

GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS

CAC/GL 47-2003

SECTION 1 -SCOPE

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.

SECTION 2 – DEFINITIONS³

Appropriate Level of Protection (ALOP) is the level of protection deemed appropriate by the country establishing a sanitary measure to protect human life or health within its territory. (This concept may otherwise be referred to as the “acceptable level of risk”.)

*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.

*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.

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

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 (12th edition) are marked with **.

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

SECTION 3 - GENERAL CHARACTERISTICS OF FOOD IMPORT CONTROL SYSTEMS

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 for the competent authority or authorities;
- clearly defined and transparent legislation and operating procedures;
- precedence to the protection of consumers;
- provision of the importing country for recognition of the food control system applied by an exporting country's competent authority;
- uniform nationwide implementation;
- implementation that ensures the levels of protection achieved are consistent with those for domestic food.

REQUIREMENTS FOR IMPORTED FOOD THAT ARE CONSISTENT WITH REQUIREMENTS FOR DOMESTIC FOODS

Requirements are commonly expressed as end-point standards with specific limits and complementary sampling regimes. These requirements may consist of standards, provisions for sampling, process controls, conditions of production, transport, storage, or a combination of these.

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 specific and/or similar situations in the region of origin, technology employed, compliance history, etc. and/or examination of relevant attributes of a sample of products at import.

As far as possible, requirements should be applied equally to domestically produced and imported food. Where domestic requirements include process controls such as good manufacturing practices, compliance may be determined or equivalence confirmed by auditing the relevant inspection and certification systems and, as appropriate, the facilities and procedures in the exporting country⁴.

CLEARLY DEFINED RESPONSIBILITIES OF COMPETENT AUTHORITY OR AUTHORITIES

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. Multiple inspection and duplicative testing for the same analyte(s) on the same consignment should be avoided to the extent possible.

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.

Where the competent authorities of an importing country use third party providers as officially recognised inspection bodies and/or officially recognized 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:

⁴ *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997), Para. 54.*

- sampling of target consignments;
- 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.

CLEARLY DEFINED AND TRANSPARENT LEGISLATION AND OPERATING PROCEDURES

The object of legislation 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.

Legislation 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 risk-based sampling plans, taking into consideration the compliance history of the particular food, the validity of accompanying certification, and other relevant information;
- charge fees for the inspection of consignments and sample analysis;
- recognize accredited or accredit laboratories;
- accept; reject; detain; destroy; order to destroy; order reconditioning, processing, or re-export; return to country of export; designate as non-food use;
- recall consignments following importation;
- retain control over consignments in transit during intra-national transport or during storage prior to import clearance; and,
- implement administrative and/or judicial measures when the specific requirements are not satisfied.

In addition, the legislation may make provisions for:

- licensing or registration of importers;
- recognition of verification systems used by importers;
- an appeal mechanism against official actions;
- assessing the control system of the exporting country; and
- certification and/or inspection arrangements with competent authorities of exporting countries.

PRECEDENCE TO THE PROTECTION OF CONSUMERS

In the design and operation of food import control systems, precedence should be given to protecting the health of consumers and ensuring fair practices in food trade over economic or other trade considerations.

PROVISION OF THE IMPORTING COUNTRY FOR RECOGNITION OF THE FOOD CONTROL SYSTEM APPLIED BY AN EXPORTING COUNTRY'S COMPETENT AUTHORITY

Food import control systems should include provisions for recognition as appropriate of the food control system applied by an exporting country's competent authority. 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 and unilateral recognition. Such recognition should, as appropriate, include controls applied during the production, manufacture, importation, processing, storage, and transportation of the food products, and verification of the export food control system applied.

UNIFORM NATION-WIDE IMPLEMENTATION

Uniformity of operational procedures is particularly important. Programmes and training manuals should be developed and implemented to assure uniform application at all points of entry and by all inspection staff.

IMPLEMENTATION THAT ENSURES THE LEVELS OF PROTECTION ACHIEVED ARE CONSISTENT WITH THOSE FOR DOMESTIC FOOD

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 provided they are necessary to ensure that the level of protection achieved is consistent with that of domestically produced food.

SECTION 4 - IMPLEMENTATION OF THE CONTROL SYSTEM

Operational procedures should be developed and implemented to minimize undue delay at the point or points of entry without jeopardizing effectiveness of controls to meet requirements. Implementation should take into account the factors listed in this section and the possibility of recognizing guarantees at origin that includes implementation of controls in the exporting countries.

POINT OF CONTROL

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

- origin, where agreed upon with the exporting country;
- entry to the country of destination;
- further processing;
- transport and distribution;
- storage; and,
- sale, (retail or wholesale).

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.

Pre-shipment clearance 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.

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

INFORMATION ABOUT FOOD TO BE IMPORTED 5

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

- date and point of entry;
- mode of transport;
- comprehensive description of the commodity (including for example product description, amount, means of preservation, country of origin and/or of dispatch, identifying marks such as lot identifier or seal identification numbers etc);
- exporter's and importer's name and address;
- manufacturer and/or producer, including establishment registration number;
- destination; and,
- other information.

