

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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**ALINORM 97/30**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX ALIMENTARIUS COMMISSION  
Twenty-second Session  
Geneva, 23 - 28 June 1997**

**REPORT OF THE FOURTH SESSION OF THE  
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND  
CERTIFICATION SYSTEMS  
*Sydney, Australia, 19-23 February 1996***

**NOTE:** This report includes Codex Circular Letter CL 1996/6 - FICS

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CX 4/70.2

CL 1996/6-FICS  
March 1996

**TO:** - Codex Contact Points  
- Interested International Organizations  
- Participants at the Fourth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems

**FROM:** Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy

**SUBJECT:** Distribution of the Report of the Fourth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems

The report of the fourth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) is attached. It will be considered by the Twenty-second Session of the Codex Alimentarius Commission in Geneva from 23 - 28 June 1997.

## MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION

1. **Draft Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food at Step 8; ALINORM 97/30, paras. 4 - 6 and Appendix 2.**

Governments wishing to propose amendments or to comment on the above matters should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 of the Procedure for the Elaboration of Codex Standards Including Consideration of Any Statements Relating to Economic Impact (*Codex Alimentarius Procedural Manual*, Ninth Edition, pages 33 - 35) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, **not later than 1 April 1997.**

2. **Proposed Draft Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems at Step 5; ALINORM 97/30, paras. 7 - 9 and Appendix 3.**

Governments wishing to submit comments regarding the implications which the proposed draft Guidelines or any provisions thereof may have for their economic interest should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (at Step 5) (*Codex Alimentarius Procedural Manual*, Ninth Edition, pages 27 - 29) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, **not later than 1 April 1996.**

## SUMMARY AND CONCLUSIONS

The fourth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems reached the following conclusions:

### **MATTERS FOR CONSIDERATION BY THE EXECUTIVE COMMITTEE AND/OR THE COMMISSION:**

- Agreed to advance the draft **Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food** to the Commission for adoption at Step 8 (para. 6);
- Agreed to advance the proposed draft **Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems** to the Executive Committee for adoption at Step 5 (para. 8);
- Agreed that the Australian Secretariat would prepare a discussion paper on the feasibility of developing Codex-wide guidelines and criteria with respect to a **Generic Format for Official Certificates** for consideration at its 5th Session (para. 24); and,
- Agreed that a discussion paper on **Guidelines on Food Import Control Systems** would be developed by the Codex Secretariat, in cooperation with Mexico, for consideration at its 5th Session (para. 31).

### **OTHER MATTERS OF INTEREST TO THE COMMISSION**

- Agreed that a revised version of the proposed draft **Guidelines on the Principal Elements in an Electronic Documentation System** would be prepared by Australia at Step 2, together with additional information, for circulation and comment at Step 3 (para. 13);
- Agreed that the proposed draft **Guidelines on the Application of the ISO 9000 Series to Food Inspection and Certification Systems** be revised under the direction of the Codex Secretariat at Step 2, in cooperation with France, for comment at Step 3 (paras.17 - 18);
- Agreed to return the proposed draft **Guidelines for the Development of Agreements Between Exporting and Importing Countries** for redrafting by the United States at Step 2, followed by circulation for comment at Step 3 (para. 20);
- Agreed to forward the proposed draft **Model Certificate for the Certification of Fish and Fishery Products** to the Codex Committee on Fish and Fishery Products for its consideration and further elaboration (para. 24);
- Decided to discuss the implications of deleting the phrase "**or risk of contamination**" from the **Principles for Food Import and Export Inspection and Certification** at its next Session (para. 26); and,
- Suggested that the Codex Secretariat should arrange for the further development of a document concerning **Development of Objective Criteria for Assessing the Competence of Testing Laboratories Involved in the Official Import and Export Control of Foods**, with the understanding that the Codex Committee on Methods of Analysis and Sampling would be responsible for its further elaboration (paras. 28 - 29).

