CODEX ALIMENTARIUS

ISSN 0259-2916

Food import and export inspection and certification systems

Fifth edition

World Health Organization

Food and Agriculture Organization of the United Nations

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WORLD HEALTH ORGANIZATION

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

Rome, 2012

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ISBN 978-92-5-107077-2

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THE CODEX ALIMENTARIUS COMMISSION

The Codex Alimentarius Commission is an intergovernmental body with over 180 members established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO).

The **CODEX** ALIMENTARIUS is the main result of the Commission's work: a set of international food standards, guidelines and codes of practice with the goal to protect the health of consumers and ensure fair practices in the food trade.

FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS
Fifth edition

Official and officially recognized inspection and certification systems are fundamentally important and very widely used means of food control systems. The confidence of consumers in the safety and quality of their food supply depends in part on their perception as to the effectiveness of these systems as food control measures. A substantial part of the worldwide trade in food depends upon the use of inspection and certification systems. Following the FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade in 1991, the Codex Alimentarius Commission undertook the development of guidance documents for governments and other interested parties on food import and export inspection and certification systems. This fifth edition includes texts adopted by the Codex Alimentarius Commission up to 2011.

Further information on these texts, or any other aspect of the Codex Alimentarius Commission, may be obtained from:

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PRINCIPLES FOR FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION

CAC/GL 20-1995

SECTION 1 – INTRODUCTION

1. Official and officially recognized inspection and certification systems are fundamentally important and very widely used means of food control; the following principles apply to such systems. The confidence of consumers in the quality (including safety) of their food supply depends in part on their perception as to the effectiveness of food control measures. A substantial part of the worldwide trade in food, for example in meat and meat products, depends upon the use of inspection and certification systems. However, inspection and certification requirements may significantly impede international trade in foodstuffs. Consequently it is desirable that the design and application of these systems should reflect appropriate principles.

2. Inspection of food may occur at any stage in the production and distribution process. For some foods, inspection oversight of harvesting, processing, storage, transport, and other handling of product may be the most appropriate means of ensuring food safety. According to the methods of preservation used, it may be necessary to maintain inspection oversight on a continuous basis up to the time of retail sale. Inspection systems may be focused on the foodstuffs themselves, on the procedures and facilities employed in the production and distribution chain, on the substance and materials which can be incorporated into or contaminate foodstuffs.

3. Inspection should be carried out at the most appropriate stages (e.g. control of refrigeration at every stage of the cold chain). For some requirements, e.g. those pertaining to product description, it may be possible to limit inspection to the distribution process and prior to final sale.

4. In both design and use, food inspection and certification systems should be governed by a number of principles which will ensure an optimal outcome consistent with consumer protection and facilitation of trade.

SECTION 2 – DEFINITIONS

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 or officially recognized certification 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.

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 is the evaluation of the likelihood and severity of adverse effects on public health arising, for example, from the presence in foodstuffs of additives, contaminants, residues, toxins or disease-causing organisms.

SECTION 3 – PRINCIPLES

5. Food inspection and certification systems should be used wherever appropriate to ensure that foods, and their production systems, meet requirements in order to protect consumers against foodborne hazards and deceptive marketing practices and to facilitate trade on the basis of accurate product description.

Fitness for purpose

6. Inspection and certification systems should be fully effective in achieving their designated objectives having regard to the determination of the acceptable level of protection which is required.

Risk assessment

7. Inspection systems to ensure food safety should be designed and operated on the basis of objective risk assessment appropriate to the circumstances. Preferably the risk assessment methodology employed should be consistent with internationally accepted approaches. Risk assessment should be based on current available scientific evidence.

8. Inspection systems should be applied to particular commodities and processing methods in proportion to the assessed risks. In undertaking a risk assessment or in applying the principles of equivalence, importing countries should give due consideration to statements by exporting countries on a national or area basis of freedom from food-related disease.

Non-discrimination

9. Countries should ensure that they avoid arbitrary or unjustifiable distinctions in the level of risk deemed to be appropriate in different circumstances so as to avoid discrimination or a disguised restriction on trade.

Efficiency

10. Inspection and certification systems should have adequate means to perform their task. In the choice of inspection and certification systems, there should be regard to costs to consumers and to the costs in money and time to the affected food industry and government consulting with interested bodies as appropriate. Such systems should be no more restrictive of trade than is necessary in order to achieve the required level of protection.

Harmonization

11. Member countries should use Codex standards, recommendations and guidelines (or those of other international organizations whose membership is open to all countries) whenever appropriate as elements of their inspection and certification systems. Countries should participate actively in the work of the Codex Alimentarius Commission and other relevant international bodies to promote and facilitate the development, adoption and review of Codex norms.

Equivalence

12. Countries should recognise that different inspection/certification systems may be capable of meeting the same objective, and are therefore equivalent. The obligation to demonstrate equivalence rests with the exporting country.

Transparency

13. While respecting legitimate concerns to preserve confidentiality, the principles and operations of food inspection and certification systems should be open to scrutiny by consumers and their representative organizations, and other interested parties.

14. Importing countries should provide information on existing requirements and proposed changes to requirements should be published and, except in the case of serious and immediate danger, an adequate time period permitted for comment. The views of exporting countries, and particularly those received from developing countries, should be taken into account in taking a final decision. A reasonable period should be allowed before a new requirement takes effect in order to permit exporting countries, and in particular developing countries, to make necessary changes to methods of production and control measures.

15. Importing countries should make available to the exporting countries, upon request, timely advice as to the basis of the decision they have taken regarding the compliance of foods with their relevant requirements.

16. Upon request by the competent authorities of the importing countries, the exporting countries should provide access to view and assess the actual working of their relevant inspection and certification systems.

Special and differential treatment

17. In the design and application of food inspection and certification systems, importing countries should take into account of the capabilities of developing countries to provide the necessary safeguards.

Control and inspection procedures

18. Importing countries should complete without undue delay any procedures necessary to assess compliance with requirements. Information requirements and any fees imposed by importing countries should be limited to what is reasonable and necessary.

Certification validity

19. Countries that certify exports of food and those importing countries which rely on export certificates should take measures to assure the validity of certification. Validation measures by exporting countries may include achieving confidence that official or officially recognised inspections systems have verified that the product or process referred to in the certificate conforms with requirements.

Measures by importing countries may include point of entry inspection systems, audit of exporting inspection systems, and ensuring that certificates themselves are authentic and accurate.

GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS

CAC/GL 47-2003

SECTION 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].

SECTION 2 – DEFINITIONS[3]

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.

[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 are marked with**.

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.

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

SECTION 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 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

3. 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.

4. 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.

5. 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 country[4].

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

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.

8. 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

9. 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.

10. 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.

11. 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

12. 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

13. 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

14. 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

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 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

16. 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

17. 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).

18. 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.

19. 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.

20. 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]

21. 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);

[5] Generic Official Certificate Formats and the Production and Issuance of Certificates (CAC/GL 38-2001).

- 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

22. 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.

23. 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.

24. 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

25. 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.

26. 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

27. 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.

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 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.

29. 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

[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.

conforms to international standards, the option of withdrawing the rejected consignment should be considered.

Dealing with emergency situations

30. 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.

31. 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

32. Consistent with paragraph 13 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.

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

33. 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

34. 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.

35. Any changes to import protocols, including specifications, which may significantly affect trade, should be promptly communicated to trading partners, allowing a reasonable interval[10] between the publication of regulations and their application.

Other considerations

36. 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.

37. 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.

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

[10] WTO Decision WT/MIN (01)17.

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.

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 a food import control system 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

41. 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.

42. 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.

43. 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

44. 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

45. 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.

APPENDIX

PRINCIPLES AND GUIDELINES FOR IMPORTED FOOD INSPECTION BASED ON RISK[11]

SECTION 1 – INTRODUCTION

1. This Annex elaborates on paragraphs 22–26 of the main text (CAC/GL 47-2003).

2. The implementation of an imported food inspection programme based on risk provides a more effective means for addressing the food safety risks that are associated with imported food[12], ensuring compliance of imported foods with importing countries' food safety requirements and allows greater attention to be given to foods that present a higher level of risk to human health.

3. This document should be read in conjunction with all relevant Codex guidelines.

SECTION 2 – OBJECTIVE

4. This annex is intended to provide competent authorities with information to assist them with the design and implementation of inspection programmes for imported food, based on the food safety risks.

SECTION 3 – PRINCIPLES

5. The following principles apply to the development and implementation of an imported food inspection programme based on risk.

- In determining the level of risk assigned to an imported food an importing country should consider the assessed food safety risk to human health the food presents or is likely to present based on available scientific information in relation to the consumption of the food.
- Requirements for an imported food inspection programme based on risk should be developed using a risk analysis approach, and should not be applied arbitrarily or in a discriminatory manner, and should not result in unjustified barriers to trade or unnecessary delays.

[11] A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food. Definition of Risk Analysis Terms Related to Food Safety, Codex Alimentarius Procedural Manual.

[12] Imported food in this annex also includes food ingredients. Inspection may also cover feeding stuffs for food producing animals where appropriate.

- The nature[13] and frequency of inspection of a specific imported food should be proportionate to the level of risk attributed to it and take into account, all relevant factors.[14]
- Sampling plans[15] and methods of analysis should, be based on Codex standards, guidelines, and recommendations. In the absence of Codex sampling plans, reference should be made to internationally accepted or scientifically based sampling plans when practically feasible.[16]
- Information regarding a country's imported food inspection programme based on risk should be transparent, easily accessible, and up to date.

SECTION 4 – DESIGNING AN IMPORTED FOOD INSPECTION PROGRAMME BASED ON RISK

6. The competent authority should use relevant information to assess the level of risk associated with the imported food. This information could include, *inter alia*:

- The scientific determination of the food safety risk to the extent possible[17].
- The adequacy of processing controls in place in the exporting country as evidenced by its laws, regulations, and other policies; its infrastructure; and its ability to effectively enforce food safety requirements, as may be verified by audits and on-site visits by the competent authority of the importing country[18].
- The compliance history of the food generally, irrespective of the source of the food.
- The compliance history of the food with respect to the source of the food including, where available, the compliance history of:
  - the exporting country or region/area within an exporting country;
  - the producer and manufacturer;
  - the exporter;
  - the shipper; and
  - the importer.
- Reports from officially recognized inspection and/or certification bodies.

[13] Examples of the nature of inspection could include documentation check, visual examination, sampling and testing.

[14] Examples of relevant factors where appropriate are included in paragraph 22 of CAC/GL 47-2003.

[15] Principles for the Establishment or Selection of Codex Sampling Procedures, Codex Alimentarius Procedural Manual.

[16] Statistical validation of sampling requirements should always be the aim but may not be practical where the consignment is not homogenous.

[17] Risk assessments, foodborne illness outbreak and epidemiological findings/history, contaminant and/or residue information can be key components of this information.

[18] Laboratory sampling programmes and results may provide this type of information. Audits are another way of gaining information.

7. The level of risk assigned to a food should be reviewed periodically or when new information that may affect the food safety risk associated with the food becomes known in order to maintain the proportionality between the nature and frequency of inspection and the risk assessed.

8. The competent food safety authority may establish levels of inspection based on the above factors in order to determine the nature and frequency of inspections at the border/point of control of a given food from a given country, producer/manufacturer, exporter, shipper, and importer. The nature and frequency of inspection may then be adjusted according to the demonstrated compliance to food safety requirements. The nature and frequency of inspection should be fully documented.

9. The importing country should adjust the nature and frequency of inspection of the imported food based on information from competent authorities in the exporting country regarding the exported foods. This information may include:

- certificates;
- equivalence determinations;
- memoranda of understanding;
- mutual recognition agreements; or
- other appropriate means acceptable between countries.

10. The importing country may also adapt/alter the nature and frequency of inspection of the imported food based on an assessment by the importing country's competent authority of controls its importers exercise over their suppliers.

11. Exporting countries can provide information on the control systems in place in their country and, as appropriate, may provide assurance to the importing country that a particular food complies with the food safety requirements of the importing country.

12. Audits by the importing country may, where appropriate, verify an exporting country's inspection controls, and the information gained from these audits could be used as part of the review of the level of risk assigned to the food from that country.

13. When an importing country does not have prior knowledge of an exporting country's processing controls or of the food itself, that is those items listed in paragraph 6, a compliance history is lacking or such information cannot be readily obtained, an importing country may, until there is such knowledge, initially

establish inspections of a more comprehensive nature and of a higher frequency than that which it might assign to the food when such information is available.

14. Sustained conformance with the importing country's requirements, as demonstrated, for example, by audit results and results of border/point of control checks, provides an opportunity for importing countries to adjust the nature and frequency of inspection at the border/point of control, in proportion to the level of compliance verified.

15. Foodborne illness outbreaks; epidemiological findings; results of audits conducted in the exporting country; the detection of non-compliances with food safety requirements at the point of import and detection of pathogens, contaminants and harmful residues in imported food; and the results of border/point of control checks, may lead an importing country to adjust the nature and frequency of inspection, or in extreme cases, to suspend the trade in that food until it is confirmed that corrective measures have been introduced and are being implemented effectively[19]. An importing country may work with an exporting country to prevent the occurrence of further outbreaks.

16. The level of adjustment/modification of the nature and frequency of inspection applied to a food should be proportional to the changes in the level of assessed risk for the food in question.

SECTION 5 – DEVELOPING REQUIREMENTS AND PROCEDURES

17. Competent authorities should take into account Codex standards, recommendations, and guidelines, in developing requirements for border/point of control checks of imported food and make use, when available, of:

- Relevant information from risk assessments conducted according to internationally recognized protocols for the biological, chemical, and physical hazards associated with the type of food.
- Internationally accepted or scientifically based sampling plans, to the extent possible.
- Appropriate inspection procedures, appropriate sampling techniques, and official or officially accredited laboratories using validated analytical methods.

[19] In such cases, the importing country will ensure that corrective measures put in place by the exporting country are evaluated in a reasonable interval.

18. The nature of inspection may consist of a range of procedures to ensure that imported foods meet the importing country's food safety requirements. When defining these procedures to verify compliance with safety requirements, the proportionality of these measures with the level of risk of the food or group of foods should be considered. These procedures may include for example:

- checking the documentation and/or the general condition of the shipment;
- checking documentation plus periodic food sampling (e.g., 1 in 20 or 1 in 40 shipments) to confirm the accuracy of the documentation;
- sensory examination;
- random or targeted sampling and testing of, or within, shipments according to a sampling plan; or
- lot-by-lot inspection, sampling, and testing, which, in general, should be reserved for those foods that present, or have the potential to present, the highest food safety risk.

SECTION 6 – IMPLEMENTING THE IMPORT INSPECTION PROGRAMME BASED ON RISK

19. Competent authorities with responsibility for imported food inspection programs based on risk should ensure that relevant policies and procedures are implemented in a transparent, coordinated, and consistent manner. Personnel should be appropriately trained to enable such coordination, and information should be shared among competent authorities.

20. A failure of food shipments to meet importing country food safety requirements might, besides other actions, trigger a change in the manner in which risk is managed by the importing country for the food concerned. The response could include food being held pending final judgment combined with enhanced sampling and testing from the establishment involved. These actions may also be applied to other exporting establishments from the same country producing similar foods where there is evidence of a systemic problem. The suspension of the importation of a food by an importing country should be reserved only for those situations involving a serious food safety risk that has not been managed by other means. Procedures should provide for appeal.

21. When the results of border/point of control checks indicate failure of a shipment to meet the requirements of the importing country, competent authorities of the importing countries should consider action as described in the Codex *Guidelines for the Exchange of Information Between Countries on Rejection of Imported Food* (CAC/GL 25-1997) or in the Codex *Principles and*

Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC/GL 19-1995).

22. Competent authorities of the importing country should ensure adequate laboratory competency, capability and capacity is available to conduct the testing of imported food.

GUIDELINES FOR THE DESIGN, OPERATION, ASSESSMENT AND ACCREDITATION OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

CAC/GL 26-1997

SECTION 1 – OBJECTIVES

1. These guidelines provide a framework for the development of import and export inspection and certification systems consistent with the *Principles for Food Import and Export Inspection and Certification*.[1] They are intended to assist countries[2] in the application of requirements and the determination of equivalency, thereby protecting consumers and facilitating trade in foodstuffs.[3]

2. The document deals with the recognition of equivalence of inspection and/or certification systems and not with standards related to specific food products or their components (e.g., food hygiene, additives and contaminants, labelling and quality requirements).

3. Application by governments of the guidelines presented in this document should help build and maintain the necessary confidence in the inspection and certification system of an exporting country and facilitate fair trade, taking account of the expectations of consumers for an appropriate level of protection.

SECTION 2 – DEFINITIONS

Audit is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.[4]

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

[1] CAC/GL 20-1995.

[2] For the purpose of these guidelines, "countries" includes regional economic integration organizations to which a group of countries have transferred competences as regards food import and export inspection and certification systems and/or the negotiation of equivalency agreements with other countries.

[3] The Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995) includes that in the design and application of food inspection and certification systems, importing countries should take into account the capabilities of developing countries to provide the necessary safeguards (Paragraph 18).

[4] Consistent with the Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995).

