

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 4

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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

PROPOSED DRAFT GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS (at Step 3)

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 29 September 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; E-mail: codex.contact@affa.gov.au), with a copy to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy (Fax No + 39.06.5705.4593; E-mail: codex@fao.org).

BACKGROUND

1. The 8th Session (February 2000) of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS)¹ had extensive discussions on the proposed draft Guidelines for Food Import Control Systems, but could not reach the necessary level of agreement to forward the text to the Executive Committee for adoption at Step 5.
2. The Committee therefore decided that a revised first draft of the proposed draft Guidelines would initially be prepared by the Secretariat with its subsequent consideration by a drafting group consisting of Australia, Canada, France, India, Japan, Mexico, Morocco, the United Kingdom and the United States. The Committee decided that the drafting group would take into account the discussions at its 8th Session, written comments submitted and the proposed revisions to Sections 4.1 and 4.2 presented by the informal drafting group.

¹ ALINORM 01/30, paras. 8-32

3. The Committee further agreed that the revised proposed draft Guidelines for Food Import Control Systems would be circulated for comment at Step 3 and further consideration at its 9th Session.
4. The proposed draft *Guidelines for Food Import Control Systems* is attached for comments at Step 3. The comments submitted will be considered by the Committee at its 9th Session when discussing the attached proposed draft Guidelines at Step 4.

PROPOSED DRAFT GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS

1 SCOPE

1. This document provides a framework for the development and operation of an import control system to protect consumers and facilitate fair practices in food trade while ensuring unjustified technical barriers to trade are not introduced. The Guideline is consistent with the *Codex Principles for Food Import and Export Inspection and Certification*¹ and provides specific information about imported food control that is an adjunct to the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems*².

2 DEFINITIONS³

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

*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.

*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.

*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.

¹ CAC/GL 20-1995 *Principles for Food Import and Export Inspection and Certification*

² *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997).

³ Definitions drawn from the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997) are marked with *. Definitions drawn from Codex Alimentarius Commission, Procedural Manual (11th edition) are marked with **.

*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 assessment** A scientifically based process consisting of the following steps (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment, and (iv) risk characterisation.

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

3 GENERAL CHARACTERISTICS OF FOOD IMPORT CONTROL SYSTEMS

2. Food import control systems should have the following main characteristics:

- requirements for imported food that are consistent with requirements for domestic foods;
- clearly defined responsibilities of the imported food control authority or authorities;
- clearly defined and transparent legislation/regulations and operating procedures;
- priority focus on the health protection of consumers;
- provision for recognition of the food controls applied by an exporting country's competent authority or authorities
- uniform nationwide implementation by the importing country of its requirements;
- implementation that ensures the achieved outcomes/objectives are consistent with those for domestic food.

3.1 Requirements for imported food that are equivalent with requirements for domestic foods

3. Requirements should be applied equally to domestic produced and imported food. These requirements may be expressed as end-point or limit value standard with complementary requirements for sampling etc, and provisions concerning process controls, or a combination of these.

4. Where domestic requirements include process controls such as good manufacturing practice, compliance may be determined by auditing the facilities and procedures in the exporting country. The extent and stringency of requirements applied in specific circumstances should be proportionate to risk, noting that risk may vary from one source to another because of factors such as technology employed, compliance history, etc. and /or examination of relevant attributes of a sample of products at import.

5. A special case which may arise in relation to the application of requirements to imported versus domestic food, is where an importing country applies a zero tolerance for residues of a pesticide or veterinary drug because use of that chemical is prohibited in the importing country. The chemical may be prohibited for reasons other than consumer health, for example occupational health and safety reasons, or because there is no technical need in the importing country. In these cases a tolerance could be permitted while still protecting consumer health. In such circumstances it would be appropriate for the importing country on the basis of a risk assessment process, or on the basis of relevant Codex standards, to provide an appropriate tolerance of the chemical in imported food. The importing country can decide whether to provide the same tolerance for residues in domestically produced food.