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## **INTRODUCTION AND OPENING OF THE SESSION (Agenda Item 1)**

1. The Fourth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems was held in Sydney, Australia, at the kind invitation of the Government of Australia. Mr. Digby Gascoine, Australia Quarantine and Inspection Service, chaired the Session. The meeting was attended by 186 Delegates representing 42 Member nations of the Commission and by 19 persons representing 13 international observer organizations. The Session was opened by Mr. G.F. Taylor, Secretary, Commonwealth Department of Primary Industries and Energy, Canberra, Australia.

## **ADOPTION OF THE AGENDA (Agenda Item 2)<sup>1</sup>**

2. The Committee adopted the Provisional Agenda as proposed. It agreed that a number of matters referred by the Commission, the Codex Committee on Methods of Analysis and Sampling and the Codex Committee on Fish and Fisheries Products would be discussed under Other Business (see paras. 21-31).

## **MATTERS REFERRED FROM CODEX COMMITTEES (Agenda Item 3)<sup>2</sup>**

3. The Committee noted that the 21st Session of the Codex Alimentarius Commission approved the strategic approach for implementing the Medium - Term Plan<sup>3</sup>, and supported the project plans<sup>4</sup> submitted to it.

## **DRAFT GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD (Agenda Item 4)<sup>5</sup>**

4. The Committee agreed to revise the title "Scope" to read as "Preamble" in order to reflect the applicability of the general principles in this section to the Guidelines in their entirety. In view of the desire to keep consumers fully informed, a new paragraph was added to reflect the transparency provisions contained in the Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995).

5. Some delegations expressed their concern that the opening paragraph of the section on General Considerations concerning the provision of information to exporters on the reasons for rejection was overly detailed and onerous. The Committee, however, decided to leave the paragraph unchanged. The Committee also agreed to rearrange the section to indicate that notifications of rejection were applied differently depending on the seriousness of the reasons for rejection.

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1 CX/FICS 96/1

2 CX/FICS 96/2

3 ALINORM 95/37, paras. 9 - 12

4 ALINORM 95/6, Appendix II, relevant parts of which are reproduced in the Annex to CX/FICS 96/2.

5 CL 1995/36-FICS and comments from Argentina, Canada, Czech Republic, France, Republic of Korea, Latvia, Slovak Republic, Spain, Vietnam, United States of America (CX/FICS 96/3 Revised), Thailand (CRD 3) and Malaysia (CRD 4).

## Status of the Draft Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food

6. The Committee advanced the Guidelines to the Commission for adoption at Step 8. The draft Guidelines are attached to this report as Appendix 2.

### PROPOSED DRAFT GUIDELINES FOR THE DESIGN, OPERATION, ASSESSMENT AND ACCREDITATION OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (Agenda Item 5)<sup>6</sup>

7. The Committee endorsed the approach taken but made several changes to the document. The most significant points raised during the Committee's discussion were the following:

- It was noted that the Commission had requested comments on harmonized definitions for "risk analysis" and related terms<sup>7</sup> and that these definitions, once finalized would be applied uniformly to all relevant Codex texts. The definition for "risk assessment" contained in the **Principles for Food Import and Export Inspection and Certification** was retained in the interim. The delegation of the Netherlands reserved its opinion on the amendment made to the definition of "official accreditation".
- The previous section dealing with **Objectives** was deleted, but its essential statements were transferred to the relevant sections of the document to which they applied.
- It was agreed that controls on "labelling integrity" included controls on claims, including claims relating to religious requirements.
- A new section dealing with **Transparency** of all of the matters covered by the Guidelines was included and linked to the relevant provision of the **Principles for Food Import and Export Inspection and Certification**.
- It was agreed that the objectives of control systems covered all *requirements* as defined, including requirements intended to protect against potential fraud and deception and requirements to ensure fair practices in trade.
- It was suggested that greater emphasis should be given to control of requirements for equipment and technologies applied to the food production system, and to include reference to the approval or registration of establishments and products.
- Provisions were included for recognition by an importing country of inspection and certification being undertaken by sub-national authorities in an exporting country where such an arrangement was acceptable to all parties concerned.
- Concern was expressed at the perception that the issuance of certificates was encouraged by the guidelines and several changes were made to the text to stress alternative arrangements.