Adopted 1997. Revision 2010.

continuous on-line inspection, auditing of quality assurance systems, and examination of finished products.[4]

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.[4]

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.[4]

Officially recognized inspection systems and officially recognized certification systems are systems which have been formally approved or recognized by a government agency having jurisdiction.[4]

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.[4]

Risk analysis is a process consisting of three components: risk assessment, risk management and risk communication.[5]

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.[5]

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.[5]

Risk communication is the interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties.[5]

[5] Codex Alimentarius Procedural Manual.

SECTION 3 – RISK ANALYSIS

4. Consistent and transparent application of risk analysis will facilitate international trade by increasing confidence in the food safety and in the inspection systems of trading partners. It will also enable inspection resources to be targeted effectively on hazards to public health arising at any stage of the food production and distribution chain.

5. The principles of Hazard Analysis Critical Control Point (HACCP) developed by the Codex Committee on Food Hygiene[6] provide a systematic basis for the identification and control of hazards so as to ensure the safety of food. The use of a HACCP approach by food businesses should be recognized by governments as a fundamental tool for improving the safety of foodstuffs.

SECTION 4 – QUALITY ASSURANCE

6. The voluntary utilization of quality assurance by food businesses should also be encouraged in order to achieve greater confidence in the quality of products obtained. If safety and/or quality assurance tools are used by food businesses, the official inspection and certification systems should take them into account in particular through the adaptation of their control methodologies.

7. Governments do, however, retain the fundamental responsibility to ensure by official inspection and certification[7] the conformity of foodstuffs to requirements.

8. The degree to which industry effectively utilizes quality assurance procedures can influence the methods and procedures by which government services verify that requirements have been met, where official authorities consider such procedures to be relevant to their requirements.

SECTION 5 – EQUIVALENCE

9. The recognition of equivalence of inspection and certification should be facilitated where it can be objectively demonstrated that there is an appropriate system for inspection and certification of food by the exporting country in accordance with these guidelines.

[6] Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application, Annex to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

[7] For the purpose of these guidelines, "inspection and certification" means "inspection and/or certification".

10. For the determination of equivalence, governments should recognize that:

- inspection and certification systems should be organized for the risk involved, considering that the same food commodities produced in different countries may present different hazards; and,
- control methodologies can be different but achieve equivalent results. For example, environmental sampling and the strict application of good agricultural practices, with limited end product testing for verification purposes, may produce a result equivalent to extensive end product testing for the control of agriculture chemical residues in raw products.

11. Controls on imported food and domestically produced foods should be designed to achieve the same level of protection. The importing country should avoid the unnecessary repetition of controls where these have been already validly carried out by the exporting country. In these cases a level of control equivalent to domestic controls should have been achieved at the stages prior to import.

12. The exporting country should provide access to enable the inspection and certification systems to be examined and evaluated, on request of the food control authorities of the importing country. Evaluations of inspection and certification systems carried out by the authorities of an importing country should take into account internal programme evaluations already carried out by the competent authority or evaluations performed by independent third-party bodies recognized by the competent authority in the exporting country.

13. Evaluations of inspection and certification systems by an importing country for purposes of establishing equivalence should take account of all relevant information held by the competent authority of the exporting country.

Equivalency agreements

14. The application of equivalence principles may be in the form of agreements or letters of understanding established between governments either for inspection and/or certification of production areas, sectors or parts of sectors. Equivalence may also be established through the administration of a comprehensive agreement which would cover inspection and certification of all food commodity forms traded between two or more countries.

15. Agreements on the recognition of equivalence of inspection and certification systems may include provisions concerning:

- the legislative framework, control programmes and administrative procedures;
- contact points in inspection and certification services;

- demonstration by the exporting country of the effectiveness and adequacy of its enforcement and control programmes, including laboratories;
- where relevant, lists of products or establishments subject to certification or approval, accredited facilities and accredited bodies;
- mechanisms supporting continued recognition of equivalence, e.g., exchange of information on hazards and monitoring and surveillance.

16. Agreements should include mechanisms to provide for periodic review and updating and include procedural mechanisms for resolving differences arising within the framework of the agreement.

SECTION 6 – INSPECTION AND CERTIFICATION SYSTEM INFRASTRUCTURE

17. Countries should identify the main objectives to be addressed through import and export inspection and certification systems.

18. Countries should have in place the legislative framework, controls, procedures, facilities, equipment, laboratories, transportation, communications, personnel and training to support the objectives of the inspection and certification programme.

19. Where different authorities in the same country have jurisdiction over different parts of the food chain, conflicting requirements must be avoided to prevent legal and commercial problems and obstacles to trade. For example, while provincial or state laws may exist there should be a competent authority at the national level capable of ensuring uniform application. However, an importing country authority may recognize a sub-national competent authority for purposes of inspection or certification where this arrangement is acceptable to the national authorities concerned.

Legislative framework

20. For the purposes of this section, legislation includes acts, regulations, requirements or procedures, issued by public authorities, related to foodstuffs and covering the protection of public health, the protection of consumers and conditions of fair trading.

21. The effectiveness of controls related to foodstuffs depends on the quality and completeness of legislation for foods. Legislation should provide authority to carry out controls at all stages of production, manufacture, importation, processing, storage, transportation, distribution and trade.

22. Legislation may also include provisions as appropriate for the registration of establishments or listing of certified processing plants, establishment approval, licensing or registration of traders, equipment design approval, penalties in the event of non-compliance, coding requirements and charging of fees.

23. The national competent authority in the exporting or importing country should have the ability to enforce and take action based on adequate legislation. It should take all necessary steps to insure the integrity, impartiality and independence of official inspection systems and officially recognized inspection systems and to ensure that the inspection programme contained in national legislation is delivered to a prescribed standard.

Control programmes and operations

24. Control programmes help to ensure that inspection actions relate to objectives, since the results of these programmes can be assessed against the objectives set for the inspection and certification system. Inspection services should draw up control programmes based on precise objectives and appropriate risk analysis. In the absence of detailed scientific research, control programmes should be based on requirements developed from current knowledge and practice. Every effort should be made to apply risk analysis based on internationally-accepted methodology, where available.

25. In particular, countries should require or encourage the use of a HACCP approach by food establishments. Official inspectors should be trained in the assessment of the application of HACCP principles. Where programmes include the drawing and analysis of samples, adequate sampling and appropriately validated analytical methods should be established to ensure that the results are representative and reliable in relation to the specific objectives.

26. The elements of a control programme should include, as appropriate:

- inspection;
- sampling and analysis;
- checks on hygiene, including personal cleanliness and clothing;
- examination of written and other records;
- examination of the results of any verification systems operated by the establishment;
- audit of establishments by the national competent authority;
- national audit and verification of the control programme.

27. Administrative procedures should be in place to ensure that controls by the inspection system are carried out:

- regularly in proportion to risk;
- where non-compliance is suspected;
- in a co-ordinated manner between different authorities, if several exist.

28. Controls should cover, as appropriate:
- establishments, installations, means of transport, equipment and material;
- raw materials, ingredients, technological aids and other products used for the preparation and production of foodstuffs;
- semi-finished and finished products;
- materials and objects intended to come into contact with foodstuffs;
- cleaning and maintenance products and processes, and pesticides;
- processes used for the manufacture or processing of foodstuffs;
- the application and integrity of health, grading and certification marks;
- preserving methods;
- labelling integrity and claims.

29. The elements of the control programme should be formally documented including methods and techniques.

Decision criteria and action

30. The controls programme should be targeted at the most appropriate stages and operations, depending on the specific objectives. Control procedures should not compromise the quality or safety of foods, particularly in the case of perishable products.

31. The frequency and intensity of controls by inspection systems should be designed so as to take account of risk and the reliability of controls already carried out by those handling the products including producers, manufacturers, importers, exporters, and distributors.

32. Physical checks applying to import should be based on risks associated with the importation. Countries should avoid systematic physical checks on imports except in justified cases such as products associated with a high level of risk; a suspicion of non-conformity for a particular product; or a history of non-conformity for the product, processor, importer or country.

33. When physical checks are to be undertaken, sampling plans for imported products should take into account the level of risk, the presentation and type of commodity to be sampled, the reliability of controls of the exporting country and of those responsible for handling the product in the importing country.

34. Where an imported product is found not to be in conformity, the resulting measures should take into account the following criteria to ensure that any action is proportionate to the degree of public health risk, potential fraud or deception of consumers:

- repeated non-conformity in the same product or in the same category of products;
- history of non-conformity of those responsible for handling the products;
- reliability of checks made by the country of origin.

35. The specific measures applied may be cumulative if necessary and may include:

In respect of the product not in conformity

- requirement for the importer to restore conformity (e.g. where problems relate to labelling for consumer information and have no effect on inspection or health);
- rejection of consignments or lots, in whole or in part;
- in the case of potentially serious health risk, destruction of the product;

In respect of future imports

- control programmes implemented by the importer or exporter to ensure problems do not re-occur;
- increased intensity of checks on categories of products identified as being not in conformity and/or the undertakings concerned;
- request for information and cooperation on the product or the category of products found not to be in conformity by the responsible authorities in the country of origin (increased checks at origin including controls as indicated in paragraphs 27-28);
- on-site visits;
- in the most serious or persistent cases, imports from establishments or countries may be suspended.

36. Where possible, and upon request, the importer or their representative should be given access by the relevant food control authority of the importing country to a rejected or detained consignment and in the latter case, the opportunity to contribute any relevant information to assist the control authorities of the importing country to make their final decision.

37. Where product is rejected, information should be exchanged in accordance with the Codex Guidelines for the Exchange of Information between Countries on Rejections of Imported Food.[8]

[8] CAC/GL 25-1997.

Facilities, equipment, transportation and communications

38. Inspection staff should have access to adequate facilities and equipment to undertake inspection procedures and methodologies.

39. Reliable transportation and communication systems are essential to ensure delivery of inspection and certification services when and where they are needed and for the transmission of samples to laboratories.

40. Communications facilities should be provided to ensure adequate compliance action and to address potential recalls. Consideration should be given to developing electronic information exchange systems, in particular to facilitate trade, protect consumer health, and to combat fraud.

Laboratories

41. Inspection services should utilize laboratories that are evaluated and/or accredited under officially recognized programmes to ensure that adequate quality controls are in place to provide for the reliability of test results. Validated analytical methods should be used wherever available.

42. Inspection systems' laboratories should apply the principles of internationally accepted quality assurance techniques to ensure the reliability of analytical results.[9]

Personnel

43. Official inspection services should have, or have access to, a sufficient number of qualified personnel as appropriate in areas such as: food science and technology, chemistry, biochemistry, microbiology, veterinary science, human medicine, epidemiology, agro-nomic engineering, quality assurance, audit and law. Personnel should be capable and appropriately trained in the operation of food inspection and control systems. They should have a status which ensures their impartiality and have no direct commercial interest in the products or establishments being inspected or certified.

SECTION 7 – CERTIFICATION SYSTEMS

44. An effective certification system depends on the existence of an effective inspection system as described above in Section 6.

[9] Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Foods (CAC/GL 27-1997).

45. Demand for certification should be justified by risk to health or risk of fraud or deception. Alternatives to certification should be considered wherever possible, in particular where the inspection system and requirements of an exporting country are assessed as being equivalent to those of the importing country. Bilateral or multilateral agreements, such as mutual recognition agreements or pre-certification agreements, may provide for dispensing with certification and/or the issuance of certificates which were previously required in certain cases.

46. Certification should provide assurance of the conformity of a product or batch of products, or that a food inspection system conforms to specified requirements, and will be based, as appropriate, on:

- regular checks by the inspection service;
- analytical results;
- evaluation of quality assurance procedures linked to compliance with specified requirements;
- any inspections specifically required for the issuance of a certificate.

47. Competent authorities should take all necessary steps to ensure the integrity, impartiality and independence of official certification systems and officially-recognized certification systems. They should ensure that personnel empowered to validate certificates are appropriately trained and fully aware, if necessary from notes of guidance, of the significance of the contents of each certificate which they complete.

48. Certification procedures should include procedures to ensure the authenticity and validity of certificates at all the relevant stages and to prevent fraudulent certification. In particular, personnel:

- should not certify matters without their personal knowledge or which cannot be ascertained by them;
- should not sign blank or incomplete certificates, or certificates for products which have not been produced under appropriate control programmes. Where a certificate is signed on the basis of another supporting document, the person signing the certificate should be in possession of that document;
- should have no direct commercial interest in the products being certified.

SECTION 8 – OFFICIAL ACCREDITATION

49. Countries may officially accredit inspection or certification bodies to provide services on behalf of official agencies.

50. To be officially accredited, an inspection or certification body must be assessed against objective criteria and must comply at least with the standards set out in these guidelines, particularly in relation to the competence, independence and impartiality of personnel.

51. The performance of officially accredited inspection or certification bodies should be regularly assessed by the competent authority. Procedures should be initiated to correct deficiencies and, as appropriate, enable withdrawal of official accreditation.

SECTION 9 – ASSESSMENT AND VERIFICATION OF INSPECTION AND CERTIFICATION SYSTEMS

52. A national system should be subject to audit separate from routine inspection. Inspection and certification services should be encouraged to carry out self-evaluation or have their effectiveness evaluated by third parties.

53. Self-assessment or third-party audits should be carried out periodically at various levels of the inspection and certification system, using internationally-recognized assessment and verification procedures. The inspection services of a country may undertake self-assessment for such purposes as assuring the adequacy of consumer protection and other matters of national interest, improving internal efficiency or facilitating exports.

54. A prospective importing country may undertake a review with the agreement of the exporting country of the inspection and certification systems of an exporting country as part of its risk analysis process, with a view to determining requirements for imports from that country. Periodic assessment reviews may be appropriate following the commencement of trade.

55. For the purpose of assisting an exporting country to demonstrate that its inspection or certification systems are equivalent, the importing country should make readily available adequate information on its system and its performance.

56. Exporting countries should be able to demonstrate adequate resources, functional capabilities and legislative support in addition to effective administration, independence in the exercise of their official function and, where relevant, performance history.

57. Guidelines on procedures for conducting an assessment and verification of the systems of an exporting country by an importing country are in the Annex.

SECTION 10 – TRANSPARENCY

58. Consistent with the principles on transparency contained in the Principles for Food Import and Export Inspection and Certification, 1 and in order to promote consumer confidence in the safety and quality of their food, governments should ensure that the operations of their inspection and certification systems are as transparent as possible, while respecting any legitimate constraints of professional and commercial confidentiality and avoiding the creation of new barriers to trade by giving a misleading impression of the quality or safety of imported products in comparison with domestic products.

ANNEX

PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF ASSESSMENTS OF FOREIGN OFFICIAL INSPECTION AND CERTIFICATION SYSTEMS

SECTION 1 – INTRODUCTION

1. An importing country may determine that it is necessary to assess an exporting country's official inspection and certification systems[10]. This annex is not intended to mandate the use of such assessments but to provide guidance that should be taken into account where they are used.

2. These assessment activities should concentrate primarily on evaluating the effectiveness of the official inspection and certification systems rather than on specific commodities or establishments in order to determine the ability of the exporting country's competent authority(s) to have and maintain control and deliver the required assurances to the importing country. A number of tools are available for the conduct of an assessment of an exporting country's official inspection and certification system these include, but are not limited to, audits, inspections and visits. The level of experience, knowledge and confidence[11] the importing country has in the exporting country's official inspection and certification system is important in determining the appropriate tool to undertake the assessment, including whether a visit to the country is required.

3. This annex is to be read in conjunction with section 9 - Assessment and verification of inspection and certification systems of Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997). In addition, the relevant sections of the OIE Performance of Veterinary Service Tool for Evaluation of Veterinary Services, Chapter 3.2 of the OIE Terrestrial Animal Health Code should be considered where appropriate

[10] ***Official inspection and certification systems*** refers to both 'Official inspection systems and official certification systems' and 'Officially recognized inspection systems and Officially recognized certification systems' as defined in the parent document.

[11] Experience, knowledge and confidence in an exporting country's food inspection and certification system by an importing country includes the history of food trade between two countries and the history of compliance of foods with the importing country's requirements, particularly the food products involved. Further examples that may inform the importing country's experience, knowledge and confidence are listed in paragraph 10 points (a) to (n) in CAC/GL 53-2003.

SECTION 2 – SCOPE

4. This annex provides guidance for use by competent authorities of both importing and exporting countries to ensure an effective, efficient, transparent[12], and consistent approach when using audits or inspections for assessment of an exporting country's official inspection and certification system(s), or component thereof. This annex should also apply to any other visit or request for information that may be part of an assessment which has the ability to impact on the exporting country.

SECTION 3 – OPENING MEETING

5. The overarching principle of this annex is that the competent authority of an importing country may conduct an assessment of an exporting country's official inspection and certification system with the agreement of the exporting country. In conducting assessments of an exporting country's official inspection and certification systems, the following additional principles apply.

Principles A to C apply to the conduct of the competent authorities of the importing and exporting countries throughout the assessment process

A. Assessments should be outcome focused, transparent, evidence-based and conducted in a cooperative, ethical and professional manner respecting confidential information, where appropriate.
B. The importing and exporting countries should have an agreed process to address any issues that may arise throughout the assessment process.
C. The importing and exporting countries should agree on an appropriate tool for the conduct of the assessment prior to its commencement based on the agreed scope and objectives. In most cases the preferred assessment approach would consider the official inspection and certification system as a whole or part.