3.2 Clearly defined responsibilities of imported food control authority or authorities.

6. The competent authority(ies) involved in any of the imported food inspection functions at the point or points of entry, during storage and distribution and/or at point of sale, should have clearly defined responsibilities and authority. When responsibility for ensuring conformance with requirements is shared among agencies of the importing country, multiple inspection and duplicative testing for the same analyte(s) on the same consignment by the different agencies should be avoided to the extent possible. In such situations, agencies having jurisdiction should share inspection, testing, and other information on the consignment.

7. Some countries, for example those that are part of a regional economic grouping, may rely on import controls implemented by another country. In such cases, the functions, responsibilities, and operating procedures undertaken by the country which conducts the imported food control should be clearly defined and accessible to authorities in the country or countries of final destination with the aim of delivering an efficient and transparent import control system that provides the appropriate level of protection.

8. Where the competent authorities of an importing country use third party providers as officially recognised inspection and or certification bodies to implement controls, such arrangements should be conducted in the manner discussed in CAC/GL 26-1997, Section 8, Official Accreditation. The functions that can be conducted by such providers may include:

- sampling of target food shipments;
- analysis of samples;
- compliance evaluation of relevant parts or all of a quality assurance system that may be operated by importers in order to comply with official requirements.

3.3 Clearly defined and transparent legislation/regulations and operating procedures

9. The object of legislation/regulations is to provide the basis and the authority for operating a food import control system. The legal framework allows for the establishment of the competent authority(ies) and the processes and procedures required to verify the conformity of imported products against requirements.

10. Legislation/regulations should provide the competent authority with the ability to:

- appoint authorised officers;
 - require prior notification of the importation of a consignment of a foodstuff;
 - require documentation;
 - inspect, including the authority to enter premises within the importing country, physically examine the food and its packaging; collect samples and initiate analytical testing; inspection of documentation provided by an exporting country authority, exporter or importer; and verification of product identity against documentary attestations;
 - apply differential sampling rates depending on risk posed by the particular food, its compliance history and the validity of accompanying certification;
 - charge fees for the inspection of consignments and sample analysis;
 - accredit laboratories for the examination of samples;
 - accept, refuse entry, detain, destroy, order reconditioning or re-export,
 - recall consignments following importation;
 - retain bond over consignments during intra-national transport or during storage prior to import clearance;
 - implement administrative and legal sanctions when the specific requirements are not satisfied; and
 - develop certification arrangements with competent authorities of exporting countries.
11. In addition the legal framework may make provisions for:
- licensing or registration of importers;
 - recognition of self checking by importers; and
 - an appeal mechanism against official actions.

3.4 Priority focus on the health protection of consumers

12. Food safety standards including Codex and related texts, and national standards should focus on health protection of consumers and contain fair trading elements, (e.g. prevention of fraud) as well. Health protection should be assigned the highest priority, as discussed in Section 4.

3.5 Provision for recognition of the food control system applied by an exporting country's competent authority

13. Importing countries can recognise the food safety controls of an exporting country in a number of ways that facilitate the entry of goods, including the use of memoranda of understanding, mutual recognition agreements and equivalence agreements. Such recognition should, as appropriate, include controls applied during the production, manufacture, importation, processing, storage, transportation, and distribution of the food products, and verification of the export food control system applied.

3.6 Consistent national implementation

14. Uniformity of operational procedures is particularly important. The program should be developed and implemented to assure its uniform application at all points of entry and by inspection staff.

3.7 Implementation that ensures the outcomes/objectives achieved are consistent with those for domestic food.

15. As an importing country has no direct 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. Such differences in approach are justifiable on the basis that the objectives of the import controls are the same as those applied to domestically produced food.