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<sup>6</sup> CX/FICS 96/4 and comments from Australia (CRD 2) and Malaysia (CRD 4).

<sup>7</sup> CL 1995/40-CAC.

- It was noted that several Codex Committees and organizations such as the OIE were working on and in some cases had already adopted procedures to ensure the authenticity and validation of certification, and it was recommended that the work of these bodies should be considered when the Draft Guidelines were to be reviewed at the Committee's next session.
- In relation to the inclusion of a paragraph to enable importers to have access to rejected or detained consignments, several delegations expressed concern at the practical implications of applying this provision.
- It was agreed to include in the Annex on *Procedures for Conducting an Assessment and Verification by an Importing Country of Inspection and Certification Systems of an Exporting Country* a paragraph to indicate that where food control in an importing country was carried out by more than one agency, procedures for the assessment and verification should be coordinated between these agencies. One delegation also proposed that there should be appropriate coordination between the relevant agencies of the exporting country.
- Concern was expressed about the procedures for preparing the report of the audit included in the annex on *Procedures for Conducting an Assessment and Verification by an Importing Country of Inspection and Certification Systems of an Exporting Country* with some delegations questioning whether the proposals were consistent with international standards of auditing.
- The Committee identified certain other issues arising from its consideration of the document which may require further attention. Among these was to give practical effect in a way which was balanced and open to all interested parties to establishment of a global mechanism for the exchange of information on problems of food moving in international trade.

### **Status of the Proposed Draft Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems**

8. The Committee advanced the revised text to Step 5 of the Codex procedure for consideration by the Executive Committee at its forty-third session. The complete text of the Guidelines is included as Appendix 3 to the present report.

9. The Committee expressed its appreciation to the delegation of Canada and the representatives of the European Community for their work in preparing the basic discussion document.

### **PROPOSED DRAFT GUIDELINES ON THE PRINCIPAL ELEMENTS IN AN ELECTRONIC DOCUMENTATION SYSTEM (Agenda Item 6)<sup>8</sup>**

10. Although several delegations supported the elaboration of a checklist or general recommendations on the use of electronic documentation systems, it was noted that specific guidelines for electronic documentation may have far reaching legally binding implications for governments in their application, especially in the context of the WTO Agreements. Some delegations also stated that their elaboration was premature and impractical given the current status of the technology and the limited experience with its application. The high costs associated with the use of electronic documentation in multilingual environments was also noted.

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<sup>8</sup> ALINORM 95/30A, Appendix V and comments from Thailand (CRD 3).

11. Other delegations noted that there was wide international interest in the elaboration of guidelines for a technology which was already being applied in many different disciplines and areas of the world. It was stated that the guidelines as currently drafted did not impose an obligation on governments to implement electronic documentation systems for certification. It was felt by some delegations that the elaboration of guidelines was an area in which Codex could take the lead in establishing parameters for what was thought to be a highly efficient and practical technology.

12. Several delegations proposed that the document should be elaborated in the form of an information document rather than as guidelines. The Committee agreed that the document should be revised to provide a factual presentation of elements required in the use of electronic documentation systems, and that all references to their mandatory application should be removed. It was also agreed that terms throughout the text would need to be defined and specific provisions would require harmonization with other principles established by the Committee. The recognition of other internationally-based electronic documentation systems and the various government agencies involved in electronic documentation were also highlighted. The importance of adequate system controls to ensure limited access and the authenticity, integrity, confidentiality and reliability of electronic documentation was stressed.