Principles for the assessment process are provided in Principles D to G

D. The assessment process should be planned, systematic, transparent, consistent, fully documented and well communicated.
E. The plan incorporating rationale, objective, scope, assessment tools and, requirements against which the exporting country's official inspection and certification system is assessed should be clearly identified by the importing country, notified to and agreed by the exporting country's competent authority(s), within a reasonable period of time prior to the commencement of the assessment.

[12] CAC/GL 20 1995, paragraphs 13-16, and CAC/GL 26-1997, paragraph 58.

Principles F and G cover assessment reporting

F. Agreed corrective actions, timeframes and follow-up verification procedures should be clearly established and documented.
G. The final assessment report should be accurate and transparent and may be published respecting confidentiality of information, where appropriate.

SECTION 4 – CONDUCT OF ASSESSMENT

Principle A

Assessments should be outcome focused, transparent, evidence-based and conducted in a cooperative, ethical and professional manner, respecting confidential information where appropriate.

6. The importing country's competent authority should be able to demonstrate that its assessment findings, conclusions and recommendations are primarily focused on whether the required outcomes are likely to be achieved by the system and that they are supported by objective evidence or data which can be verified as accurate and reliable.

7. Where there are multiple competent authorities in an importing country, these authorities should coordinate their assessments in order to avoid any duplication of effort on the part of the exporting country.

8. The exporting country's competent authority or authorities should cooperate, coordinate and assist in the performance of the assessment so that the assessment objectives are achieved.

9. Throughout the course of the assessment, all issues arising should be dealt with in a cooperative, ethical and professional manner by the competent authorities.

10. The importing country's competent authority should ensure the impartiality of their auditors, inspectors or auditing organization. The assessors should have the appropriate qualifications, experience and training both in the relevant area of technical expertise and in audit techniques.

11. In conducting an assessment importing countries should ensure that confidential information is protected. For countries with specific laws relating to confidentiality, an agreement between the two parties should be reached as to how the laws will be adhered to, in order to proceed.

12. The anticipated costs for undertaking the assessment should be understood by both competent authorities in advance of undertaking the assessment.

13. The costs incurred in undertaking an assessment, including all travel costs, costs of technical experts and auditors or inspectors, and costs of support staff should normally be borne by the competent authority of the importing country except as may otherwise be agreed.

14. The costs incurred by the competent authority of the exporting country, in supporting the assessment, for support staff and technical experts in the exporting country should normally be borne by the competent authority of the exporting country except as may otherwise be agreed.

Principle B

The importing and exporting countries should have an agreed process to address any issues that may arise throughout the assessment process.

15. Prior to the commencement of the assessment the key elements of a process to address issues that may arise throughout an assessment should be agreed. Where they are available, the competent authorities of the importing and exporting countries should use existing processes to resolve issues arising from the assessment to the extent possible. The competent authorities of the importing and exporting country should aim to resolve any issues which may arise in the course of the assessment in an open, transparent and cooperative manner. If any issues remain outstanding they should be indicated in the assessment report with appropriate justification.

Principle C

The importing and exporting countries should agree on an appropriate tool for the conduct of the assessment prior to its commencement based on the agreed scope and objectives. In most cases the preferred assessment approach would consider the official inspection and certification system as a whole or a part.

16. The most efficient and effective tool that can assess the effectiveness of the exporting country's official inspection and certification system including the exporting country's competent authority(s) ability to have and maintain control and deliver the required assurances to the importing country should be selected.

17. In selecting the assessment tool, it is important to consider the reason the assessment is being undertaken. Assessments can, for example, be part of a risk analysis prior to commencement of trade, can assess the official inspection and certification system, or controls for a particular component e.g. commodity (e.g. dairy, fish or meat) or controls for a particular element (e.g. chemical residues) or specific exporting establishments.

18. The importing country's experience, knowledge and confidence[13] in an exporting country's official inspection and certification systems, should be considered in selecting an assessment tool.

19. In general, the preferred assessment tools would be audits of all or part of an exporting country's official inspection and certification system including the ability of the competent authority. Inspections can also be an appropriate assessment tool. Where competent authorities use other terms to describe assessment activities, e.g. visits, information exchanges, such activities should also be subject to these guidelines.

Audit Tools

20. The audit tool, often described as 'systems based audit' should focus on assessing whether the implementation of the official inspection and certification system or components thereof in operation in the exporting country is capable of meeting its objectives.

21. Systems-based audits rely on the examination of a sample of system procedures, documents or records and, where required, a selection of sites within the scope of the system under audit, as opposed to examining all procedures.

22. A system-based approach focuses on the control system(s) and recognizes that any compliances/non-compliances found must be viewed in the context of the over-all system.

23. In conducting a systems-based audit, the audit may involve examination of the elements as contained in Section 6, Inspection and Certification System Infrastructure or other elements as appropriate.

[13] Paragraphs 9-14 of the Appendix to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003) provides additional guidance relating to what constitutes experience, knowledge and confidence and expands on information presented in paragraph 10-12 of that Guideline.

Inspection Tool

24. The inspection tool may be used in some instances to confirm the effectiveness of controls by the competent authority(s) in the exporting country.

25. Inspections may involve the examination of:

a) how establishments meet requirements, including review of specific activities and product specifications, observation and review of establishment operations and appropriate operating records;
b) establishment's personnel capabilities, when specified in requirements;
c) inspectors' capability, if specified in requirements.

SECTION 5 – ASSESSMENT PROCESS

Principles D to G cover the assessment process.

Principle D

The assessment process should be planned, systematic, transparent, consistent, fully documented and well communicated.

26. The transparency and consistency of the assessment process may be facilitated by good documentation and communication. Documents supporting findings, conclusions and recommendations should be standardised as much as possible in order to make the performance of the assessment and the presentation of its outcome uniform, transparent and reliable.

27. In order to prepare and carry out an assessment, ongoing and transparent communication is required. Consultation should occur between the competent authorities of the importing and exporting countries at all points in the process, from developing the assessment plan through to final reporting and resolution of any issues arising during the assessment. To ensure ongoing and transparent communication the competent authorities of the importing and exporting country should designate responsible contact persons or contact points for assessments.

28. Processes and protocols for addressing assessment findings and recommendations should be documented and agreed prior to the assessment.

Principle E

The plan incorporating the rationale, objective, scope, assessment tools and requirements against which the exporting country's official inspection and certification system is assessed, should be clearly identified by the importing country, notified to and agreed by the exporting country's competent authority(s), within a reasonable period of time prior to the commencement of the assessment.

29. When establishing the rationale, objective, scope, frequency of assessment and assessment tools, the importing country's competent authority should take into account the established level of experience, knowledge and confidence together with the history of previous assessments, the period since the last assessment and any other relevant factors.

30. A systematic evaluation procedure for undertaking the assessment should be used based on a predetermined and structured program consistent with the purpose of the assessment.

Notification

31. The following information should be exchanged during the initial request and prior to commencing an assessment of a country's official inspection and certification system:

a) The rationale or need to conduct an assessment may arise from a number of reasons including, an importing country's legal obligations or the need to understand the respective roles of the competent authorities in both importing and exporting countries or the need to verify the capability of an exporting country's system or food production/processing facilities to meet requirements.

b) The objective of the assessment, for example is; to verify the effective application/implementation of specific measures or technical requirements of the exporting country's inspection and certification system; to verify compliance with measures of the importing country that the exporting country is implementing; to assess compliance with equivalency agreements or other types of mutual acceptance of systems, conduct an investigation of outbreaks of foodborne diseases related to imported/exported food and to follow up corrective action resulting from previous assessments or of situations derived from food safety issues. The risk assessment component of an exporting country's food control system may be audited where it is necessary to support a risk management approach.

c) The scope of the assessment, that is, whether the assessment is to cover a whole system or its sub-components, measures, technical requirements, or products should be defined.
d) The assessment tool intended to be used including the requirements against which the official inspection and certification system of the exporting country will be assessed should be identified.

32. In all cases, the competent authority of the importing country should provide the competent authority of the exporting country with sufficient notice of the intended assessment, in order to enable it to make the necessary arrangements such as logistics and information gathering. If the rationale for the assessment is a critical public health issue the advance notice should reflect the urgency related to the public health risk.

33. In the case of a request for assessment from an exporting country, the importing country should respond in a timely manner providing a commitment to conduct the assessment.[14]

Assessment Preparation

34. A plan for undertaking the assessments, including the assessment tool, timeframes and exchange of required information should be prepared and communicated to the exporting country's competent authority within a reasonable period of time. The plan should include the following:

a) objective and scope of the assessment including whether it is a stand-alone assessment or related to another assessment (e.g. follow-up of previous assessment) or series of assessments;
b) items/ elements to be reviewed/ undertaken which may include records and assessment checklists;
c) the anticipated timeframe within which the assessment will be conducted and reported;
d) criteria against which the assessment of the exporting country's official inspection and certification system will be carried out;
e) a contact person for the assessment team who can negotiate the details of the assessment plan and if required, assessment team members including foreign auditors/inspectors, the lead auditor/inspector, technical experts and translators;
f) the language that will be utilised during the assessment including, translation, availability of impartial and knowledgeable interpretation and resources.

[14] CAC/GL 20-1995 para 18.

g) an indication of the type or where possible/relevant the identity of locations to be visited (e.g. offices, laboratories or other facilities) and the timing and responsibility for the notification to the sites where necessary (although this task may be completed at the assessment opening/entry meeting);
h) the dates for the conduct of the assessment, the dates of the opening and closing meeting and the anticipated date for reporting the observations of the assessment;
i) travel schedules and other logistics, as necessary for an assessment visit; and
j) provisions to protect confidential information.

35. While efforts should be made to adhere to the assessment plan it should be designed to be flexible in order to permit changes in emphasis based on information gathered prior to, or during the assessment. Proposed significant amendment(s) to the assessment plan should only be made in extenuating circumstances and should be communicated by the proposing competent authority to the other competent authority as soon as possible.

36. As part of the assessment plan, the competent authorities of both countries should reach agreement on how the results of the evaluation will be conveyed to the exporting country, such as findings, non-compliance and recommendations.

37. Advanced agreement should be reached on the language that will be utilised during the assessment including, translation, availability of impartial and knowledgeable interpretation and resources.

38. To the extent possible documentary information required for planning, conducting and completing the assessment should be requested and provided in advance of the assessment, utilizing electronic means wherever possible.

a) The assessment preparation request should be focused and related to the stated scope and objectives.
b) If this is a follow-up assessment, then the exporting country should only need to provide any information that has changed since the previous assessment or that has not been requested during a previous assessment.
c) In case the purpose of an information-request is not clear to the exporting country and it has some issues related to the requested information, it may seek clarification from the importing country as to the purpose and use of such information.

d) When an on-site visit is the assessment tool proposed a review of documents describing the system including legislative support should be conducted prior to commencement of the assessment visit. This is to allow the most efficient and effective use of time spent on-site i.e. to reduce the burden of assessments on the competent authorities of both countries.

39. In some cases the assessment may be suspended or concluded prior to an on-site visit depending on the nature of information provided by the competent authority of the exporting country and in which case the reason should be communicated clearly to the competent authority of the exporting country by the competent authority of the importing country. The competent authority of the exporting country should have the opportunity to clarify the information provided should they consider this necessary.

40. Agreement should be reached in advance concerning the use of information sharing from assessments and the parties with whom information can be shared.

Assessment Logistics

41. When an assessment includes an on-site visit the competent authority of the exporting country should have primary responsibility for the logistical aspects of the assessment including advising on internal travel and accommodation arrangements. It is the responsibility of the competent authority of the exporting country to communicate with the responsible parties of the site(s) to b e assessed.

Assessment Opening / Entry Meeting

42. In the case of an assessment involving a visit an opening or entry meeting should be held.

a) The meeting should be held at a place designated by the competent authority of the exporting country.
b) The meeting should review all aspects of the assessment plan including any final adjustments and is intended to provide an overview of the official inspection and certification system of the exporting country and to confirm the parameters and logistics of the assessment.
c) Agreement should be reached on the methods to ensure continuous liaison and communications between the parties during the assessment.

Assessment Closing / Exit Meeting

43. In the case of an assessment involving a visit a closing or exit meeting should be held.

a) The meeting should be held at a place designated by the competent authority of the exporting country.
b) The assessment team should summarize main findings and preliminary conclusions. Any non-conformities should be identified and outline the objective evidence to support the conclusions. Correction of non-conformities should be left to the competent authority of the exporting country and verified by the competent authority of the importing country including a follow-up assessment if required.
c) This meeting provides an opportunity for the competent authority of the exporting country to raise questions or seek clarification of the findings and observations provided at the meeting.

SECTION 6 – ASSESSMENT REPORTING

Principles F and G cover assessment reporting.

Principle F

Agreed corrective actions, timeframes and follow-up verification procedures should be clearly established and documented.

Principle G

The final assessment report should be accurate and transparent and may be published respecting confidentiality of information, where appropriate.

44. A collaborative approach to report preparation and a process for distribution and presentation should be agreed in advance.

45. The assessed party should have the opportunity to review the draft report in an agreed timeframe, provide comments and correct factual errors before its finalization. The final report should incorporate, or be accompanied by, the comments provided by the competent authority of the exporting country.

46. The report of assessment should provide a balanced picture of the findings and include conclusions and recommendations that accurately reflect those findings. It should:

a) describe the objective, scope, and outcome;
b) describe the criteria and assessment process;
c) include assessment findings with supporting evidence for each conclusion, along with any details of significance discussed during the closing meeting;
d) be made available as agreed to between the importing and exporting country's competent authorities, including and addressing the comments made by the competent authority of the exporting country to enhance the accuracy of the report;
e) take into account the timeframe for the finalisation of the report and response procedures agreed upon between importing and exporting countries' competent authorities;
f) include how corrective actions will be communicated and agreed to, including how follow-up verification will be completed;
g) include any checklists of elements evaluated, where required to support the findings;
h) include a summary of the assessment outcome;
i) include outstanding matters and issues arising during the assessment in the report if there is no agreement on the conclusions and the corresponding corrective actions;
j) include uncertainties and/or any obstacles encountered that could affect the reliability of the assessment conclusion; and
k) indicate any areas not covered in the assessment process, though within the scope, and the reasons for such deviation from the agreed scope.

47. The timeframe and protocol for any follow-up verification should be clearly stated. Verification of corrective actions may include:

a) review of assurances provided by the competent authority of the exporting country;
b) review of documentation provided by the competent authority of the exporting country; or
c) review of stated corrective action in a subsequent assessment.

48. Confidential information must be respected in the preparation and subsequent distribution of the assessment report.

49. Once an assessment report has been finalised the competent authorities of the importing and exporting countries should discuss and if possible agree if and how

any or all of the report will be published respecting confidentiality of information where appropriate.

GUIDELINES FOR THE DEVELOPMENT OF EQUIVALENCE AGREEMENTS REGARDING FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

CAC/GL 34-1999

SECTION 1 – SCOPE

1. This document provides practical guidance for governments desiring to enter into bilateral or multilateral equivalence agreements concerning food import and export inspection and certification systems. Such agreements may be binding instruments taking the form of "international agreements" under the Vienna Convention on the Law of Treaties, or they may be other less formal arrangements such as memoranda of understanding.

SECTION 2 – DEFINITIONS

Audit is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.[1]

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.[1]

Certification system means official and officially recognized certification systems.

Equivalence is the capability of different inspection and certification systems to meet the same objectives.[2]

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.[1]

[1] Codex Alimentarius: *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995).

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

Inspection system means official and officially recognized inspection systems.

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.[1]

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]

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.[1]

SECTION 3 – PURPOSE OF AGREEMENTS

2. Countries[3] may wish to enter into agreements[4] concerning food import and export inspection and certification systems to:

a) provide an enhanced means of assuring that exported products conform to importing country requirements;
b) eliminate duplication of activities and use collective resources more efficiently and effectively;
c) provide a mechanism for the cooperative exchange of expertise, assistance and information to help assure and enhance conformity with requirements.

3. Equivalence agreements are not generally intended as a condition for trade but rather as a means for ensuring that importing country requirements are met with minimal trade impediments. For example, such agreements may result in reducing the importing country's rate of physical checks or sampling to test against standards or to avoid additional certification in the country of origin.

[3] 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 equivalence agreements with other countries.

[4] See Section 1 – Scope. Although this guideline refers to "countries" and "agreements," in many cases competent authorities will enter into agreements or other arrangements.

SECTION 4 – SCOPE AND TYPES OF AGREEMENTS

4. The guidelines herein are intended to cover both bilateral and multi-lateral agreements. Such agreements may cover trade in one or both directions between trading partners.

5. As agreed by the parties, an equivalence agreement covering control and certification systems may relate to any aspect of food safety or other relevant requirement for food. Such agreements may be limited to specific areas of trade or specific products. Such agreements may be entered into where equivalence has been established in respect of some or all requirements.

