanded of the domestic food supply.

#### **4.4 Defined roles and functions of authorities involved.**

15. When more than one agency is involved in the acceptance of imported foods or their inspection at the port of entry, transit, distribution and/or destination, responsibilities and authorities should be clearly defined.

16. If regional or local government bodies have responsibilities for the control of imports, the divisions of responsibilities, functions and competence should be clearly and transparently defined and consistent with priorities and procedures of the central administration.

17. Some countries, for example those, which are part of a regional economic grouping, may rely on import controls implemented by another country. In such cases, the country charged with conducting the inspection functions must have the system clearly and transparently defined.

18. Where the responsible authorities of a country use third party providers to implement inspection controls under contractual arrangements such arrangements should be conducted in the manner discussed in the CAC/GL 26-1997, Section 8, Official Accreditation. The functions that could be conducted by such agencies include sampling of target food shipments

- laboratory analysis and operation of reference laboratories
- verification of the official system
- evaluation of the compliance of industry operating quality assurance system.

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<sup>3</sup> CAC/GL 26-1997

#### **4.5 Administrative requirements.**

19. The authority responsible for developing and implementing imported food control systems should have access to facilities and equipment to operate the programme (See Section 5). Facilities and equipment required may include:

- laboratory and testing capacity
- trained personnel
- reliable transport
- appropriate communication systems
- recording and data analysis systems.

### **5. MANAGEMENT OF THE CONTROL SYSTEM ELEMENTS**

#### **5.1 Risk Analysis**

20. The goals of the food import control system should be to ensure public health and consumer protection while minimizing trade disruptions. On the basis of sound risk assessment, management procedures should be developed and implemented to minimize undue delay at the port of entry without jeopardizing food safety considerations.

#### **5.2 Application of performance history to inspection**

21. The frequency of inspection and testing of imported foods should be based on the risk presented by the product and the history of conformance to applicable standards.

22. Control systems can be designed to account for several factors including:

- the risk posed by the product
- the target consumer group
- the extent and nature of any further processing of the product
- factors relating to the food inspection and certification system in the exporting country.

23. Lot by lot inspection can be justified only when there is a continuing lack of conformance to applicable standards by a particular food manufacturer, importer or exporter, or when a food safety problem of emergency nature affecting a commodity is demonstrated. Where this is the case inspections should target the identified problem.

#### **5.3 Point of control**

24. Control of imported food can be conducted at the point of

- manufacture,
- entry,
- further manufacture
- storage
- sale, (either retail or wholesale).

25. The system should be structured to deliver the same outcomes regardless of the point of control.

26. The application of controls during manufacture and subsequent transit should be encouraged. This will maximize food safety since early detection and possible correction of any problem can occur.

27. Implementing control towards the retail / wholesale end of the chain is less efficient as recalls of widely distributed food is costly and time consuming. Correction of the problem at source may be considerably delayed,

resulting in continued production and distribution of suspect food. If not detected early, the problems and costs are transferred from the export to the importing country

#### 5.4 Recognition of foreign food export controls

28. The importing country should be willing to accept the established control system and standards in an exporting country where they provide 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. The importing country should develop procedures to conduct assessment of the exporting country systems consistent with the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26 1997).

29. The development of the equivalence agreement should consider using as a basis the “*Draft Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems*” Evaluations should be based on section 9 and related annexes of CAC/GL 26 1997 and other relevant internationally recognized criteria.

30. Once an Export Inspection and Certification System has been accepted, occasional random sampling and analysis of products upon arrival may be conducted to verify that the system is delivering safe food.

#### 5.5 Data exchange

31. Imported food control systems involve data exchange between trading partners, which may include:

- “hard copy” certificates attesting to food safety aspects of the particular shipment
- electronic data or certificates
- information about rejected food shipments.
- list of manufacturing establishments that conform to requirements

32. Authorities should refer to *Draft Guidelines for the Exchange of Information between countries on rejections of Imported Food*<sup>4</sup> and (proposed) *Draft Guidelines and Criteria for Official Certificate Formats and Rules relating to the Production and Issuance of Certificates*<sup>5</sup>

## SECTION 6. OPERATION AND ADMINISTRATION OF FOOD IMPORT CONTROL SYSTEMS

### 6.1 Details of the food import program operation

33. Section 30 to 37 of the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems*, covers decision criteria and action relevant to imported food control. The particularly relevant points include:

- checks on imports should be based on risks associated with the food or to the priorities assigned by the importing country;
- systematic physical checks on import entries should be avoided unless justified by a risk assessment or there is a valid suspicion of, or confirmed non-conformity for a particular product, processor, importer or country.

34. Uniformity of operational procedures is particularly important for imported food inspection. The program should be developed and implemented to avoid discrepancies between ports or inspection staff.

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<sup>4</sup> CAC/GL 19-1995

<sup>5</sup> CX/FICS 00/4

35. Section 6 (Paragraph 26) of the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* covers the operation of food control programs in general. Operational elements that should be considered in developing an imported food control program are: notification of shipment arrival; inspection procedures including criteria for inspection frequency; sampling procedures and methods of analysis; use of certificates; use of product pre-shipment approval; product, establishment, exporter, or importer registration requirements; criteria for determining compliance with requirements; decision making for product disposition; means to communicate decisions; alternative inspection procedures; dealing with emergency situations.

36. To operate efficient, targeted control measures, the program must be developed to obtain information about shipments of food entering the jurisdiction. Details of shipments that should be obtained include:

- date and port of arrival
- consignment details (commodity, amount, country of origin, identifying marks such as lot codes)
- owner or importer
- manufacturer (if possible)

37. Inspection procedures should be developed to include defined sampling frequencies or inspection intensities. These should be based on a risk management approach such less inspection effort is directed towards product from suppliers or importers with a good record of compliance.