#### **Status of the Proposed Draft Guidelines on the Principal Elements in an Electronic Documentation System**

13. The Committee agreed that a revised draft of the Guidelines should be prepared by Australia at Step 2 in light of the above discussion for circulation, together with additional relevant information, for comment at Step 3.

#### **PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF THE ISO 9000 SERIES TO FOOD INSPECTION AND CERTIFICATION SYSTEMS (Agenda Item 7)<sup>9</sup>**

14. The Committee recalled that this matter had been discussed at its Second Session, when it had been decided to request the Delegation of France to prepare proposed draft Guidelines for consideration at the present session.<sup>10</sup>

15. The Committee welcomed the revised draft, especially the emphasis in the document on the fact that the use of the ISO 9000 standards by industry was entirely voluntary. It noted that the development of *Guideline Notes for the Application of ISO 9001 for the Food and Drink Industry* by ISO Technical Committee 34 was an exercise separate from but complementary to the present one. The proposed draft Guidelines under consideration by the CCFICS dealt exclusively with the interface between the application of ISO quality control systems by food businesses and official control systems. The Committee also noted that ISO Standards 9001, 9002 and 9003 dealt with contractual obligations between parties, whereas Standards 9000 and 9004 were more relevant to the field of quality assurance.

16. Several delegations raised concern that the paper dealt exclusively with the application of ISO standards in the field of quality systems. They drew attention to the fact that other quality assurance systems were also available which could be used by control authorities to enhance the efficacy of official control, inspection and certification systems, and the Guidelines should be generic in this regard. Some delegations referred to the Hazard Analysis/Critical Control Point (HACCP) system

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<sup>9</sup> CX/FICS 96/6 and comments from France (CX/FICS 96/6 - Add. 1), Thailand (CRD 3) and Malaysia (CRD 4).

<sup>10</sup> ALINORM 95/30A, paragraphs 84 - 89.



which they considered more appropriate to control food-borne hazards to consumer health. On this point, certain delegations drew attention to the compatibility of the HACCP System to the ISO Standards.

17. The Committee noted the need for taking structured quality assurance systems applied voluntarily by industry into account in the application of official food export and import inspection and certification systems, while at the same time not emphasizing or promoting any particular system. It requested the Codex Secretariat to consider all points made at the present session, and with the assistance of the Delegation of France and other interested parties, to revise the present document with the inclusion of additional information as necessary. The revised Guidelines would address the relationship between the use of ISO 9000 Standards and other quality assurance systems, and food safety assurance systems such as HACCP.

#### **Status of the Proposed Draft Guidelines on the Application of the ISO 9000 Series to Food Inspection and Certification Systems**

18. The Committee returned the Proposed Draft Guidelines for redrafting at Step 2, followed by circulation for comments at Step 3.

#### **PROPOSED DRAFT GUIDELINES FOR THE DEVELOPMENT OF AGREEMENTS BETWEEN EXPORTING AND IMPORTING COUNTRIES (Agenda Item 8)<sup>11</sup>**

19. The Committee welcomed the document prepared by the Delegation of the United States and approved its approach to the subject and its general content. The following main points were raised during discussion on the document:

- Several Delegations raised the question as to whether there should be a distinction between *Equivalence Agreements* and *Certification Agreements*. Opinions were expressed that a certification agreement was a particular case which could be dealt within an overall equivalence agreement. Other delegations proposed that the document should be more explicit in covering inspection agreements and agreements concerning requirements for the registration of establishments.
- The Committee agreed that provision should be made in the Guidelines for the dissemination of information under the agreements to industry and consumer and their representative organizations. It was also proposed that where possible provision should be made for public consideration at the national level prior to conclusion of agreements.
- The Committee agreed that agreements should include, as appropriate, reference to dispute settlement procedures and provisions for the administration of agreements.

#### **Status of the Proposed Draft Guidelines for the Development of Agreements Between Exporting and Importing Countries**

20. The Committee returned the proposed draft Guidelines for redrafting at Step 2 by the Delegation of the USA in light of this discussion, followed by circulation for comments at Step 3.