6. Equivalence agreements may include provisions for certificates or other forms of certification of particular traded products or may provide for dispensing with certificates and other forms of certification.[5]

SECTION 5 – CONSIDERATIONS BEFORE ENTERING INTO BILATERAL OR MULTILATERAL DISCUSSIONS

7. The importing country considers and determines whether the exporting country's measures meet the importing country's requirements. Any decision must, however, be made on the basis of objective criteria.

8. In general, significant resources are needed to develop agreements. Exporting and importing countries may therefore need to establish priorities for consultations leading to development of agreements in recognition of the limited resources available to conduct the necessary assessments. Such priorities should not conflict with World Trade Organization (WTO) rights and obligations.

9. Countries may wish to consider some or all of the following issues in setting priorities:

a) whether priority should be given to certain product categories because of the public health risks they pose;
b) whether there is significant trade between the exporting and importing countries for the product(s) that will be the subject of an agreement, and whether an agreement between the two countries would facilitate trade;
c) whether the exporting country appears to have sufficient infrastructure and resources to maintain an appropriate control system;
d) whether the exporting country's products have a low rate of non-compliance with importing country requirements;

[5] See paragraph 45 in CAC/GL 26-1997.

e) whether the exporting country recognizes and abides by the Codex Code of Ethics in International Trade in Food;
f) whether significant resources would be conserved as a result of the agreement.

10. A country entering into discussions towards an equivalence agreement should be prepared to facilitate assessment and verification activities both before and after conclusion of the agreement.[6]

11. Countries that are not yet ready to enter into equivalence agreements may wish to work jointly toward the development of such agreements. Amongst other things, information exchange, joint training, technical cooperation, and the development of infrastructure and food control systems can serve as building blocks towards the later development of agreements. An importing developed country should consider providing technical assistance to exporting developing countries to establish systems that enable food exports to meet importing country requirements and facilitate the development of equivalence agreements.

SECTION 6 – INITIATING DISCUSSIONS TOWARD AN EQUIVALENCE AGREEMENT

12. The country initiating discussion towards an equivalence agreement should identify:
a) the type of equivalence agreement proposed;
b) the product(s) to be covered;
c) the competent authority or authorities for each product; and
d) the scope of requirements to be addressed by the agreement (e.g., health and safety, quality assurance systems, labelling, consumer fraud, etc.).

13. A country which receives such an approach should respond in a timely manner.

14. In the event that the recipient of such an approach has difficulty in responding positively to the approach it should provide a statement of reasons and any relevant recommendations to facilitate the future development of equivalence agreements.

15. Both parties should verify that legal authority exists to discuss and enter into such an agreement.

[6] See CAC/GL 26-1997 for guidelines on the conduct of such assessment and verification activities.

SECTION 7 – CONSULTATIVE PROCESS FOR EQUIVALENCE AGREEMENTS

16. As a first step in the consultative process, the importing country should make readily available the texts of its relevant control measures and identify the objectives of these measures. For food safety control measures, the importing country should identify the health risk(s) addressed by each measure. Where certain health hazards, such as foodborne pathogens, are known to exist in the exporting country and not in the importing country, these hazards and the measures to address them should be identified.

17. The exporting country should provide information that demonstrates that its own safety control system achieves the importing country's objectives and/or level of protection, as appropriate:

- Equivalence agreements for food safety (sanitary) control measures are entered into after an importing country determines that an exporting country's control measures, even if different from those of the importing country, achieve the importing country's appropriate level of health protection.
- Equivalence agreements for other relevant requirements for food are entered into after an importing country determines that the exporting country's control measures, even if different than those of the importing country, meet the importing country's objectives.

18. The development of equivalence agreements is facilitated by the use of Codex standards, recommendations and guidelines by both parties.

19. To facilitate the consultative process, information should be exchanged, as appropriate, on:

a) legislative framework, including the texts of all relevant legislation, which provides the legal basis for the uniform and consistent application of the food control system that is the subject of the agreement;[7]
b) control programs and operations, including the texts of all the exporting country's pertinent measures that would be the subject of the agreement, as well as other materials that relate to control programs and operations;[8]
c) decision criteria and action;[9]

[7] See paragraphs 20–23 in CAC/GL 26-1997.
[8] See paragraphs 24–29 in CAC/GL 26-1997.
[9] See paragraphs 30–37 in CAC/GL 26-1997.

d) facilities, equipment, transportation and communications as well as basic sanitation and water quality;[10]
e) laboratories, including information on the evaluation and/or accreditation of laboratories, and evidence that they apply internationally accepted quality assurance techniques;[11]
f) details of the exporting country's systems for assuring competent and qualified inspection[12] through appropriate training, certification, and authorization of inspection personnel; and the number and distribution of inspectors;
g) details of the exporting country's procedures for audit of national systems, including assurance of the integrity and lack of conflict-of-interest of inspection personnel;[13]
h) details of the structure and operation of any rapid alert systems in the exporting country.

20. Countries may wish to prepare side-by-side tables to organize the above-mentioned information and identify differences between the countries' control systems.

21. The importing and exporting countries should identify a process for jointly considering differences in measures/requirements.

22. Representatives of the importing country should have the opportunity to satisfy themselves that the exporting country's control systems operate as outlined. This can be accomplished by appropriate assessment and verification of processes as described in Section 9 and the related Annex of the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems*.

23. Participants in the agreement should establish procedures to:
a) periodically audit and verify that equivalence continues to exist after conclusion of an equivalence agreement; and
b) resolve any problems identified during audit and verification.

[10] See paragraphs 38–40 in CAC/GL 26-1997.
[11] See paragraphs 41–42 in CAC/GL 26-1997.
[12] See paragraph 43 in CAC/GL 26-1997.
[13] See paragraphs 47 and 52–57 in CAC/GL 26-1997.

24. A problem resolution procedure should be developed including provision for the importing country to re-examine products to verify that the exporting country has corrected its deficiencies.

25. The participants in the agreement should discuss and decide whether the equivalence agreement should include provisions for the use, in addition to or in lieu of certificates, of a list of establishments which have been shown to be in compliance with the exporting country's equivalent control measures. The importing country can use this list of establishments to monitor imported shipments. The exporting country would be responsible for providing the list, and updates when appropriate, to the importing country. The importing country retains the right to refuse imports from an establishment and to arrange with the exporting country the removal of an establishment from the list, providing reasons for its action.

26. Participants in the agreement should agree to procedures for information exchange in the event of a food emergency control situation.[14]

27. Participants in the agreement should agree to procedures to follow in the case of food shipments that are found not to comply with the terms of the equivalence agreement.

28. Participants in the agreement should agree to procedures for terminating the agreement, in case either party is not satisfied that the terms of the agreement are being met.

29. To enhance public confidence in the agreement while respecting legitimate concerns to retain confidentiality, the relevant competent authorities of the particular countries should provide the public – including consumers, industry, and other interested parties – an opportunity to comment at an appropriate time on the proposed content of the agreement.[15]

SECTION 8 – PILOT STUDIES

30. Before entering into an agreement, the competent authorities in the importing and exporting countries may agree to the conduct of a trial or pilot study.

[14] See Codex Principles and Guidelines for the Exchange of Information in Food Control Emergency Situations (CAC/GL 19-1995).
[15] See paragraph 58 in CAC/GL 26-1997.

31. The pilot study draft agreement and protocol may include, but are not limited to, provisions in relation to:

a) description and time frame of the trial program;
b) roles and capabilities of involved government and officially recognized private organizations;
c) procedures for inspection and certification;
d) audit procedures and frequency;
e) description of training or information needs.

SECTION 9 – DRAFTING THE AGREEMENT

32. Information which may be included as appropriate in an agreement is listed in Appendix A.

SECTION 10 – IMPLEMENTING THE AGREEMENT

33. A notice announcing the agreement, or the text of the agreement itself, should be published by all the signatory governments. The text of the agreement should be made available to the public of each country in that country's official language(s).

34. After the agreement comes into effect, each party should promptly notify the other party or parties of any proposed new or revised measures that pertain to the agreement.

APPENDIX A

CONTENTS OF EQUIVALENCE AGREEMENTS

The following information may be included, as appropriate, in equivalence agreements.

(a) ***Title:*** The name given to the agreement may vary, depending on the preferences and legal requirements of the parties to the agreement.

(b) ***Parties:*** The name of the parties to the bilateral or multilateral agreement.

(c) ***Purpose:*** A brief statement of the specific purpose of the agreement.

(d) ***Scope:*** Identification of the products and measures that are the subject of the agreement. Note exceptions where necessary.

(e) ***Definitions:*** Definitions of terms in the agreement, as needed. Where possible, definitions in WTO and Codex documents should be used.

(f) ***Substantive obligations:*** A comprehensive description of each participant's obligations and specific responsibilities.

(g) ***Competent authorities:*** The title of each competent authority that will be responsible for the implementation of the agreement.

(h) ***Equivalence finding:*** A statement of the control systems or parts of systems that have been found to be equivalent by the importing party(ies) to the agreement.

(i) ***Assessment and verification provisions:*** A description of the methods to verify compliance with the provisions of the agreement, including audit procedures and/or provisions for participants to utilize officially recognized third parties (including competent authorities in countries that are not signatories to the officially recognized agreement). The plans for continuing verification should be clearly described.

(j) ***Criteria for certification:*** When certificates are part of agreements to meet requirements, a list of the criteria, by attribute, which should be used by the competent authorities of the exporting and importing countries to determine if the product meets the importing country's standards.

(k) ***Sample collection:*** A listing of references and sample procedures that the importing and/or exporting country will use for testing and/or certification.

(l) ***Analytical and other methodology:*** A listing of the methods and equivalence procedures that the participating competent authorities will use to determine the compliance of product(s) covered by the agreement.

(m) ***Administrative procedures:*** Procedures and guidance for the practical implementation and application of the agreement.

(n) ***Information exchange and cooperation:*** A listing of the types of sharing of expertise, providing assistance, and exchanging information that will help assure the quality and safety of the product(s) covered by the agreement.

(o) ***Transparency:*** Description of the types of information that should be exchanged on a routine basis, including but not limited to revised laws and standards, analytical findings, and inspection results.

(p) ***Notification:*** A description of the situations and procedures that should be followed when reporting significant changes in factors affecting the safety of traded products; situations where there is an identified risk of serious health effects related to traded products; and steps being taken to resolve such situations.

(q) ***Dispute settlement:*** A description of the consultative procedures, joint committee, and/or other mechanisms that should be employed by the participants to resolve disputes under the agreement. Such procedures and mechanisms should not limit the rights or obligations of the parties under the World Trade Organization (WTO) Agreements.

(r) ***Liaison officials:*** For each participating competent authority, at least one liaison official should be identified by title/position, address, telephone number, fax number and e-mail address. (It is not necessary to include the name of a specific individual.)

(s) ***Entry into force:*** The date on which the provisions of the agreement enter into force.

(t) ***Review, modification and termination:*** The methods for the review, modification and termination of the agreement.

(u) ***Signatures:*** Signatures, title, and names of officials representing the competent authority that are participants in the agreement and the date(s) of signature.

GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS[1]

CAC/GL 53-2003

SECTION 1 – PREAMBLE

1. It is often the case that importing and exporting countries operate different food inspection and certification systems. The reasons for such differences include differences in prevalence of particular food safety hazards, national choice about management of food safety risks and differences in the historical development of food control systems.

2. In such circumstances, and in order to facilitate trade while protecting the health of consumers, an exporting and an importing country may work together to consider the effectiveness of sanitary measures of the exporting country in achieving the appropriate level of sanitary protection of the importing country, consistent with the principle of equivalence as provided for in the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement).[2]

3. Application of the principle of equivalence has mutual benefits for both exporting and importing countries. While protecting the health of consumers, it serves to facilitate trade, and minimize the costs of regulation to governments, industry, producers, and consumers by allowing the exporting country to employ the most convenient means in its circumstances to achieve the appropriate level of protection of the importing country.[3]

[1] These guidelines should be read in conjunction with other relevant Codex texts, including in particular the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* – CAC/GL 34-1999.

[2] Consistent with the definition of *equivalence* in Section 3, measures that are *equivalent* (i.e., are different from the measures used by the importing country but nonetheless achieve the importing country's appropriate level of protection) should be distinguished from measures that are the same as the measures of the importing country.

[3] The benefits to an exporting country of application of the principle of equivalence would be offset or negated if a request for an equivalence determination were, by itself, used as a pretext for the disruption of established trade. Such action by an importing country would be contrary to the principles of international trade.

Adopted 2003. Appendix adopted 2008.

4. Importing countries should avoid the application of unnecessary measures when they have already been carried out by the exporting country. Importing countries may be able to reduce the frequency and extent of verification measures following a judgment of equivalence of measures applied in the exporting country.

SECTION 2 – SCOPE

5. This document provides guidelines on the judgement of the equivalence of sanitary measures associated with food inspection and certification systems. For the purpose of determining equivalence, these measures can be broadly characterized as infrastructure; programme design, implementation and monitoring; and/or specific requirements (refer paragraph 13).

SECTION 3 – DEFINITIONS

6. The definitions presented in this document are derived from and consistent with those of the Codex Alimentarius Commission and the WTO SPS Agreement.

Sanitary measure: Any measure applied to protect human life or health within the territory of the country from risks arising from additives, contaminants, toxins or disease-causing organisms in food or feedstuffs, or from risks arising from diseases carried by foods which are animals, plants or products thereof or from risks arising from any other hazards in foods.

Note: Sanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.[4]

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.[4]

[4] Codex Alimentarius Commission: Procedural Manual.

***Risk Assessment*:** A scientifically-based process consisting of the following steps: (i) hazard identification; (ii) hazard characterization; (iii) exposure assessment; and (iv) risk characterisation.[4]

Appropriate level of sanitary protection (ALOP): 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".)

Equivalence of sanitary measures:[5] Equivalence is the state wherein sanitary measures applied in an exporting country, though different from the measures applied in an importing country, achieve, as demonstrated by the exporting country, the importing country's appropriate level of sanitary protection.

SECTION 4 – GENERAL PRINCIPLES FOR THE DETERMINATION OF EQUIVALENCE

7. Determination of the equivalence of sanitary measures associated with food inspection and certification systems should be based on application of the following principles:

a) An importing country has the right to set a level of sanitary protection it deems appropriate in relation to the protection of human life and health.6 The ALOP may be expressed in qualitative or quantitative terms.
b) The sanitary measure7 applied in an importing country should in practice achieve the ALOP of the importing country and be applied consistent with article 2.3 of the SPS agreement.8
c) An importing country should describe how its own sanitary measure achieves its ALOP.
d) An importing country should recognize that sanitary measures different from its own may be capable of achieving its ALOP, and can therefore be found to be equivalent.
e) The sanitary measure that the exporting country proposes as equivalent must be capable of achieving the importing country's ALOP.

[5] Equivalence is defined in CAC/GL 26-1997 as "the capability of different inspection and certification systems to meet the same objectives".
[6] The SPS Agreement sets out the rights and obligations of WTO Members in relation to the determination of an appropriate level of sanitary protection.
[7] Where this guideline refers to 'measure' in the singular it may also be taken to refer to 'measures' or 'a set of measures', as appropriate to the circumstances.
[8] Equivalent measures may achieve the ALOP of the importing country or, in combination with other measures, they may contribute to the achievement of the importing country's ALOP. In the remainder of this guideline any reference to the former should be taken to include the latter possibility.

f) An importing country should, upon request by an exporting country, promptly enter into consultations with the aim of determining the equivalence of specified sanitary measures within a reasonable period of time.[9]
g) It is the responsibility of the exporting country to objectively demonstrate that its sanitary measure can achieve the importing country's ALOP.
h) The comparison of countries' sanitary measures should be carried out in an objective manner.
i) Where risk assessment is used in the demonstration of equivalence, countries should strive to achieve consistency in the techniques applied, using internationally accepted methodology where available and taking into account relevant Codex texts.
j) The importing country should take into account any knowledge and past experience it has of the food inspection and certification systems in the exporting country to make the determination as efficiently and quickly as possible.
k) The exporting country should provide access to enable the inspection and certification systems which are the subject of the equivalence determination to be examined and evaluated upon request of the food control authorities of the importing country.
l) All judgments of equivalence should consider the means by which that equivalence will be maintained.
m) Countries should ensure transparency in both the demonstration and judgment of equivalence, consulting all interested parties to the extent practicable and reasonable. The exporting and importing countries should approach an equivalence determination procedure in a cooperative way.
n) An importing country should give positive consideration to a request by an exporting developing country for appropriate technical assistance that would facilitate the successful completion of an equivalency determination.

SECTION 5 – THE CONTEXT OF AN EQUIVALENCE DETERMINATION

8. To facilitate judgement of equivalence between countries and promote harmonisation of food safety standards, Codex members should base their sanitary measures on Codex standards and related texts.[10]

[9] Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems - CAC/GL 26-1997.

[10] Article 3 of the WTO SPS Agreement states, inter alia, that WTO Members may introduce or maintain sanitary measures which result in a higher level of sanitary protection than would be achieved based on Codex standards, if there is a scientific justification, or as a consequence of the member's chosen level of protection. Such measures must be based on a risk assessment appropriate to the circumstances.

9. An equivalence determination can be sought for any sanitary measure or set of measures relevant to a food product or group of food products. Relevant sanitary measures making up a food control system in the exporting country that are not the subject of an equivalence determination should meet importing country requirements.