4 IMPLEMENTATION OF THE CONTROL SYSTEM

16. The food import control system should ensure public health and consumer protection while minimizing trade restrictions. Operational procedures should be developed and implemented to minimize undue delay at the point or points of entry without jeopardizing effectiveness of controls to ensure food safety. Implementation should take into account the factors listed in this section.

4.1 Point of control

17. Control of imported food by the importing country can be conducted at one or more points including:

- entry to the country of destination;
- further processing;
- storage; and,
- sale, (retail or wholesale).

18. The system should be structured to deliver the same outcomes regardless of the point or points of control.

19. The importing country can recognize controls implemented by the exporting country. The application of controls by the exporting country, during production, manufacture and subsequent transit should be encouraged, with the aim of identifying and correcting problems when and where they occur, and preferably before costly recalls of food already in distribution are required.

20. Pre-shipment approval is a possible mechanism for ensuring compliance with requirements of, for example, valuable bulk packed products that if opened and sampled upon

entry, would be seriously compromised, or for products that require rapid clearance to maintain safety and quality.

21. If the inspection system encompasses pre-shipment clearance then the authority to conduct the clearance should be determined and procedures defined. The importing authority may choose to accept pre-shipment clearance from an exporting country's official certification system or from officially recognised third party certification bodies working to defined criteria.

4.2 Information about incoming food

22. The efficacy of the control system in applying efficient targeted control measures depends upon information about shipments of food entering the jurisdiction. Details of shipments that may be obtained include:

- date and point of entry;
- mode of transport;
- consignment details (including commodity, amount, country of origin, identifying marks such as lot codes, date of manufacture, etc);
- exporter or importer;
- manufacturer (if possible); and
- destination.

4.3 Frequency and types of inspection

23. The frequency of inspection and testing of imported foods should be based on the risk to health presented by the product and the history of conformance to requirements. Control should be designed to account for factors such as:

- the assessed risk to human health posed by the product;
- the risk of non-compliance with requirements;
- 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 and existence of any equivalence, mutual recognition agreements or other trade agreements.

24. Physical checks on imported product, using random statistically based sampling plans, are valid means of checking product compliance. Inspection procedures should be developed to include defined sampling frequencies or inspection intensities. The frequency of sampling should be proportionate to the assessed risk, which may take into account evidence of, or confirmed non-conformity for a particular product, processor, importer or country.

25. Sampling frequency of products supplied from a source for which there is no compliance history, should be set at a higher rate than for products from other sources. The

sampling process enables a compliance history to be created. Similarly, food from suppliers or imported by parties with a known poor compliance history should be sampled at higher intensity. In these cases, every shipment may need to be physically inspected, until a defined number of consecutive shipments meets requirements. Alternatively the inspection procedures can be developed to automatically detain product from suppliers with a known poor compliance history and the importer may be required to prove the fitness of each consignment through use of an accredited laboratory until a satisfactory compliance rate is achieved.

4.4 Sampling and analysis

26. The inspection system should have defined sampling procedures based on Codex sampling plans for the particular commodity/contaminant combination where available.
27. Where samples are selected for analysis standard methods of analysis, or methods validated through appropriate protocols, should be used. Where possible, analysis should be conducted in appropriately accredited laboratory facilities.
28. Results of inspection and, if required, laboratory analysis, should be carefully interpreted in making decisions relating to acceptance or rejection of a consignment. The inspection program should include decision making rules for situations where results are borderline, or sampling indicates that only some lots within the consignment comply with requirements. Procedures may include further testing and examination of previous compliance history.

4.5 Decision criteria

29. Decision criteria should be developed that determine whether shipments are given
 - free entry;
 - entry if cleared upon inspection or verification of conformance;
 - entry of non-conforming product after corrective measures have been taken, or redirecting product for uses other than human consumption;
 - rejection notice, with re-exportation option;
 - rejection notice without re-exportation (ie destruction order).
30. The system should include formal means to communicate decisions about results of analysis, clearance and status of shipments. Advice on decisions should be provided to importers without delay. There should be an appeal mechanism or review of rejections of consignments.

