WORLD TRADE ORGANIZATION

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Committee on Sanitary and Phytosanitary Measures

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RELEVANT CODEX DOCUMENTS ON EQUIVALENCE OF SANITARY MEASURES

Information submitted by the Codex Alimentarius Commission (Codex)

At its June 2000 meeting, the Committee agreed that discussions on equivalence of sanitary and phytosanitary measures would continue at the next Committee meeting. The Chairman requested that the observer organizations provide any relevant information regarding their work on equivalence. Members will find attached information provided by the Codex Alimentarius Commission.

PREFACE

THE CODEX ALIMENTARIUS COMMISSION AND THE FAO/WHO FOOD STANDARDS PROGRAMME

The Codex Alimentarius Commission implements the Joint FAO/WHO Food Standards Programme, the purpose of which is to protect the health of consumers and to ensure fair practices in the food trade. The *Codex Alimentarius* (Latin, meaning Food Law or Code) is a collection of internationally adopted food standards presented in a uniform manner. It also includes provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures to assist in achieving the purposes of the Codex Alimentarius. The Commission has expressed the view that codes of practice might provide useful checklists of requirements for national food control or enforcement authorities. The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods, to assist in their harmonization and, in doing so, to facilitate international trade.

COMBINED TEXTS ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Following the FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade in March 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. A series of texts has been developed over the period 1993 to 1999. These are presented for the first time in a combined volume for the convenience of users. Further information on these texts, or any other aspect of the Codex Alimentarius Commission, may be obtained from:

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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 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.

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[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 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).

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]

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.

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[5] Codex Alimentarius Procedural Manual, Tenth Edition, 1997

[6] Hazard Analysis and Critical Control Point System and Guidelines for its Application, Annex to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1 -1969, Rev. 3, 1997).

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

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.

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 coordinated 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 control 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, agronomic 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.

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;

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

- 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 is 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: GUIDELINES ON PROCEDURES FOR CONDUCTING AN ASSESSMENT AND VERIFICATION BY AN IMPORTING COUNTRY OF INSPECTION AND CERTIFICATION SYSTEMS OF AN EXPORTING COUNTRY

1. INTRODUCTION

1.1 Assessment and verification should concentrate primarily on effectiveness of the inspection and certification system in operation in the exporting country rather than on specific commodities or establishments.

1.2 Assessment and verification may be conducted by officials of the importing country. The subject of assessment and verification may be an exporting country's inspection and certification infrastructure, or a specific inspection and certification regime applied to a single producer or group of producers.

2. PREPARATION

2.1 Those responsible for conducting the audit should prepare a plan that covers the following points:

- the subject, depth and scope of the audit and the standards or requirements against which the subject will be assessed;
- the date and place of the audit, along with a timetable up to and including the issue of the final report;
- the identity of the auditors including, if a team approach is used, the leader;
- the language(s) in which the audit will be conducted and the report issued;
- a schedule of meetings with officials and visits to establishments, as appropriate;
- confidentiality requirements.

2.2 This plan should be reviewed in advance with representatives of the country and, if necessary, the organization(s) being audited.

2.3 Where different authorities of an importing country have jurisdiction over different aspects of food control in the importing country, such authorities should coordinate their conduct of an audit in order to avoid any duplication of visits in the assessment of the exporting countries' inspection and certification infrastructure.

3. OPENING MEETING

An opening meeting should be held with representatives of the exporting country, including officials responsible for the inspection and certification programmes. At this meeting the auditor will be responsible for reviewing the audit plan and confirming that adequate resources, documentation, and any other necessary facilities are available for conducting the audit.

4. EXAMINATION

This may comprise both the examination of documentary material and an on-site verification.

4.1 Document Review

The document review may consist of a preliminary review of the national food inspection and certification system, with emphasis on the implementation of elements of the system of inspection and

certification for commodity(ies) of interest. Based upon this preliminary review, the auditors may examine inspection and certification files relevant to these commodities.

4.2 On-site Verification

4.2.1 The decision to proceed to this step should not be automatic but should be based upon a variety of factors such as risk assessment of the food commodity(ies), history of conformity with requirements by the industry sector or exporting country, volume of product produced and imported or exported, changes within a country's infrastructure, changes to the food inspection and certification systems, and training (theoretical and practical) of inspectors.

4.2.2 On-site verification may involve visits to manufacturing facilities and food handling or storage areas to check on compliance with the information contained in the documentary material referred to in 4.1.

4.3 Follow-up Audit

Where a follow-up audit is being conducted in order to verify the correction of deficiencies, it may be sufficient to examine only those points which have been found to require correction.

5. WORKING DOCUMENTS

Forms for reporting assessment findings and conclusions should be standardized as much as possible in order to make the approach to audit, reporting and assessment more uniform and efficient. The working documents also include any checklists of elements to evaluate. Such checklists may cover:

- legislation and policy;
- establishment structure and working procedures;
- the adequacy of inspection and sampling coverage and inspection standards;
- sampling plans and results;
- certification criteria;
- compliance action and procedures;
- reporting and complaint procedures;
- training of inspectors.

6. CLOSING MEETING

A closing meeting should be held with representatives of the exporting country, including officials responsible for the inspection and certification programmes. At this meeting the auditor will be responsible for presenting the findings of the audit as well as, where appropriate, an analysis of conformity. The information should be presented in a clear, concise manner so that the conclusions of the audit are clearly understood. If possible, an action plan for correction of any deficiencies should be agreed.