10. The extent of the equivalence determination will depend on the prior experience, knowledge, and confidence that the importing country has regarding the food control measures of the exporting country.

11. When an importing country has prior experience, knowledge, and confidence in food control measures relevant to those being evaluated for equivalence and the countries agree that import requirements are being fully met, e.g. where trade experience exists, determination of the equivalence of sanitary measures may be made without further consideration of those other relevant measures making up the food control system.

12. When an importing country does not have prior experience, knowledge, and confidence in food control measures relevant to those being evaluated for equivalence and the countries have not determined that import requirements are being fully met, e.g., where trade in a food product or group of food products is being proposed for the first time, determination of the equivalence of sanitary measures will require further consideration of those other relevant measures making up the food control system.

13. For the purposes of determining equivalence, the sanitary measures associated with a food inspection and certification system can be broadly categorised as:

a) infrastructure; including the legislative base (e.g., food and enforcement law), and administrative systems (e.g., organization of national and regional authorities, enforcement systems, etc.);
b) programme design, implementation and monitoring; including documentation of systems, monitoring, performance, decision criteria and action, laboratory capability, transportation infrastructure and provisions for certification and audit; and/or
c) specific requirements; including requirements applicable to individual facilities (e.g., premises design), equipment (e.g., design of food contact machinery), processes (e.g., HACCP plans), procedures (e.g., ante- and post-mortem inspection), tests (e.g., laboratory tests for microbiological and chemical hazards) and methods of sampling and inspection.

14. Categorization in this manner is likely to facilitate agreement between countries on the basis for comparison of sanitary measures subject to an equivalence determination (see section 6). Further, allocation of measures to a particular category may assist countries in simplifying the extent of the equivalence determination relative to other sanitary measures making up the food control system.

SECTION 6 – OBJECTIVE BASIS OF COMPARISON

15. Since the sanitary measures applied by an importing country have the purpose of achieving its ALOP, an exporting country may demonstrate achievement of the importing country's ALOP by demonstrating that the measures it proposes as equivalent have the same effect, relative to the achievement of the importing country's ALOP, as the corresponding sanitary measures applied by the importing country by using an objective basis of comparison.

16. The importing country should, at the request of the exporting country, specify as precisely as possible an objective basis for comparison of the sanitary measures proposed by the exporting country and its own measures.[11] Dialogue between the exporting and importing country will assist in the development of understanding and, desirably, agreement on the objective basis for comparison. Supporting information to be provided by the importing country may include:

a) the reason/purpose for the sanitary measure, including identification of the specific risks that the measure is intended to address;
b) the relationship of the sanitary measure to the ALOP, i.e., how the sanitary measure achieves the ALOP;
c) where appropriate, an expression of the level of control of the hazard in a food that is achieved by the sanitary measure;
d) the scientific basis for the sanitary measure under consideration, including risk assessment where appropriate;
e) any additional information that may assist the exporting country in presenting an objective demonstration of equivalence.

[11] The objective basis for comparison of sanitary measures categorized as "Infrastructure" is likely to be of a qualitative nature, e.g., the ability of food control legislation to achieve broad food safety goals. The objective basis of comparison of sanitary measures categorized as "Specific Requirements" is likely to be quantitative in nature e.g., a comparison of levels of hazard control achieved by the measure. The objective basis of comparison of sanitary measures categorized as "Programme" is likely to contain a mixture of qualitative and quantitative elements e.g., correct application of principles, and establishment of appropriate critical limits, in HACCP food control systems.

SECTION 7 – PROCEDURE FOR THE DETERMINATION OF EQUIVALENCE

17. The importing country should make available details of its sanitary measures to the exporting country on request. The exporting country should review all applicable sanitary measures of the importing country for the food involved and identify those it will meet and those for which it seeks determination of equivalence. The importing and exporting countries should then use an agreed process for exchange of the relevant information to facilitate the determination of equivalence. This information should be limited to that which is necessary for this purpose.

18. The determination of equivalence is facilitated by both exporting and importing countries following a sequence of steps, such as those described below and illustrated in Figure 1. The parties should work through these steps in a cooperative manner with the aim of reaching agreement:

a) The exporting country identifies the sanitary measure of the importing country for which it wishes to apply a different measure, and requests the reason/purpose for the measure.
b) The importing country provides the reason/purpose for the identified sanitary measure and other relevant information in accordance with section 6.
c) In accordance with section 6 the importing country should specify as precisely as possible an objective basis for comparison of the sanitary measures proposed by the exporting country and its own measures. On the initiative of the exporting country, the importing and exporting countries should enter into a dialogue concerning this objective basis for comparison with a view to reaching agreement.
d) The exporting country develops a submission using risk assessment or other relevant methodology as appropriate, to demonstrate that the application of the different sanitary measure achieves the ALOP of the importing country, and presents it to the importing country.
e) The importing country reviews the submission and, if adequate, uses the submission to determine whether the exporting country's measure achieves the importing country's ALOP.
f) If the importing country has any concerns with the submission as presented, it should notify them to the exporting country at the earliest opportunity and should detail the reasons for concern. If possible, the importing country should suggest how the concerns might be addressed.
g) The exporting country should respond to such concerns by providing further information, modifying its proposal or taking other action as appropriate.

h) The importing country notifies the exporting country of its judgement within a reasonable period of time and provides the reasoning for its decision, should the judgement be that the sanitary measure is not equivalent, i.e., does not achieve the importing country's ALOP.
i) An attempt should be made to resolve any differences of opinion over judgement of a submission, either interim or final.

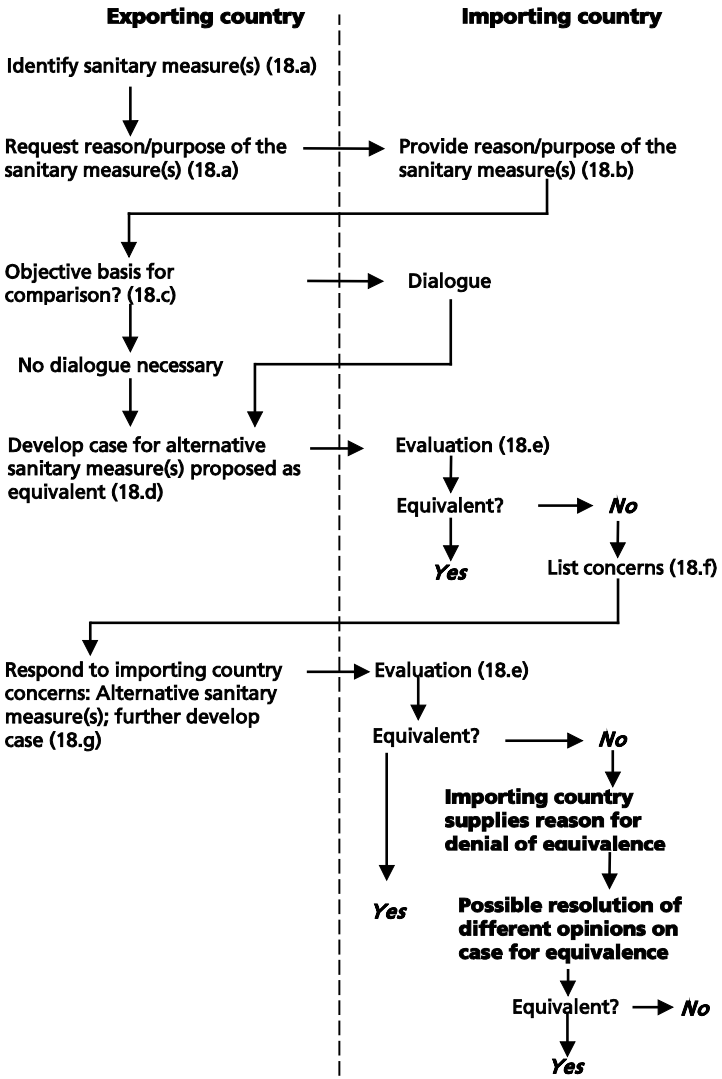
SECTION 8 – JUDGEMENT

19. Judgement of equivalence by the importing country should be based on a transparent analytical process that is objective and consistent, and includes consultation with all interested parties to the extent practicable and reasonable.

20. Judgement of the equivalence of sanitary measures should take into account:
a) experience, knowledge and confidence of an exporting country's food inspection and certification systems (see section 5);
b) supporting data submitted by the exporting country;
c) analysis of the strength of the relationship between the exporting country's specified sanitary measure, and the achievement of the ALOP of the importing country as reflected in the objective basis for comparison (see section 6);
d) that parameters should be stated in quantitative terms to the extent possible;
e) adequacy of qualitative descriptions where the level of control of hazards in foods is not quantified;
f) consideration of variability and other sources of uncertainty in data;
g) consideration of all expected human health outcomes of the exporting country's identified sanitary measure;
h) those Codex texts relevant to the food safety matters under consideration.

21. Following any judgment of equivalence, exporting and importing countries should promptly advise each other of significant changes in their supporting programmes and infrastructure that may affect the original determination of equivalence.

FIGURE 1: Simplified flow chart for the determination of equivalence (individual steps may be iterated)



APPENDIX

ADDITIONAL GUIDANCE TO ASSIST EXPORTING AND IMPORTING COUNTRIES IN UNDERTAKING AN EQUIVALENCE DETERMINATION OF SANITARY MEASURES

1. This Appendix relates to the equivalence determination of sanitary measures associated with a food inspection and certification system and clarifies certain aspects of the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (CAC/GL 53-2003 referred to below as "the Guidelines").

PRELIMINARY CONSIDERATIONS RELATING TO UNDERTAKING AN EQUIVALENCE DETERMINATION

2. There is a broad spectrum of circumstances where an exporting country may wish to seek an equivalence determination with an importing country. While each circumstance will likely need to be considered on a case-by-case basis, it can vary from seeking equivalence for a set of sanitary measures making up a food control system associated with a certain type of food or group of foods (e.g. dairy products) to seeking equivalence for a sanitary measure (e.g. analytical method).

3. Factors that may facilitate the equivalence determination of sanitary measures could include the following:

a) the experience, knowledge and confidence the importing country has with the exporting country's food control system (see paragraphs 9 to 14 below);
b) the prior history in food trade between the importing and exporting countries;
c) the level of compliance of the exporting country's food products with the importing country's requirements;
d) the level of cooperation that exists between the food safety competent authorities of the importing and exporting countries;
e) the extent to which importing and exporting countries' food control systems are similar (e.g., the similarity of food laws and regulations, the capabilities of professional staff and laboratories, the similarity of inspection and monitoring programs);
f) being well prepared to undertake an equivalence determination, including that the importing and exporting countries have access to the necessary resources such as the scientific and technical capabilities;
g) consideration of the relevance of any previous equivalence determinations made by the importing country.

Preparatory steps to undertaking an equivalence determination

4. Preparatory steps, that should be considered include:

a) the exporting country considering the benefits and cost/resource implications of an equivalence determination in comparison to other arrangements that meet the same outcome;
b) as appropriate, taking into account the considerations relating to setting priorities contained in Section 5 Paragraph 9, "Considerations before entering into bilateral or multilateral discussions", of the Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999);
c) whether the importing and exporting countries have access to the necessary scientific and technical resources to carry out an equivalence determination, recognizing that a proposal for equivalence will need to be well considered and documented;
d) where appropriate the importing and exporting country should at an early stage in the equivalence determination process develop a plan containing objectives, milestones, timelines and/or expected outcomes.

GUIDANCE ON UNDERTAKING AN EQUIVALENCE DETERMINATION

Scoping the equivalence determination

5. The exporting country should appropriately scope the request for an equivalence determination by identifying the sanitary measures and food commodity combination to be submitted for consideration.

6. The exporting country must decide on which of the importing country's measures it will meet by compliance and for which measures it will seek equivalence.

7. In some situations it will be clear as to the specific measure or group of measures that are the subject of the equivalence determination.

8. In other situations the scope of the equivalence determination may not be clear and categorization of sanitary measures as referred to in paragraphs 13 and 14 of the Guidelines may assist in determining the scope of the equivalence determination. Specifically, categorisation may assist with organising sanitary measures, carrying out side-by-side comparisons of those measures where appropriate, and identifying which measures will be the subject of the equivalence determination.

Experience, knowledge and confidence

9. The following section expands on information presented in paragraph 10-12 of the Guidelines and provides additional guidance relating to what constitutes experience, knowledge and confidence.

10. Experience, knowledge and confidence in an exporting country's food inspection and certification system by an importing country includes the history of food trade between the two countries and the history of compliance of foods with the importing country's requirements, particularly the food products involved in the equivalence determination. Other examples that may inform the importing country's experience, knowledge and confidence could include:

a) general knowledge of the exporting country's food control system which may be demonstrated by, among other things, a side by side comparison;
b) results of audits/inspections/field examinations by the importing country, exporting country, other countries, or other officially recognized third party organizations;
c) knowledge of the exporting country's application and implementation of the risk analysis principles in their food control system;
d) point of entry inspection and test results, including records of import rejections and alerts by the importing country as well as from other trading partners;
e) agreements the importing country may already have with the exporting country, including equivalence agreements;
f) bilateral or multilateral agreements on recognition of equivalence that either importing or exporting countries may have with other countries;
g) impact on food control systems as a consequence of organisational/structural/administrative changes in the exporting countries competent authority/ies;
h) contingency plans for containing and mitigating the effects of food safety emergencies;
i) food borne disease surveillance data associated with the food product;
j) the degree to which industry in the exporting country uses appropriate processing controls;
k) adequacy of the exporting country's legislation and, as appropriate, quality control systems;
l) level/form of oversight of the food production system by the exporting country's certifying authority;
m) acknowledgement and evaluation of pre-existing certification systems conducted or carried out by the exporting country;
n) any specific export control system in operation.

11. The importing country can apply such experience, knowledge and confidence at any point throughout the equivalence determination process.

12. Experience, knowledge and confidence may assist in facilitating familiarity with the information provided by the exporting country and therefore reduce the resources required to form a judgement of equivalence of the measures proposed.

13. Situations where experience, knowledge and confidence can assist include:

a) in making a decision how to proceed with a request for a judgement of equivalence;
b) in setting priorities, as may be appropriate (reference should also be made to Section 5, "Considerations Before Entering into Bilateral or Multilateral Discussions", of the Codex Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999));
c) in informing the process of comparing the exporting country's relevant sanitary measures with the importing country's sanitary measures;
d) in reducing the number of sanitary measures that are to be the subject of a detailed examination;
e) in reducing the extent of the scientific evidence required to determine equivalence.

14. In applying experience, knowledge and confidence to a determination of equivalence, transparency is essential so that the use and application of this information is clear to all parties.

Objective Basis of Comparison

15. The following section expands on information presented in paragraphs 15 and 16 of the Guidelines and provides additional guidance relating to what constitutes the development of an objective basis of comparison.

16. An objective basis of comparison is a tool that may be quantitative and/or qualitative in nature. The information in footnote 11 of the Guidelines is particularly relevant in explaining this point and provides some useful examples.

17. Depending on the scope of the equivalence determination there may be more than one OBC.

18. When developing OBC(s) the importing country should gather and assess scientific data and other information[12] and enter into a dialogue with the exporting country to seek agreement on the OBC(s). The OBC development process should, as appropriate:

[12] In the context of this appendix data is taken to mean both quantitative and qualitative data and other information.

a) ensure sufficient data to provide valid support for conclusions;
b) ensure the adequacy and accuracy of the data;
c) utilize risk assessments, as available; and
d) ensure sufficient knowledge and technical expertise of the subject matter experts.

Information and Documentation Contained in Submissions for Evaluation of a Request for an Equivalence Determination

19. The following section provides additional guidance on what information should be contained in a country's submission for an equivalence determination.

20. Information and documentation required by the importing country should be confined to essential information that is related to the defined objective for the determination of equivalence.

21. Requests for information from the importing country should be presented in a coordinated manner.

22. Paragraphs 16-20 of Section 7 "Consultative process for equivalence agreements" of the Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999) provide guidance and the type of information that may need to be included in a submissions package.

23. Before forwarding a submission package to the importing country, an exporting country should initiate an official request for the determination of equivalence, including identifying the food products or group of food products concerned, and have made appropriate contact with its counterpart in the importing country.

24. The submission package should specify the measure(s) for which equivalence is sought.

25. It may often be the case that a submission package is done in steps. For example the exporting country provides the measures for which an equivalence determination is sought. The importing country then provides the OBC if required.

26. Depending upon the nature of the OBC (see the section on Objective Basis of Comparison in this appendix), exporting countries should provide the following information and data:

a) For a qualitative OBC, references to pertinent scientific information should be provided. The submission package should also contain a written analysis by the exporting country's subject matter experts explaining how they arrived at their conclusion that the exporting country's measures are equivalent to the importing country's measures.
b) For a quantitative OBC, the submission package should include: the data used to assess the equivalence of the measure; the methodology used to obtain the data; the methodology used to assess the data including, as appropriate, the risk assessment models employed, and the assumptions made and the nature and extent of uncertainty of the findings. The submission package should also contain a written analysis that clearly shows how the exporting country arrived at the conclusion that its measure(s) are equivalent to the importing country's measure(s).