4.6 Dealing with emergencies

31. The responsible authority should have procedures that can respond appropriately to emergency situations. This will include holding suspect product upon arrival and recall procedures for suspect product already cleared and, if relevant, rapid notification of the problem to international authorities.

4.7 Recognition of export controls

32. Consistent with section 3.5 of this guideline, the importing country should establish mechanisms to accept control systems in an exporting country where these system achieve the same level of protection required by the importing country. In this regard, the importing country should:

- develop procedures to conduct assessment of the exporting country systems consistent with the Annex of the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997);
- take into account the scope of the arrangement, for example, whether it covers all foods or is restricted to certain commodities or certain manufacturers;
- develop clearance procedures that provide an appropriate level of protection if arrangement developed with an exporting country are limited in scope;
- provide recognition of export controls through, for example, exemption from routine import inspection;
- conduct verification procedures for example, occasional random sampling and analysis of products upon arrival. (Section 5 and Annex of CAC/GL 26-1997 deal with the provision and verification of systems that provide certification for food in trade);
- recognise that arrangements need not rely on the presentation of certificates or documentation with individual shipments, when such an approach is acceptable to both parties.

33. Where there is limited access to sophisticated facilities such as laboratories and shipment tracking systems, the competent authority of the importing country can, as an initial step, develop certification agreements with exporting country official certification bodies or officially recognized certification bodies, with the aim of ensuring requirements are met.

4.8 Information exchange

34. Imported food control systems involve information exchange between competent authorities and countries that are trading partners. The information may include:

- requirements of food control systems;
- “hard copy” certificates attesting to conformity with requirements of the particular shipment;
- electronic data or certificates where accepted by the parties involved;
- details about rejected food shipments;
- list of establishments or facilities that conform to importing country requirements.

35. 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.

4.9 Alternatives to traditional inspection

36. The authority may consider developing alternative arrangements in lieu of routine inspection. This may include agreements where the inspection authority assesses the controls that importers implement over suppliers and the procedures that are in place to verify compliance of suppliers. Alternative arrangements may include some sampling of product by the authority as an audit, rather than routine inspection.

37. The inspection authority may consider developing a system where registration of importers is mandatory. Advantages include the ability to provide the importing and exporting community with information about their responsibilities and mechanisms to ensure imported food complies with requirements.

38. If a product registration system exists or is implemented, a clear rationale for such product registration (e.g. specific and documented food safety concerns) should exist. Such product registrations should treat imported and domestic product in the same or equivalent manner.

4.10 Documenting the system

39. A food import control system should be fully documented, including a description of its scope and operation, responsibilities and actions for staff, in order that all parties involved know precisely what is expected of them.

40. Documentation of an imported food control system should include

- an organizational chart of the official inspection system, including the roles of each level in the hierarchy;
- job descriptions of all personnel;
- operating procedures;
- relevant legislation and requirements that should be met by imported food;
- important contacts; and,
- reference information about food contamination and food inspection.

4.11 Trained inspectorate

41. It is fundamental to have adequate, reliable, well trained and organised inspection staff, with supporting infrastructure, to deliver the imported food control system. Training, communication, and supervisory elements should be organised to provide consistent implementation of requirements by the inspectorate throughout the food import control system.

42. Where third parties are officially recognised 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, or company inspection staff, should be at least the same for inspection staff of the competent authority.

43. 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.

4.12 System verification

44. Consistent with Section 9 of the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification System* (CAC/GL 26-1997) an imported food control system should be independently assessed on a regular basis.

5 FURTHER INFORMATION

45. The Food and Agriculture Organization *Manual of Food Quality Control. Imported Food Inspection* (Food and Nutrition Paper 14/15, 1993) and 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) contribute valuable information for those engaged in the design and re-design of imported food control systems.