38. Sampling frequency of products supplied from an unknown source or 'new' importers should be set a high rate, so that a compliance history can be created. Similarly, food from suppliers or purchased by importers with a known poor compliance history, or who are suspect for any reason must be sampled at high intensity. In these cases, every shipment may need to be inspected, until a defined number of consecutive shipments meet the standards. Alternatively the inspection procedures could be developed to automatically detain product from known poor suppliers and the authority insisting that the importer proves the fitness of each consignment through use of an accredited laboratory until the compliance rate is satisfactory. This should encourage importers to source product from suppliers that consistently meet specifications, and in doing so, reduce the frequency of inspection.

39. The inspection system should have defined sampling procedures based, where possible, on Codex sampling plans for the particular commodity/contaminant combination.

40. Where samples are selected for analysis, standard methods of analysis, or methods validated through appropriate protocols should be used. Analysis should be conducted, where possible in appropriately accredited laboratory facilities.

41. CAC/GL 26 - 1997 deals with the provision and verification of systems that provide certification for food in trade. The imported food inspection system should consider the scope of acceptable certification. For example, whether it covers all foods or is restricted to certain commodities or whether the certification is restricted to certain manufacturers. Clearance procedures should be developed to account for any limitations.

42. Policy should encourage the acceptance of certificates and appropriate relief from routine inspection should be incorporated into procedures.

43. Appropriate MRAs should be encouraged where the use of certificates is not essential.

44. Pre shipment approval is a useful mechanism to deal with products that are less prone to deterioration during transport, or valuable bulk packed products that if opened and sampled upon entry, would be seriously compromised, or products that require rapid clearance to maintain safety and quality.

45. If the inspection system encompasses pre shipment clearance then the authority to conduct the clearance including defined procedures should be determined. The importing authority may choose to accept pre shipment

clearance from official certification system from exporting countries, or third party certification bodies working to defined criteria.

46. The inspection authority may consider developing a system where registration of importers or exporters, premises to which imported foods transported before release, is mandatory. The considerable administrative costs may be balanced by advantages including the ability to provide importing and exporting community with information about their responsibilities to ensure imported food complies with requirements.

47. Results of inspection and, if required, analytical analysis, determines compliance or failure of the particular sample. The inspection program should be developed to deal with situations where results are borderline, or sampling indicates that only some lots within the consignment comply. Procedures may include further testing and examination of previous compliance history.

48. Decision criteria should be developed, that determine whether shipments are given free entry, entry if cleared upon inspection verification of conformance, entry of non-conforming product after corrective measures have been taken, rejection and re-exportation, rejection without re-exportation, and destruction.

49. The system should include formal means to communicate decision about results of analysis, clearance and status of shipments. The system must be efficient and delivered to the importers without delay, to facilitate trade.

50. Where importers engage in strict supplier contracts that include food safety and compliance measures, the authority may consider developing alternative arrangements in lieu of routine inspection. This may include agreements where the inspection authority assesses the controls that the importers implements over suppliers and the verification procedures that are in place to verify compliance of suppliers. The alternative arrangements may include some sampling of product by the authority as an audit, rather than routine inspection.

51. The responsible authority should have procedures that can respond to emergency situations. This will include impeding suspect product upon arrival, recall procedures for suspect product already cleared. Decisions should be made on the basis of sound advice and reliable information.

## **6.2 Documenting the system**

52. The Food Import Control System should be fully documented, including a description of its scope and operation, responsibilities and actions for staff, in order to help every officer involved to know the who, what, how, when, and where things should be done. This enables effective and efficient operation of the system and achieves its goals in protecting consumers and facilitating trade, regardless of changes in personnel.

53. Some of the details, which should be considered in documenting an imported food control system, include

- Organizational chart of the official inspection system, including the roles of each level in the hierarchy;
- job descriptions of all personnel;
- operating procedures;
- important contacts; and
- reference information about food contamination and food inspection.

## **6.3 Trained inspectorate**

54. The inspection staff is one of the essential elements of the system, therefore is fundamental to have a reliable, well trained and organized staff and a supporting infrastructure which enable the operating and public relations functions that are required. The system should provide training and maintain an adequate communication for the consistent implementation throughout the food import control system.

55. Where third parties are authorized to perform inspection work or there are alternative arrangements in place, such as a quality assurance arrangement with the importing company, the qualifications of the auditors, company inspection staff should be at least to the same competency as inspection staff of the authority.

56. The authority responsible for conducting assessment of food control systems of exporting countries should engage personnel with the qualifications and training expected of personnel assessing domestic food controls.

#### **6.4 System verification**

57. Consistent with Section 9 of the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems*, the imported food control system that is in place should be independently assessed regularly to ensure principles and objectives are met. Standard, internationally accepted audit techniques should be used.

58. A clearly documented system should be the basis for assessing whether the system achieves conformance to the stated aims and priorities. It should also contribute to the transparency of the country's whole food inspection system.

**Principles of Imported Food Control Systems**

- Principle No 1: Transparent system with documented procedures and standards
- Principle No 2: Clearly defined authority for legislation, regulation and official inspection system
- Principle No 3: Application of risk analysis
- Principle No 4: A food import control system should be consistently implemented and provide for parity with domestic control
- Principle No 5: Recognition of food controls in the exporting country
- Principle No 6: Adherence to the Codex *Code of Ethics for International Trade in Food* (CAC/RCP 20 – 1979)

**References**

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 general and for specific products. It details sampling techniques, equipment and inspection staff responsibilities. Its primary focus is a working (procedural) document for inspection staff.