Details on Judgement of Equivalence

27. The following expands on Sections 7 and 8 of the Guidelines.

28. In the process of judging equivalence the importing country should focus on those measures or groups of measures which the exporting country and importing country have mutually agreed will be the subject of the equivalence determination.

29. Ongoing communication between the importing and exporting countries may assist with the judgement of equivalence process to, among other things, clarify technical points and respond to the need for additional information.

30. Importing countries may undertake to judge equivalence based only on a review of the data and information. Subject matter experts in the importing country may also be utilised especially in reviewing the conclusions of the exporting country.

31. The importing country should consult the exporting country throughout the process of judgement and at the earliest opportunity if preliminary assessment indicates that the application is likely to be unsuccessful.

32. A favourable decision regarding the judgement of equivalence based on the assessment of available information taking into account experience, knowledge and confidence can be made at any point in the process including:
a) at initial contact by the exporting country;
b) following review of the submission package by the importing country, including the opinions of subject experts where necessary;
c) following an assessment based on an objective basis of comparison.

d) following an assessment of the information gathered during onsite visits by the importing country;
e) following the resolution of outstanding issues.

33. Within a reasonable period of time the importing country should provide to the exporting country a written report as to whether or not equivalence has been found. Where equivalence is not found, the reasoning for this should be given to the exporting country and should be included in the written report with suggestions for solutions where possible.

Use of On-site visits

34. To complement the documentary review by the importing country, the use of on-site visits may be beneficial in clarifying information provided by the exporting country. The rationale for on-site visits related to the determination of equivalence may include:

a) to help clarify information provided by the exporting country relevant to its sanitary measures subject to the equivalence determination;
b) to gather additional information on the exporting country's proposed measures that may be required by the importing country to undertake a judgement of equivalence;
c) to improve knowledge and confidence in the exporting country's food control system.

35. In preparing for an on-site visit, both the importing and exporting country should consider:

a) the development of a protocol for the on-site visit;
b) limiting the scope of on-site visits to the food product or group of food products and the associated sanitary measures that are the subject of the equivalence determination.

Provision of Technical Assistance

36. The following expands on paragraph 7 (n) of the Guidelines the principle relating to technical assistance, and provides additional guidance relating to the provision of technical assistance. It is possible that technical assistance may be needed by importing and exporting countries in carrying out equivalence determinations.

37. Countries considering the need for technical assistance with respect to equivalence determinations or countries considering providing technical assistance, may wish to consider the following:

a) assistance in evaluating which measures would be the subject of an equivalence determination;
b) assistance with the preparation of documentation, including the submittal package;
c) assistance in undertaking necessary risk assessments;
d) assistance with data analysis;
e) assistance in assessing whether measures meet the importing country's stated objective basis of comparison;
f) exchange of technical expertise between the importing and exporting countries; and
g) assistance in providing appropriate training programs.

GUIDELINES FOR DESIGN, PRODUCTION, ISSUANCE AND USE OF GENERIC OFFICIAL CERTIFICATES[1]

CAC/GL 38-2001

SECTION 1 – PREAMBLE

1. These guidelines recognize that the importing country's competent authority may, as a condition for clearance of food presented for international trade, require importers to present official certificates issued by or with the authority of the exporting country's competent authority.

2. These guidelines are not intended to encourage or mandate the use of official certificates for food presented for international trade or to diminish the trade facilitating role of commercial or other types of certificates, including third party certificates that are not issued by, or with the authority of, the government of the exporting country.

3. These guidelines recognize that while official certificates may help importing countries to achieve their objectives relating to food safety and ensuring fair practices in the food trade there may also be other approaches, which can complement or substitute for official certificates, e.g., establishment listing.

SECTION 2 – SCOPE AND OBJECTIVES

4. These guidelines provide guidance to countries on the design, production, issuance and use of official certificates to attest that food presented for international trade has met the importing country requirements relating to food safety, and/or ensuring fair practices in the food trade.

5. These guidelines provide assistance in identifying the information and attestations that can be provided by competent authorities.

6. These guidelines are equally applicable to official certificates regardless of their mode of transmission, e.g., paper or electronic.

[1] These Guidelines should be read in conjunction with the Codex Guidelines for the Design, Operation, Assessment, and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997), particularly Section 7, certification systems. Reference should also be made to Codex-developed model certificates.

Formerly Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates. Adopted 2001. Revisions 2005, 2007, 2009.

7. These guidelines do not deal with matters of animal and plant health unless directly related to food safety. However, it is recognized that, in practice, a single official certificate may contain information relevant to several matters (e.g., food safety and animal and plant health).

SECTION 3 – DEFINITIONS

Certificates are those paper or electronic documents, which describe and attest to attributes of consignments of food destined for international trade.

Certification is the procedure by which official certification bodies or officially recognized certification bodies provide written or equivalent assurance that food 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.[2]

Official certificates are certificates issued by, or under the control of the exporting country's competent authority, including by a certifying body recognized by the competent authority to issue such certificates.

Certifying bodies are official certification bodies and officially recognized certification bodies.[3]

Certyfing officers are officers authorized or recognized, by the exporting country's competent authority, to complete and issue official certificates.

Consignment means a defined collection of food products normally covered by a single certificate.

SECTION 4 – PRINCIPLES

8. The following principles apply to the design, production, issuance and use of official certificates.

A. Official certificates should be required only where attestations and essential information are necessary to ensure that food safety and/or fair practices in the food trade requirements are met.

[2] *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995).

[3] Recognition of certification bodies is addressed under Section 8 – Official Accreditation of the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997).

B. Exporting countries may provide assurances through means other than consignment- by-consignment certificates, as appropriate.
C. Attestations and information required by the importing country should be confined to essential information that is related to the objectives of the importing country's food inspection and certification system.
D. The rationale and requirements for specific attestations and identifying information should be communicated to exporting countries in a consistent and transparent manner and be applied by the importing country in a non-discriminatory manner.
E. Official certificates, regardless of their mode of transmission and their contents, should present information in a form that simplifies and expedites the clearance process while meeting the importing country requirements.
F. The competent authority of the exporting country is ultimately responsible for any certificate it issues or authorizes to be issued.
G. All relevant attestations and identifying information required by the importing country should be included on a single official certificate, where possible, to avoid multiple or redundant certificates.
H. Competent authorities should take appropriate action to prevent the use of fraudulent certificates and should assist, as appropriate, in the timely investigation of such use.

SECTION 5 – USE OF OFFICIAL CERTIFICATES

Principle A

Official certificates should be required only where attestations and essential information are necessary to ensure that food safety and/or fair practices in the food trade requirements are met.

9. Specific attestations and information related to the product identified in the certificate can provide assurances that the food or group of food products:

- complies with the food safety requirements of the importing country; and
- complies with requirements of the importing country related to fair practices in the food trade.

10. It may be the case that national legislation does not authorize an exporting country's competent authority to issue the certificate required by the importing country. Such information should be communicated to the importing country. In such instances, the importing country should consider the need to provide flexibility to allow such assurances to be provided by alternative means so long as food safety and fair practices in food trade are assured.

SECTION 6 – ALTERNATIVES TO USE OF OFFICIAL CERTIFICATES

Principle B

Exporting countries may provide assurances through means other than consignment- by-consignment certificates, as appropriate.

11. Alternative arrangements that provide equivalent assurances with respect to food safety or ensuring fair practices in the food trade should be considered.

12. In some circumstances, an importing country may agree to accept from an exporting country a listing of establishments that meet the specific requirements of the importing country. This listing may be used to accomplish the same objectives as consignment-by-consignment certificates, recognizing that the importing country may still need additional information (e.g. mode of transport) for each consignment.

13. The mechanisms and criteria for establishing, maintaining and reviewing such lists should be made transparent by the exporting country and agreed to by the importing country.

14. Recognising that a consignment is normally covered by a single official certificate, it is also possible for certain certificates to apply to multiple consignments if agreed by the importing country. In such cases multiple consignment certificates should have a fixed duration.

SECTION 7 – EXTENT OF INFORMATION, TRANSPARENCY AND NON-DISCRIMINATION

Principle C

Attestations and information required by the importing country should be confined to essential information that is related to the objectives of the importing country's food inspection and certification system.

15. The particular official attestations and information to be included on a certificate will be determined by the requirements of the importing country. Importing countries should make use of international standards, if available, with the objective of reducing the need for extensive detail in certificates.

16. Official attestations and information should be clearly identified in the text of the certificate and not be any more complex or detailed or onerous for the exporting country than is necessary to meet the objectives of the importing country's food inspection and certification system. Such attestations may include, but are not limited to:

- compliance with particular standards, production or processing requirements, if relevant;
- the status (e.g., licensing details) of production, processing, packaging and/or storage establishments in the exporting country;
- the exporting country's animal health status, if it may affect the safety of the food; and
- reference to any associated bilateral/multilateral agreement.

17. Commercial or marketing specifications, such as specific product attributes or conformance to importer specifications should not be required in official certificates.

18. A consignment consisting of a food sample intended for evaluation, testing or research in the importing country should be clearly identified according to its intended use. It should be clearly indicated on the certificate or the package that the sample is not intended for retail sale and has no commercial value.

Principle D

The rationale and requirements for specific attestations and identifying information should be communicated to exporting countries in a consistent and transparent manner and be applied by the importing country in a non-discriminatory manner.

19. In establishing requirements for certificates, importing countries should ensure that criteria will apply equitably to all exporting countries in order to avoid arbitrary or unjustifiable discrimination.

20. Competent authorities of the importing country should, on request, communicate to the exporting country the requirements for the official attestations and information in certificates and their rationale.

SECTION 8 – DESIGN OF OFFICIAL CERTIFICATES

Principle E

Official certificates, regardless of their mode of transmission and their contents, should present information in a form that simplifies and expedites the clearance process while meeting the importing country requirements.

21. The design and utilization of official certificates should:
- simplify and expedite the clearance of the consignment at the point of entry or the point of control;
- provide for accurate identification of the consignment being certified and the parties involved in the production and issuance of the certificate;
- facilitate the importing country's assessment of the validity of certificate; and
- minimize the potential for fraud.

22. To the extent practicable, a standard format should be employed for official certificates. Certificates should:
- clearly identify the certifying body and any other parties involved in the production and issuance of the certificate[4];
- be designed so as to minimize the potential for fraud including use of a unique identification number, or other appropriate means to ensure security (for example, use of watermark paper or other security measures for paper certificates use of secure lines and systems for electronic certificates);
- clearly describe the commodity and consignment to which the certificate relates;
- contain a clear reference to those official requirements for which the certificate was issued;
- contain attestations by the official or officially recognized certifying body which relates to the consignment described on that certificate and should not be required to be endorsed/re-certified after they are issued; and
- be in a language or languages fully understood by the certifying officer in the exporting country, in transit countries where appropriate, by the receiving authority in the importing country or those countries in which the inspection of the food takes place. Where required the certificates can be accompanied by official translations.

[4] When additional information is required on the certificate, it should be constructed in such a way that it is clear who has provided the various parts of the certificate (e.g. laboratory, producing establishment, certifying body).

23. The information related to the product being certified should be clearly documented on the certificate and should include as a minimum the following. It may also include additional information as agreed to by the importing and exporting country:

- nature of the food[5];
- name of product[6];
- quantity, in the appropriate units[7];
- a description of the commodity and consignment to which the certificate uniquely relates, e.g., lot identifier, means of transport, security seal number(s) or date coding;
- identity and, as appropriate, the name and address of the producer/manufacturer of the food and/or storage establishments and their approval number;
- name and contact details of the exporter or consignor;
- name and contact details of the importer or consignee;
- country of dispatch[8], or part of the country where these relate to specific attestations; and
- country of destination[9].

SECTION 9 – ISSUANCE OF OFFICIAL CERTIFICATES (RESPONSIBILITY OF CERTIFYING OFFICERS, SECURITY AND PREVENTION OF FRAUD)

Principle F

The competent authority of the exporting country is ultimately responsible for any certificate it issues or authorizes to be issued.

24. Official certificates as issued, are ultimately the responsibility of government authorities, while recognizing that it is the food production sector that is fundamentally responsible for food safety and the prevention of fraud and deception as it relates to food in international trade.

[5] The World Custom Organization classification should be used when appropriate. When species identification is needed, the Linnaeus classification should be used.
[6] Reference should be made to Codex standards if available.
[7] Quantity should be in accordance with the International System of Units (Modern Metric System).
[8] ISO country codes may be used.
[9] ISO country codes may be used.

25. The certifying body should:

- be designated and adequately empowered by national/regional[10] legislation or regulation in a transparent manner to provide the particular attestations required in an official certificate;
- have its designation/ empowerment recognized as sufficient by governments, alleviating the need for any additional endorsement/re-certification of the certificates they issue;
- provide information relating to its official empowerment to the importing country upon request;
- ensure that its procedures allow for the issue of official certificates in a timely manner so as to avoid unnecessary disruptions to trade;
- have in place an effective system to minimize, to the extent practicable, the fraudulent use of official certificates; and
- have in place an effective and timely training program for its certifying officers.

26. If the competent authority of the exporting country has legislative authority to utilize third party certification bodies and has authorized a third party body to issue certificates on its behalf, the competent authority must ensure that there is adequate oversight of the third party, including auditing arrangements.

27. Certificates should normally be issued prior to the consignment to which the certificate relates leaving the control of the certifying body. Certificates may be issued while consignments are in transit to or have arrived at the country of destination only when appropriate systems of control are in place in the exporting country to support this practice and the practice is agreed to by the importing country, and when applicable, to the transiting country.

28. Certifying officers should:

- be appropriately designated by the certifying body;
- have no conflict of interest in the commercial aspects of the consignment and be independent from the commercial parties;
- be fully conversant with the requirements to which they are attesting;
- have access to a copy of regulations or requirements that are referred to on the certificate or clear information and guidance notes issued by the certifying body or competent authority explaining the criteria that the product must meet before being certified;
- only attest to matters that are within their own knowledge (or have been separately attested to by another competent party); and

[10] Regional refers to Regional Economic Integration Organisation (REIO) as defined by Article 2, Constitution of the Food and Agriculture Organization of the United Nations.

– only certify to the circumstances that can be verified, directly or by documentation provided, including conformity with production requirements and any other specified requirements between production and date of issue of the certificate.

Principle G

All relevant attestations and identifying information required by the importing country should be included on a single official certificate, where possible, to avoid multiple or redundant certificates.

29. Requests for certificates should minimize to the extent possible the need for redundant or duplicative certificates. Examples of such situations include: (1) multiple certificates with similar attestations are required by different agencies within an importing country; (2) multiple certificates are required for different attributes when a single attestation would suffice; and, (3) multiple certificates with similar attestations are required from different certifiers within the exporting country.

30. When a certificate requires multiple attestations (e.g., food safety, animal health and/or plant health) standard attestations developed by organizations recognized in the World Trade Organization (WTO) Sanitary and Phytosanitary Agreement (SPS) may be used (i.e., Codex, OIE, IPPC).

31. In case certificates are required from different bodies, a single competent authority may issue the certificate based on information received from other official bodies. An example of such cases would be attestations of animal health status and public health matters on the same certificate.

32. In instances where the importing country requests that an official certificate contain proprietary information, such requests should be confined to the need to ensure the product meets food safety requirements and to ensure fair practices in the food trade. If such information is requested, adequate means to protect the proprietary nature of such information shall be employed and communicated to the exporter.

33. Commercially sensitive information such as contract numbers and bank arrangements should not be included in official certificates.

34. Where, in exceptional cases justified by documented public health problem, the importing country requires assurance that an ingredient originating from a specified country (or countries) is not contained in the exported food; such attestations should be included in the certificate. When the country or countries have managed the risk based on science and the measures implemented to address the hazard are satisfactory to the importing country, the use of these attestations should be discontinued.

Use of paper certificates

35. Paper certificates where used should be issued and presented to the exporter or their agent as the original certificate.

36. Paper certificates should, to the extent practicable, be in compliance with the UN Layout Key for Trade Documentation (Recommendation No 1, ECE/TRADE/137).

37. A copy of the original certificate (clearly marked as such) should be kept by the certifying body in the exporting country and be provided, on request, to the competent authority in the importing country, or in a country carrying out import controls on behalf of the importing country.

38. When issuing a paper certificate, the certifying officer should ensure that:

- the certificate contains no deletions other than those required by the text of the certificate;
- any alterations of the certified information are initialized or otherwise approved by the certifying body;
- for multiple page certificates, it is clear that the pages constitute a single certificate including official translation(s) when appropriate (e.g., each page is numbered with the same unique certificate number so as to indicate it is a particular page in a finite sequence);
- the certificate bears the official identifier of the competent authority, signature, name and official position of the certifying officer (the signature may be hand written or a controlled facsimile signature);
- the certificate bears the date, expressed unambiguously, on which the certificate was signed and issued and, where appropriate, the period of time for which the certificate will remain valid; and
- no portion of the certificate is left blank in a manner that would allow it to be amended.