FREQUENCY OF INSPECTION AND TESTING OF IMPORTED FOOD

The nature and frequency of inspection, sampling and testing of imported foods should be based on the risk to human health and safety presented by the product, its origin and the history of conformance to requirements and other relevant information. Control should be designed to account for factors such as:

- the risk to human health posed by the product or its packaging;
- the likelihood of non-compliance with requirements;
- the target consumer group;
- the extent and nature of any further processing of the product;
- food inspection and certification system in the exporting country and existence of any equivalence, mutual recognition agreements or other trade agreements; and,
- history of conformity of producers, processors, manufacturers, exporters, importers and distributors.

Physical checks of imported product, preferably using statistically based sampling plans, should represent valid methods for the verification of compliance with requirements by the product as established by the importing country, or in the case of importing a product for the purposes of re-exportation, verification should be made on the requirements of the country of final destination and said requirements should be specified in the certificate of re-exportation. Inspection procedures should be developed to include defined sampling frequencies or inspection intensities, including for re-exported product.

Sampling frequency of products supplied from a source for which there is no or known poor compliance history may be set at a higher rate than for products with a good compliance history provided this is shown through transparent and objective criteria. 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 consignment may need to be physically inspected, until a defined number of consecutive consignments 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 a laboratory (including official laboratory) recognized, accredited and/or listed by the competent authority until a satisfactory compliance rate is achieved.

SAMPLING AND ANALYSIS

The inspection system should be based on Codex sampling plans for the particular commodity/contaminant combination where available. In the absence of Codex sampling plans, reference should be made to internationally accepted or scientifically based sampling plans.

Internationally validated standard methods of analysis or methods validated through international protocols should be used where available. Analysis should be conducted in official or officially accredited laboratories.

DECISIONS

Decision criteria (without prejudice to the application of customs procedures) should be developed that determine whether consignments are given:

- acceptance;
- entry if cleared upon inspection or verification of conformance;
- release of non-conforming product after re-conditioning and/or corrective measures have been taken;
- rejection notice, with redirecting product for uses other than human consumption;
- rejection notice, with re-exportation option or return to country of export option at exporter expense;
- rejection notice with destruction order.

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 system 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.

The system should include formal means to communicate decisions regarding clearance and status of consignments.⁶ There should be an appeal mechanism and/or opportunity for review of official decisions on consignments.⁷ When food is rejected because it fails to meet national standards of the importing country but conforms to international standards, the option of withdrawing the rejected consignment should be considered.

⁶ Paragraph 4 of the *Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food* (CAC/GL 25-1997) should be consulted in this regard.

⁷ Paragraph 6 of the *Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food* (CAC/GL 25-1997) should be consulted in this regard.

DEALING WITH EMERGENCY SITUATIONS

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 bodies and possible measures to take.

If the food control authorities in importing countries detect problems during import control of foodstuffs which they consider to be so serious as to indicate a food control emergency situation, they should inform the exporting country promptly by telecommunication.⁸

RECOGNITION OF EXPORT CONTROLS

Consistent with paragraph 12 of these guidelines, the importing country should establish mechanisms to accept control systems in an exporting country where these systems 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 achieve its appropriate level of protection if arrangements 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);
- recognize that arrangements need not rely on the presentation of certificates or documentation with individual consignments, when such an approach is acceptable to both parties.

The competent authority of the importing country may, develop certification agreements with exporting country official certification bodies or officially recognized certification bodies, with the aim of ensuring requirements are met. Such agreements may be of particular value where, for example, there is limited access to specific facilities such as laboratories and consignment tracking systems.⁹

INFORMATION EXCHANGE

Food import control systems involve information exchange between competent authorities of exporting and importing countries. The information may include:

- requirements of food control systems;
- “hard copy” certificates attesting to conformity with requirements of the particular consignment;
- electronic data or certificates where accepted by the parties involved;
- details about rejected food consignment, such as destruction, re-exportation, processing, re-conditioning or redirection of consignment for uses other than human consumption;
- list of establishments or facilities that conform to importing country requirements.

⁸ *Guidelines for the Exchange of Information in Food Control Emergency Situations* (CAC/GL 19-1995)

⁹ *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999)

Any changes to import protocols, including specifications, which may significantly affect trade, should be promptly communicated to trading partners, allowing a reasonable interval between the publication of regulations and their application.

OTHER CONSIDERATIONS

The competent authority may consider developing alternative arrangements in lieu of routine inspection. This may include agreements where the competent 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 as an audit, rather than routine inspection.

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

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.

DOCUMENTING THE SYSTEM

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.

Documentation of an food import control systems should include:

- an organizational chart of the official inspection system, including geographical location and the roles of each level in the hierarchy;
- job functions as appropriate;
- operating procedures including methods of sampling, inspection and testing;
- relevant legislation and requirements that should be met by imported food;
- important contacts;
- relevant information about food contamination and food inspection; and,
- relevant information on staff training.

TRAINED INSPECTORATE

It is fundamental to have adequate, reliable, well trained and organised inspection staff, with supporting infrastructure, to deliver the food import 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.

Where third parties are officially recognised by the competent authority of the importing country to perform specified inspection work, the qualifications of the inspection staff should be at least the same as inspection staff of the competent authority who may carry out similar tasks.

The competent authority of the importing country responsible for conducting assessment of food control systems of exporting countries should engage personnel with appropriate qualifications, experience and training required of personnel assessing domestic food controls.

SYSTEM VERIFICATION

Verification should be carried out on the basis of Section 9 of the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997) and the food import control system should be independently assessed on a regular basis.

SECTION 5 - FURTHER INFORMATION

The Food and Agriculture Organization of the United Nations *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 food import control systems.