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

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CAC/GL 26-1997

## SECTION I – OBJECTIVES

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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*.<sup>1</sup> They are intended to assist countries<sup>2</sup> in the application of requirements and the determination of equivalency, thereby protecting consumers and facilitating trade in foodstuffs.<sup>3</sup>
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

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**Audit** is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.<sup>4</sup>

**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

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

<sup>2</sup> 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.

<sup>3</sup> 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).

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

inspection, auditing of quality assurance systems, and examination of finished products.<sup>4</sup>

**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.<sup>4</sup>

**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.<sup>4</sup>

**Officially recognized inspection systems and officially recognized certification systems** are systems which have been formally approved or recognized by a government agency having jurisdiction.<sup>4</sup>

**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.<sup>4</sup>

**Risk analysis** is a process consisting of three components: risk assessment, risk management and risk communication.<sup>5</sup>

**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.<sup>5</sup>

**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.<sup>5</sup>

**Risk communication** is the interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties.<sup>5</sup>

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<sup>5</sup> Codex Alimentarius Procedural Manual.

### SECTION 3 – RISK ANALYSIS

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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<sup>6</sup> 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

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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<sup>7</sup> 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

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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.

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<sup>6</sup> 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).

<sup>7</sup> 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

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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.<sup>8</sup>

**Facilities, equipment, transportation and communications**

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

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<sup>8</sup> CAC/GL 25-1997.



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.<sup>9</sup>

### **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**

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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,

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

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

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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

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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

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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 I – INTRODUCTION

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1. An importing country may determine that it is necessary to assess an exporting country's official inspection and certification systems<sup>10</sup>. 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<sup>11</sup> 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

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<sup>10</sup> *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.

<sup>11</sup> 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

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4. This annex provides guidance for use by competent authorities of both importing and exporting countries to ensure an effective, efficient, transparent<sup>12</sup>, 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

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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.

### **Principles F and G cover assessment reporting**

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<sup>12</sup> CAC/GL 20 1995, paragraphs 13-16, and CAC/GL 26-1997, paragraph 58.

- 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

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##### **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<sup>13</sup> 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.

### **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:

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<sup>13</sup> 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.

- 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

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### **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.<sup>14</sup>

### **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.
- 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);

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<sup>14</sup> CAC/GL 20-1995 para 18.

- 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 be 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.