Use of electronic certificates

39. Where export certificates are exchanged electronically between the competent authorities of the exporting and importing countries, the system should:

- consider data elements and message structure such as those set/ratified by the United Nations Centre of Trade Facilitation and Electronic Commerce for electronic certificates exchanged between government border authorities (refer ISO/UNTDED[11]). The importing and exporting countries will need to agree on the data elements to be exchanged;
- consider application of available technologies for data message exchange in such a way as to ensure that data exchange options support business continuity;
- assure integrity of the certification system during the exchange of electronic data to protect against fraud, infection from viruses and other malicious software and to maintain system integrity. Examples of security measures which may be considered include:
  - digital authentication certificates
  - encryption
  - controlled and audited access
  - firewalls
- include a mechanism to control and protect system access against unauthorized entry. This will require the competent authorities of both the exporting and importing countries to agree on access rights, including the officials authorized to access the system;
- include technical or procedural mechanisms to prevent the fraudulent reuse of electronic certificates;
- take into account the limitations of infrastructure and capabilities of developing countries; and
- include a contingency plan to ensure disruption to trade is minimal in the event of system failure.

40. The exporter or their agent should be notified when an electronic certificate has been authorized for a consignment.

[11] The UNTDED (United Nations Trade Data Elements Directory) contains descriptions of all elements by number and short description plus attributes (www.unece.org/etrades/codesindex.htm). As an example, DE1004 is a "Document/Message Number". A similar identification in X12 is 324 "Purchase Order Number", including XML data elements contained within the business requirement specifications of the export certification – Trade/CEFACT/2005/36.

Presentation of original certificates

41. In the case of paper certificates the importer or consignee is responsible for ensuring that the product and the original certificate, in accordance with the importing country's requirements, is presented to the importing country's authorities or to the authorities in a country carrying out import controls on behalf of the importing country. In the case of electronic certificates, the importer/consignee or their representative should supply the importing country authority with sufficient details concerning the consignment to allow its identity to be established against the details contained in the certificate.

Replacement of certificates

42. Replacement certificates may be issued by a competent authority to rectify certificates that have been for example, lost, damaged, contain errors, or where the original information is no longer correct. These certificates must be clearly marked to indicate that they are replacing the original certificate. A replacement certificate should reference the number of the original certificate that it supersedes and the date the original was signed. The original certificate should be cancelled and where possible, returned to the issuing authority.

Revocation of certificates

43. When, for good and sufficient reason, there is cause to revoke a certificate, the certifying body should revoke the original certificate as soon as possible and notify the exporter or their agent in hard copy or by electronic means of the revocation. The notice should reference the number of the original certificate to which the revocation refers and provide all particulars regarding the consignment and the reason(s) for the revocation. A copy of the revocation should be provided to the appropriate food control authority of the importing country if the consignment has been exported. An electronic notification should be made to the control authority of the importing country for those countries using electronic certificates. Where the consignment has been provided with a paper certificate, the original certificate should be returned to the issuing authority, if possible.

Invalid certificates

44. Despite efforts to prevent errors, official certificates may inadvertently contain incorrect or incomplete information or attestations. Upon discovery of this the export country's certifying body or the importing country's competent authority should notify one another. In such cases the certifying body should, in a timely fashion issue a replacement certificate as described in paragraph 42 or revoke the certificate as described in paragraph 43, as appropriate.

Principle H

Competent authorities should take appropriate action to prevent the use of fraudulent certificates and should assist, as appropriate, in the timely investigation of such use.

Fraudulent certificates

45. When a competent authority suspects on reasonable grounds that an official certificate may be fraudulent, because of deliberate misrepresentation or other criminal activity, it should immediately commence an investigation and involve the certifying body of the country from which the suspected fraudulent certificate is purported to have originated. Considerations should also be given to notify any third country that may have been implicated. Additionally, the competent authority should retain the associated consignment under its control, pending the outcome of the investigation.

46. Certifying bodies in the countries from which the suspected fraudulent certificate is purported to have originated should cooperate fully with the investigation of the competent authority of the importing country. If the certificate is found to be fraudulent, every effort should be made by the competent authorities to identify those responsible so that appropriate action can be taken according to national/regional law.

47. The product relating to fraudulent certificates should be considered to be in violation of the importing country's requirements since the precise condition of the product is unknown. Destruction of the product is one of the measures that can be implemented since destruction is a strong deterrent to future fraudulent activity.

48. Competent authorities in importing countries should maintain current records of certificates from certifying bodies in pertinent exporting countries, including, in relation to paper certificates, copies of official stamps and marks.

ANNEX

GENERIC MODEL OFFICIAL CERTIFICATE

Scope of the Annex

This Annex is intended to provide additional guidance to competent authorities based on the principles set out in Section 4 and elaborating on the information provided in Sections 8 and 9. When model official certificates for specific purposes are otherwise established by Codex Alimentarius, countries should refer to such guidelines.

Although certificates are primarily focused on sanitary aspects, they may also address aspects relating to fair practices in the food trade where these matters are certified by the certifying bodies.

This model certificate could cover multiple products in a single certificate.

Explanatory notes on the generic model for an official certificate

General:

The certificate should be completed in a legible manner.

If the consignee, point of entry, or transport details change after the certificate has been issued, it is the responsibility of the importer to advise the competent authority of the importing country. Such a change should not result in a request for a replacement certificate to be issued.

The model certificate as it appears includes numbers designed to facilitate establishing a link between a particular section and the corresponding explanatory note. It is not intended that these numbers appear in the actual certificates issued by the certifying body.

Specific:

Certificate type: the certificate should be marked with "ORIGINAL", "COPY" or "REPLACEMENT" as appropriate.

Country: name of the country that issues the certificate possibly accompanied by a logo or a letter head. The objective is to clearly identify the country having the responsibility of issuing the certificate.

1. **Consignor/Exporter**: name and address (street, town and region/province/state, as applicable) of the natural or legal person or entity who sends the consignment.
2. **Certificate number**: this identification number should be unique for each certificate and authorized by the competent authority of the exporting country. For multiple page certificates, see paragraph 38 of document CAC/GL 38-2001.
3. **Competent Authority**: name of the Competent Authority of the country responsible for certification.
4. **Certifying Body**: name of the Certifying Body when it is different from the Competent Authority.
5. **Consignee/Importer**: name and address of the natural or legal person or entity to whom the consignment is shipped in the country of destination, at the time the certificate is issued.
6. **Country of origin**[10]: name of the country in which the products were produced, manufactured or packaged.
7. **Country of destination**[10]: name of the country of destination of the products.
8. **Place of loading**: name of a seaport, airport, freight terminal, rail station or other place at which goods are loaded onto the means of transport being used for their carriage.
9. **Means of transport**: air/ship/rail/road/other, as appropriate and the identification (name or number) of these if available, or relevant documentary references.
10. **Declared point of entry**: if required and available the name of the point of entry authorised by the competent authority of the importing country and, its UN/LOCODE (refer to the United Nations Code for Trade and Transport Locations).
11. **Conditions for transport/storage**: appropriate temperature category (ambient, chilled, frozen) or other requirements (e.g. humidity) for transport/storage of the product.
12. **Total quantity**: in appropriate units of weight or volume for the whole consignment.
13. **Identification of container(s)/Seal number(s)**: identify the containers and seal numbers where applicable or if known.
14. **Total number of packages**: total number of packages for all products in the consignment.
15. **Identification of food product(s)**: give the descriptive information specific to the product or products to be certified.

[10] **ISO Code**: the two letter country codes, in compliance with the international standard (ISO 3166 alpha-2), could be used.

Where appropriate: nature of the food (or description of the commodity), commodity code (HS code), species, intended purpose, producer/manufacturer, approval number of establishments (slaughterhouse, production plant, store (cold store or not)), region or compartment of origin, name of the product, lot identifier, type of packaging, number of packages, net weight per type of product.

- **Nature of the food (or description of product)**: description of the product(s) precise enough to allow the product(s) to be classified in the World Customs Organisation's Harmonised System, including the commodity code (HS code) where appropriate
- **Intended purpose (or Food products certified for)**: the end use of the product should be specified in the certificate (e.g. direct human consumption, further processing, and trade samples).
  Where a certificate for trade samples is required, a consignment consisting of a food sample intended for evaluation, testing or research, in the importing country may be described using a term such as "trade samples". It should be clearly indicated on the certificate or the package that the sample is not intended for retail sale and has no commercial value.
- **Region or compartment of origin**: if applicable: This is only for products affected by regionalisation measures or by the setting up of approved zones or compartments.
- **Type of packaging**: identify the type of packaging of products as defined in Recommendation No. 21 of UN/CEFACT (United Nation Centre for Trade Facilitation and Electronic Business).

16. Attestations: information indicating compliance with the relevant regulation(s) of the importing or exporting countries in accordance with the recommendations, as appropriate, of the Codex Alimentarius Commission.

Attestations should be the minimum required for the products certified to ensure food safety and fair practices in the food trade. Attestations should be applicable to the food products certified.

Non-applicable attestations should be excluded or deleted.

There may be other attestations covering different issues (cf. paragraph 7 of document CAC/GL 38-2001).

17. **Certifying officer**: name, official position, official stamp (optional), date of signature and signature.

    Certificates should be issued in accordance with section 9 of document CAC/GL 38-2001.

LOGO/LETTERHEAD

GENERIC MODEL OFFICIAL CERTIFICATE

COUNTRY: **CERTIFICATE TYPE**

1. Consignor/Exporter:	2. Certificate number:
	3. Competent authority:
	4. Certifying body:
5. Consignee/Importer:	
6. Country of origin:	ISO Code:
7. Country of destination:	ISO Code:
8. Place of loading:	
9. Means of transport:	10. Declared point of entry:
11. Conditions for transport/storage:	12. Total quantity*
13. Identification of container(s)/Seal number(s):	14. Total number of packages:

15. Identification of food products as described below (multiple lines may be used for multiple products)

No.	Nature of the food, commodity code (HS code) where appropriate	Species*	Intended purpose

No.	Producer/Manufacturer	Approval number of establishments*	Region or compartment of origin

No.	Name of the product	Lot Identifier*	Type of packaging	Number of packages	Net weight

16. Attestations:

17. Certifying officer:

Name: Official position:

Date: Signature:

Official Stamp:

The Generic Model Official Certificate should be read in conjunction with the explanatory notes.

* If required

PRINCIPLES AND GUIDELINES FOR THE EXCHANGE OF INFORMATION IN FOOD SAFETY EMERGENCY SITUATIONS

CAC/GL 19-1995

SECTION 1 – PREAMBLE

1. When a food safety emergency arises, in order to minimize potential adverse public health effects, it is essential to communicate the nature and extent of the food safety problem to all relevant parties as expeditiously as possible. This must be done in a manner that avoids unwarranted action against other foods from the same or other countries, which are not involved in the emergency situation. The global nature of food trade requires that this communication occur between nations at the appropriate government level.

2. This document provides guidance for use by national governments and regional economic integration organisations for the exchange of information in food safety emergency situations.

SECTION 2 – SCOPE

3. These Principles and Guidelines apply to situations where the competent authorities in either the importing and/or exporting countries become aware of a food safety emergency situation, and communication of the information and risks surrounding the emergency situation must be undertaken.

4. The Principles and Guidelines apply to situations where the food safety hazard (e.g., a microbiological, chemical, radiological or physical agent) has been specifically identified. It may also apply to situations where the food safety hazard has not been identified, but relevant scientific information suggests a link between consumption of a food and the appearance of serious health effects.

5. The Principles and Guidelines apply to food safety emergencies associated with imported or exported food or food that may potentially be imported or exported. The Principles and Guidelines may also apply to such emergencies where feeding stuffs for food producing animals are implicated.[1]

[1] Provisions for emergency situations affecting animal feed are included in the *Code of Practice for Good Animal Feeding* (CAC/RCP 54-2004): Section 4.3.1 "Special conditions applicable to emergency situations".

Adopted 1995. Revisions 2004.

6. The Principles and Guidelines do not apply to routine food rejections where importing country standards have not been met. These situations are covered in the *Guidelines for the Exchange of Information between Countries on Rejections of Imported Food* (CAC/GL 25-1997).

SECTION 3 – DEFINITIONS

Food Safety Emergency: A situation whether accidental or intentional, that is identified, by a competent authority as constituting a serious and as yet uncontrolled foodborne risk to public health that requires urgent action.

SECTION 4 – PRINCIPLES

7. In the event that a food safety emergency is identified, the following principles apply to the exchange of information:

a) Its nature and extent should, where possible, be clearly and completely described by the relevant competent authorities.
b) The exchange of information on food safety emergencies should be between official contact points designated by the competent authorities.
c) A country detecting a food safety emergency situation, whether it is an importing or an exporting country, should inform all known affected and potentially affected countries without delay.
d) All relevant information should be shared by competent authorities detecting a food safety emergency to enable all affected and potentially affected countries to make informed risk management and/or risk communication decisions.
e) Competent authorities should also provide clear, relevant, factual and timely information to relevant stakeholders to the extent possible.
f) Information flow should be transparent and continue during all phases of the food emergency situation to enable continuous evaluation and development of the emergency response.

SECTION 5 – NATURE OF THE FOOD SAFETY EMERGENCY

8. The nature of the food safety emergency including its scientific basis as it becomes available should be described in a clear, concise and accurate manner. Even in circumstances where the specific food safety hazard has not been precisely identified any clear and substantial association between the consumption of a food and the appearance of serious adverse public health effects should be provided by the competent authority in accordance with the principles outlined in paragraph 8.

9. In cases where the food safety hazard is associated with a specific food or foods, these foods should be identified in as much detail as is available to facilitate the identification and location of the affected foods. In other cases, where a food safety hazard affects many different categories of foods and potentially involves a given geographical area, all affected foods should be identified.

SECTION 6 – DESIGNATED OFFICIAL CONTACT POINTS FOR INFORMATION EXCHANGE

10. Each country should designate a primary official contact point for food safety emergency situations, which can act as the national focal point for information exchange in such situations. A list of the primary official contact points for the exchange of information in food safety emergency situations as mentioned in point 8.b is available and an update is distributed to governments on a periodic basis. It is the responsibility of all countries to ensure that they regularly provide updated information on their country primary official contact points to the World Health Organization (WHO) so that the list of contacts can be kept up-to-date. Although the primary official contact point is the first contact, it is understood that in a given food safety emergency national governments may wish to designate a specific contact point for that emergency.

11. The designated contact points for the competent authorities responsible for coordinating the response to the food safety emergency should be clearly identified. Necessary information includes the name of the competent authority and the contact details including name, address, phone numbers, facsimile numbers, and email addresses of the persons or offices that are responsible for managing the emergency situation and who can provide further details about the hazard, the foods concerned, actions taken and other relevant information. A website address should also be provided if this is used to provide up-to-date information.

SECTION 7 – INFORMING ALL KNOWN AFFECTED AND POTENTIALLY AFFECTED COUNTRIES

12. Given the global nature of food trade, the impact of a food safety emergency may be widespread. The competent authority of the country where the food safety emergency is identified should, to the best of its ability and in cooperation with other competent authorities, determine all potential recipient countries of the implicated food(s) and all countries from which the potentially contaminated food or its ingredients was imported. All relevant information in relation to the

food safety emergency should be provided to the competent authorities of the countries thus identified.

13. Communication should be made by the most expedient means, as early as possible, and with verification of receipt by key parties. Communications by telephone, email, facsimile and if necessary regular mail should all be considered to achieve early communication and to ensure that the message is received by the competent authorities as quickly as possible.

14. It is recognised that the initial information provided may often be incomplete and it is therefore the responsibility of the country identifying the food emergency to ensure that the initial communication is supplemented by further notification(s), as and when more detailed information becomes available.

15. It is recognized that the nature and the extent of the information disclosure to each competent authority will be as determined to be permissible by the disclosing competent authority according to its national law.

SECTION 8 – INFORMATION TO BE EXCHANGED

16. Competent authorities should exchange with all known affected and potentially affected countries the following information, as relevant upon identification of a food safety emergency.

a) the nature of the food safety emergency including the hazards and risks identified, the methodology used and any assumptions made;
b) detailed identification of the food or foods concerned including product markings, certificate information;
c) affected and potentially affected populations group(s);
d) shipping and related information, e.g. the name and contact information for the exporter, importer, consignee and shippers;
e) action taken to reduce or eliminate the hazard;
f) full details of the designated official contact point and the relevant competent authority.

17. The communication regarding the nature and extent of a food safety emergency should include relevant scientific substantiation and assessment of risk as they become available, including how international standards have been taken into account.

18. A standard format for the relevant information to be exchanged is recommended for use by both the importing and exporting countries. A model standard format for information exchange in food safety emergency situations is

provided in the Annex. Where alternative formats are used, care should be taken to ensure that all the relevant information is included and is clearly presented.

SECTION 9 – ROLE OF COMPETENT AUTHORITY

19. Upon identification of a food safety emergency, the competent authority identifying the emergency should promptly communicate with and consult the appropriate competent authority/ies of other affected or potentially affected country/ies. The competent authorities responsible for coordinating the response should update countries receiving the affected food of action taken, as appropriate. The accuracy and veracity of the scientific and other information regarding a food safety emergency should be verified to assist in taking risk assessment, risk management and risk communication decisions. Any misinformation should be promptly corrected by competent authorities.