7. REPORT

The draft report of the audit should be forwarded to the appropriate authorities in both countries as soon as possible. It should include a report of the audit findings with supporting evidence for each conclusion, along with any details of significance discussed during the closing meeting. The final report should incorporate the comments by the appropriate authorities of the exporting country.

8. FREQUENCY OF AUDITING

The potential importing country shall decide the frequency of auditing in agreement with the exporting country. Factors to be taken into account include the findings of previous audits and the existence and effectiveness of self-audit systems or third party audit of the exporting country's control systems.

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.[10]

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.[10]

Certification system means official and officially recognized certification systems.

Equivalence is the capability of different inspection and certification systems to meet the same objectives.[11]

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.[10]

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.[10]

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.

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

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

SECTION 3 - PURPOSE OF AGREEMENTS

Countries[12] may wish to enter into agreements[13] concerning food import and export inspection and certification systems to:

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

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.

SECTION 4 – SCOPE AND TYPES OF AGREEMENTS

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.

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.

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.[14]

SECTION 5 - CONSIDERATIONS BEFORE ENTERING INTO BILATERAL OR MULTILATERAL DISCUSSIONS

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.

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.

[12] 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.

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

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

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

1. whether priority should be given to certain product categories because of the public health risks they pose;
2. 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;
3. whether the exporting country appears to have sufficient infrastructure and resources to maintain an appropriate control system;
4. whether the exporting country's products have a low rate of non-compliance with importing country requirements;
5. whether the exporting country recognizes and abides by the Codex Code of Ethics in International Trade in Food;
6. whether significant resources would be conserved as a result of the agreement.

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.[15]

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

The country initiating discussion towards an equivalence agreement should identify:

1. the type of equivalence agreement proposed;
2. the product(s) to be covered;
3. the competent authority or authorities for each product; and
4. the scope of requirements to be addressed by the agreement (e.g. health and safety, quality assurance systems, labeling, consumer fraud, etc.).

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

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.

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

SECTION 7 - CONSULTATIVE PROCESS FOR EQUIVALENCE AGREEMENTS

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

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

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.

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.

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

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

1. 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[16];
2. 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[17];
3. decision criteria and action[18];
4. facilities, equipment, transportation and communications as well as basic sanitation and water quality[19];
5. laboratories, including information on the evaluation and/or accreditation of laboratories, and evidence that they apply internationally accepted quality assurance techniques[20];
6. details of the exporting country's systems for assuring competent and qualified inspection[21] through appropriate training, certification, and authorization of inspection personnel; and the number and distribution of inspectors;
7. 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[22];
8. details of the structure and operation of any rapid alert systems in the exporting country.

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

[16] See paragraphs 20-23 in CAC/GL 26-1997.
[17] See paragraphs 24-29 in CAC/GL 26-1997.
[18] See paragraphs 30-37 in CAC/GL 26-1997.
[19] See paragraphs 38-40 in CAC/GL 26-1997.
[20] See paragraphs 41-42 in CAC/GL 26-1997.
[21] See paragraph 43 in CAC/GL 26-1997.
[22] See paragraphs 47 and 52-57 in CAC/GL 26-1997.

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

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.

Participants in the agreement should establish procedures to:

1. periodically audit and verify that equivalence continues to exist after conclusion of an equivalence agreement; and
2. resolve any problems identified during audit and verification.

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.

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.

Participants in the agreement should agree to procedures for information exchange in the event of a food emergency control situation.[23]

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.

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.

To enhance public confidence in the agreement while respecting legitimate concerns to retain confidentiality, the relevant competent authorities of the particular countries should[24] 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.[25]

SECTION 8 - PILOT STUDIES

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.

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

[24] The delegations of Singapore, Uruguay, Vietnam, Malaysia and Egypt reserved their position on use of the word "should".

[25] See paragraph 58 in CAC/GL 26-1997.

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

1. description and time frame of the trial program;
2. roles and capabilities of involved government and officially recognized private organizations;
3. procedures for inspection and certification;
4. audit procedures and frequency;
5. description of training or information needs.

SECTION 9 - DRAFTING THE AGREEMENT

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

SECTION 10 - IMPLEMENTING THE AGREEMENT

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).

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 : CONTENTS OF EQUIVALENCE AGREEMENTS

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

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

2. *Parties*: The names of the parties to the bilateral or multilateral agreement.

3. *Purpose:* A brief statement of the specific purpose of the agreement.

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

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

6. *Substantive Obligations:* A comprehensive description of each participant's obligations and specific responsibilities.

7. *Competent Authorities:* The title of each competent authority that will be responsible for the implementation of the agreement.

8. *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.

9. *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.

10. *Criteria for Certification:* When certificates are part of agreements to meet requirements, a list of the criteria, by attribute, that should be used by the competent authorities of the exporting and importing countries to determine if the product meets the importing country’s standards.

11. *Sample Collection:* A listing of references and sample procedures that the importing and/or exporting country will use for testing and/or certification.

12. *Analytical and Other Methodology:* A listing of the methods and equivalent procedures that the participating competent authorities will use to determine the compliance of product(s) covered by the agreement.

13. *Administrative Procedures:* Procedures and guidance for the practical implementation and application of the agreement.

14. *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.

15. *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.

16. *Notifications:* 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 public health effects related to traded products; and steps being taken to resolve such situations.

17. *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.

18. *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.)

19. *Entry into Force:* The date on which the provisions of the agreement enter into force.

20. *Review, modification and termination:* The methods for the review, modification and termination of the agreement.

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

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