20. It is also essential that all other relevant parties be kept informed, as appropriate, of the nature and status of the food safety emergency. Competent authorities should therefore provide clear, relevant, factual and timely information to their industry, consumers, other stakeholders and the media on the status of the food safety emergency.

SECTION 10 – INFORMATION FLOW

21. Communications between exporting and importing countries should be transparent and continue through all phases of the emergency situation, from initial notification of the food safety problem including, whenever possible, details of any relevant risk assessments that have been used through to notification of the resolution of the problem. This will enable countries to re-assess their risk assessment, risk management and risk communication strategies as the situation changes.

SECTION 11 – OTHER CONSIDERATIONS FOR INFORMATION EXCHANGE

Level of food distribution

22. In deciding on the appropriate communication measures to apply, the competent authorities should consider the quantity of food that is involved, the extent of its distribution and the level (e.g. wholesale, retail) at which it has been distributed. In some cases, the affected food may not yet have entered the importing country and communication will focus on the importers. However, in other cases the food will have entered and been distributed within the country or transhipped to other countries. The competent authority should take account of whether the food has been, or is likely to have been, distributed at the wholesale,

retail or consumer level, and implement risk management and communication measures accordingly, including a notice of recall at one or more of these levels of food distribution.

Re-export of food subject to an emergency situation

23. Food that is refused entry into a country, or in some cases food that is recalled after entry, should be dealt with in accordance with *Guidelines for the Exchange of Information between Countries on Rejection of Imported Food* (CAC/GL 25-1997) and taking into account the *Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions* (CAC/RCP 20-1979).

Food Safety Emergency Plan

24. Importing and exporting countries should develop a food safety emergency plan that would indicate the procedures to be followed in the case of a food safety emergency[2]. The plan should contain specific provision relating to the exchange of information including keeping their public informed, as appropriate, of food safety emergency.

Role of FAO and WHO

25. Although the information exchange components of these guidelines are primarily intended for use between the competent authorities of the importing and exporting countries, copies or summaries of relevant information regarding the emergency should be provided to FAO, WHO or other international organizations on request. In these situations, the FAO and WHO may be able to offer technical advice and assistance to one or more of the affected countries or countries yet to be affected.

[2] e.g. Guidelines for Strengthening National Food Control Systems (FAO/WHO); "Terrorist Threat to Food" (WHO).

ANNEX

STANDARD FORMAT FOR INFORMATION EXCHANGE IN FOOD SAFETY EMERGENCY SITUATIONS

The following constitutes the information that should be exchanged between competent authorities of both exporting and importing countries involved in a food safety emergency. A food safety emergency is a situation whether accidental or intentional, that is identified by a competent authority, as constituting a serious and as yet uncontrolled foodborne risk to public health that requires urgent action.

1. Nature of the food safety emergency

The nature of the food safety hazard causing the food safety emergency should be described, and may include the following:

- biological/microbiological contamination (specify organism or toxin of concern);
- chemical contamination (e.g. pesticides, drugs, industrial chemicals, environmental contaminants);
- physical contamination (e.g. foreign bodies);
- radionuclide contamination (specify radionuclide(s) of concern);
- undeclared allergen (the allergen should be explicitly named);
- other identified hazards (e.g. inherent chemicals in foods or produced through processing, processing/packaging faults);
- unknown agent (specify serious adverse health effects associated with consumption of specified foods).

In each of the above cases the specific food safety hazard and its level or prevalence based on available information and, as appropriate, the sampling and methods of analysis used, and any assumptions made should be notified.

2. Identification of foods concerned

The foods concerned should be described completely. The following information should be provided if available, as appropriate to the product:

- description and quantity of product(s) including brand, the name(s) of the product listed on the label, grade, preservation method (e.g. chilled or frozen) and shelf life;
- type and size of package(s);
- lot identification, including lot code, dates of production and processing, and identification of premises where last packed or processed;

- other identification marks/stamps (e.g. bar codes, UPC codes);
- name and address of producer, manufacturer, packer, seller, exporter or importer as appropriate;
- pictorial image;
- export certificate(s) reference number(s), official name and mark.

An indication of the countries to which the product has been exported should also be provided, as soon as it is known, to enable countries to quickly identify whether they are likely to be affected, and to help locate the affected foods.

3. Affected or potentially affected population group(s)

Food safety emergency situations may predominantly affect certain segments of a population, e.g. children, pregnant women, immune compromised persons or the elderly. In such instances, this information should be communicated.

The nature and extent of any adverse health effects associated with a food safety emergency should be described, e.g. incubation period, severity, other epidemiological data.

4. Shipping and related information

Information on the following should be provided:

- exporter name and contact information;
- importer name and contact information;
- container and shipping details, including port of origin and destination;
- consignee(s) and shipper(s) and contact information.

5. Action taken by exporting or importing country

Information on action taken, such as:

- measures taken to identify and prevent the sale and export of the food;
- measures taken to recall food from markets including whether these recalls are voluntary or mandatory;
- measures taken to prevent further problems;
- measures taken to reduce the risk by appropriate physical treatment;
- methods of diagnosis and treatment of affected persons;
- measures taken regarding final disposition (e.g. destruction of the food).

6. Details of the designated official contact point and of the relevant competent authority

Full contact details including: the name of the competent authority, address, telephone, email address and facsimile numbers of persons or offices that can supply further information that may be sought by affected or potentially affected

countries to assist in the management of the food safety emergency. A website address should be used where available to provide up-to-date information.

GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD

CAC/GL 25-1997[1]

SECTION 1 – PREAMBLE

1. The following guidelines provide the basis for structured information exchange on import rejections. The most important information elements to be considered in such guidelines are shown in the Annex and each category is discussed in more detail below. The guidelines are intended to cover all types of food.

2. These guidelines deal only with import rejections caused by failure to comply with importing country requirements. Information exchange in food control emergency situations is dealt with in the Guidelines for the Exchange of Information in Food Control Emergency Situations (CAC/GL 19-1995).

3. The use of these Guidelines for the Exchange of Information on Rejections of Imported Food is intended to assist countries to conform with the Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995), in particular the transparency provisions contained in paragraph 14 of the Principles.

SECTION 2 – GENERAL CONSIDERATIONS

4. When the food control authorities in an importing country reject a consignment of food presented for importation they should always provide information to the importer of the consignment giving the reasons for the rejection. Appropriate information should also be provided to the exporter if the control authorities receive such a request.

5. When the rejection of the consignment arises from:
- evidence of a serious food safety or public health problem in the exporting country; or
- evidence of serious misrepresentation or consumer fraud; or
- evidence of a serious failure in the inspection or control system in the exporting country.

[1] Governments and organizations interested in receiving a List of Contacts for Food Import Control and Information Exchange in Food Control Emergency Situations should contact the Codex Contact Point for Australia, Australian Quarantine and Inspection Service, GPO Box 858, Canberra, ACT, 2601, AUSTRALIA. Telefax: 61-6-272-3103.

The food control authorities in the importing country should notify the food control authorities in the exporting country forthwith (by telecommunication or other similar rapid means of communication) supplying the details set out in the Annex to these Guidelines.

6. Upon receipt of such a communication, the food control authorities in the exporting country should undertake the necessary investigation to determine the cause of any problem that has led to the rejection of the consignment. The food control authority in the exporting country, if requested, should provide the authorities in the importing country with information on the outcome of the necessary investigation, if available. Bilateral discussions should take place as necessary.

7. In other circumstances, for example:
- where there is evidence of repeated failures of a correctable nature (e.g. labelling errors, mislaying of documents); or
- where there is evidence of systematic failures in handling, storage or transport subsequent to inspection/certification by the authorities in the exporting countries.

The food control authorities in the importing country should also make appropriate notification to the food control authorities in the exporting country, either periodically or upon request.

8. It is also open to an importing country to supply information on rejections to an exporting country even when this is not specified in these guidelines.

9. In some countries information about the results obtained in public food control is freely available, whereas in others legal constraints may prevent or restrict the dissemination to third parties of information on, for example, import rejections. In some cases information cannot be exchanged before a certain time has elapsed. So far as possible countries should minimise restrictions on the disclosure to other countries of information on rejected foods.

10. To enable FAO and WHO to assist exporting countries in their efforts to meet the requirements of importing countries, information on rejections of imported food should be made available to FAO and WHO on request.

SECTION 3 – DETAILED INFORMATION

Identification of the food concerned

11. A certain amount of basic information is required in order to be able to identify the consignment or lot of food that has been refused entry when presented for importation. The most important information in this respect is a description of the nature and quantity of the food, any lot identification or other identification stamps, marks or numbers and the name and address of the exporter and/or food producer or manufacturer. Information about importers or sellers is also useful. Where a lot has been certified, the certificate number can provide an important method of identification.

Importation details

12. Information about importation or presentation for importation is necessary. The most important elements here are: place and date of entry, and the identity and contact details of the importer.

Rejection decision

13. It is important to obtain information about the decision to refuse importation, especially the name of the food control authority which made the decision, when the decision was made and whether the whole or only part of the consignment was refused entry.

Reasons for rejection

14. The reason(s) why a consignment of food has been refused entry should be clearly stated and reference should be made to the regulations or standards which have been contravened.

15. Foods may be rejected because they are found to be unacceptable when subjected to an organoleptic examination or because they have technical/physical defects, e.g. leaking cans, broken seals and damaged boxes. In circumstances where physical examination has led to rejection, a clear description of the criteria used should be provided.

16. When the level of a contaminant in a food has been found to be above the maximum permitted level, the contaminant should be specified, together with the level found and the maximum permitted level. In the case of biological contamination or contamination by biological toxins, where no maximum level has been fixed, the identity of the organism or toxin concerned should be given as specifically as possible, and as appropriate, the level of contamination found. Similarly, contraventions of regulations on food additive or compositional

standards should be specified. Some countries accept certain foods (e.g. fresh meat) only from specifically approved establishments in the exporting country. If such foods are refused entry because evidence that they come from such an establishment is lacking or incomplete, this should be stated.

17. Where consignments of imported food are rejected on the basis of analysis performed in the importing country, the importing country authority should make available upon request details of the sampling and analytical methods employed and the results obtained.

Action taken

18. Information should be supplied about the action taken following the rejection or retention of a consignment of food. This should include information about the fate of the consignment, such as whether it was destroyed or detained for reconditioning.

19. If the rejected food is re-exported, the conditions attached to such re-export should be stated. For example, some countries permit re-export only to the country of origin or to countries which have stated in advance that they are prepared to accept the consignment knowing that it has been refused entry elsewhere.

20. In addition to the exchange of information between the food control authorities of exporting and importing countries it may also be valuable to inform the embassy or other representative body of the exporting country of the situation so that the country concerned can take action to rectify the deficiencies found and thus avoid rejection of future shipments.

ANNEX

STANDARD FORMAT FOR EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD

The following information should be provided by countries in relation to rejections of imported food as available and appropriate to the circumstances.

Identification of the food concerned

- Description and quantity of product
- Type and size of package
- Lot identification (number, production date, etc.)
- Container number, bill of loading or similar transportation details
- Other identification stamps, marks or numbers
- Certificate number
- Name and address of manufacturer, producer, seller and/or exporter, establishment number, as appropriate

Importation details

- Port or other point of entry
- Name and address of importer
- Date presented for entry

Details of rejection decision

- Whole/part of (specify) consignment rejected
- Name and address of food control authority making decision to reject
- Date of decision
- Name and address of food control authority which can provide more information on reason for rejection

Reason(s) for rejection

- Biological/microbiological contamination
- Chemical contamination (pesticide or veterinary drug residues, heavy metals, etc.)
- Radionuclide contamination
- Incorrect or misleading labelling
- Compositional defect
- Non-conformity with food additive requirements
- Organoleptic quality unacceptable
- Technical or physical defects (e.g., packaging damage)
- Incomplete or incorrect certification

- Does not come from an approved country, region or establishment
- Other reasons

Note: Where imported food has been rejected on the basis of sampling and/or analysis in the importing country, details should be made available on request as to sampling and analytical methods and test results and the identity of the testing laboratory.

Action taken

- Food destroyed
- Food held pending reconditioning/rectification of deficiencies in documentation
- Food held pending final judgement
- Place where food is held
- Import granted for use other than human consumption
- Re-export granted under certain conditions, e.g. to specified informed countries
- Importer notified
- Embassy/food control authorities of exporting country notified
- Authorities in other likely destination countries notified
- Other

PRINCIPLES FOR TRACEABILITY/PRODUCT TRACING AS A TOOL WITHIN A FOOD INSPECTION AND CERTIFICATION SYSTEM

CAC/GL 60-2006

SECTION 1 – SCOPE

1. This document elaborates a set of principles to assist competent authorities in utilising traceability/product tracing as a tool within their food inspection and certification system. This document should be read in conjunction with all relevant Codex texts as well as those adopted by IPPC and OIE where appropriate.

2. Recognizing the dual mandate of the Codex Alimentarius, traceability/product tracing is a tool that may be applied, when and as appropriate, within a food inspection and certification system in order to contribute to the protection of consumers against food-borne hazards and deceptive marketing practices and the facilitation of trade on the basis of accurate product description.[1]

SECTION 2 – DEFINITIONS

Inspection[2]***:*** 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.

Certification[2]***:*** 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[3]***:*** is the capability of different inspection and certification systems to meet the same objectives.

Traceability/product tracing[4]***:*** the ability to follow the movement of a food through specified stage(s) of production, processing and distribution.

[1] Codex Principles for Food Import and Export Inspection and Certification (CAC/GL 20 – 1995).
[2] Codex Principles for Food Import and Export Inspection and Certification (CAC/GL 20 – 1995).
[3] Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems. (CAC/GL 26 – 1997).
[4] Codex Procedural Manual.

SECTION 3 – PRINCIPLES

3. These principles cover the context, rationale, design and application of traceability/product tracing as a tool for use by a competent authority within a food inspection and certification system.

Context

4. Traceability/product tracing, as defined above, is one of a number of tools that may be utilised by a competent authority within its food inspection and certification system.

5. An importing country should consider that a food inspection and certification system without a traceability/product tracing tool may meet the same objective and produce the same outcomes (e.g. regarding food safety, provide the same level of protection) as a food inspection and certification system with traceability/product tracing[5].

6. It should not be mandatory for an exporting country to replicate (i.e. establish the same) the traceability/product tracing tool as used by the importing country, when applicable.

Rationale

7. The application of a traceability/product tracing tool by a competent authority should improve the effectiveness and/or efficiency of the actions that may be necessary regarding its measures or requirements within its food inspection and certification system.

8. Traceability/product tracing is a tool that when applied in a food safety context does not in itself improve food safety outcomes unless it is combined with appropriate measures and requirements. It can contribute to the effectiveness and/or efficiency of associated food safety measures[6].

9. Traceability/product tracing is a tool that when applied in a food inspection and certification system can contribute to the protection of consumers against

[5] Codex Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999); Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003).

[6] For example, by providing information on suppliers or customers involved in potential food safety issues so enabling targeted product recall/withdrawal.

deceptive marketing practices and facilitation of trade on the basis of accurate product description[7].

10. In every case a traceability/product tracing tool should be justified within the context of the food inspection and certification system and the purpose, objectives and specifications of the traceability/product tracing tool clearly described. The scope and extent of application of the tool should also be consistent with the described need.

Design

11. The traceability/product tracing tool may apply to all or specified stages of the food chain (from production[8] to distribution), as appropriate to the objectives of the food inspection and certification system.

12. The traceability/product tracing tool should be able to identify at any specified stage of the food chain (from production to distribution) from where the food came (one step back) and to where the food went (one step forward), as appropriate to the objectives of the food inspection and certification system.

13. The objectives, scope and related procedures of a food inspection and certification system that includes a traceability/product tracing tool should be transparent and made available to competent authorities of the exporting country upon request.

Application

14. The application of traceability/product tracing should take into account the capabilities of developing countries.

15. If in the context of a traceability/product tracing tool an importing country has objectives or outcomes of their food inspection and certification system which cannot be met by an exporting country, the importing country should consider the provision of assistance to the exporting country, and especially in the case of a developing country. Assistance may include longer time frames for

[7] For example, by reinforcing confidence in the authenticity of the product and the accuracy of information provided on the products (e.g. country of origin, organic farming, religious concerns such as kosher or halal).

[8] Production could be interpreted in such a broad manner as to cover food producing animals, feed, fertilizers, pesticides, veterinary drugs and any input of plant or animal origin, etc. if relevant for specific applications of traceability/product tracing to food.

implementation, flexibility of design and technical assistance, so that the objectives or outcomes of the food inspection and certification system of the importing country can be met.

16. A food inspection and certification system within which a traceability/product tracing tool is applied should not be more trade restrictive than necessary.

17. The application of the traceability/product tracing tool should be practical, technically feasible and economically viable within a food inspection and certification system.

18. In deciding whether and how to apply the traceability/product tracing tool, in the context of a food inspection and certification system the competent authority should take account of the assessed food safety risks and/or the characteristics of the potential deceptive marketing practices being addressed.

19. Traceability/product tracing tool within the context of a food inspection and certification system should be implemented when and as appropriate on a case by case basis.

Food import and export inspection and certification systems

Fifth edition

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ISBN 978-92-5-107077-2 ISSN 0259-2916

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I2483E/1/11.11