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<sup>11</sup> CX/FICS 96/7, CX/FICS 96/7 - Corrigendum, and comments from Thailand (CRD 3) and Malaysia (CRD 4).

## **OTHER BUSINESS AND FUTURE WORK (Agenda Item 9)**

### **Proposed Draft Model Certificate for the Certification of Fish and Fishery Products<sup>12</sup>**

21. The Delegation of Canada prepared and presented the paper in response to the request of the 21st Session of the Codex Committee on Fish and Fishery Products<sup>13</sup> to develop criteria with respect to official certificates for fish and fishery products with a view to their international harmonization. The CCFFP proposal was supported by the 3rd Session of CCFICS, although it was agreed that it would be more appropriate to provide general advice on the layout and formats of inspection certificates and for commodity committees to provide the technical details of such certificates.

22. Canada noted that the purpose of the paper was to describe the essential components of certificates as they relate to the certification of fish and fishery products, drawing upon the needs and requirements of both exporting and importing countries. The paper provided examples of origin, health and hygiene statements or attestation which might be useful for CCFFP in developing a model certificate.

23. The Committee noted that the paper was a suggested format for the consideration of CCFFP and that the certificate itself was not subject to endorsement by the CCFICS. The paper did not address issues of animal health as this matter was outside the mandate of Codex. It was noted that identical solutions for certification would probably not be possible for both farmed and wild fish.

24. The Committee decided to forward the document to the CCFFP for their consideration and further elaboration, with the understanding that the CCFICS should be fully informed of future developments. It was also agreed that the Australian Secretariat would prepare a discussion paper, in accordance with the terms of reference of the Committee, on the feasibility of developing Codex-wide guidelines and criteria with respect to the generic format and other aspects of official certificates for consideration at its next Session. The discussion paper would take into consideration the work of other international bodies relevant to the subject.

### **Matters Referred from the Codex Alimentarius Commission<sup>14</sup>**

25. In adopting the draft Principles for Food Import and Export Inspection and Certification, the Committee noted that the 21st Session of the Codex Alimentarius Commission had deleted the phrase "or risk of contamination" at the end of paragraph 9 of the Principles, and asked the CCFICS to give further consideration to the implications of this phrase.<sup>15</sup>

26. The Committee decided to discuss the implications of deleting this phrase at its next Session, bearing in mind that the recognition of contamination-free zones of production would be an important contribution to facilitation of trade.

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12 CX/FICS 96/8.

13 ALINORM 95/18, para. 7.

14 Conference Room Document 1.

15 ALINORM 95/37, para. 54.

## **Development of Objective Criteria for Assessing the Competence of Testing Laboratories Involved in the Official Import and Export Control of Foods<sup>16</sup>**

27. The Committee was informed that the 20th Session of the Codex Committee on Methods of Analysis and Sampling (CCMAS) had discussed the above subject on the basis of CX/MAS 95/4 and had decided that the paper be revised on the basis of comments and recommendations made at the Session. It was also agreed that the revised paper should be forwarded to the CCFICS for its consideration, review and comment<sup>17</sup>.

28. In considering the revised document (CX/FICS 96/9), the Committee suggested that the Codex Secretariat should arrange for its further development by incorporating concrete proposals in the form of Guidelines or Principles based on other international texts recognized by the Codex Alimentarius Commission. It was noted that the Guidelines or Principles should be consistent with and developed within themes established in corresponding CCFICS texts.

29. The Committee agreed with this procedure, on the understanding that the CCMAS would be responsible for further development of the paper. The Committee also agreed that the document should take account of other Codex texts in this regard (e.g., texts prepared by the Codex Committee on Residues of Veterinary Drugs in Foods).

### **Guidelines on Food Import Control Systems**

30. The Delegation of Mexico suggested that the Committee might wish to consider detailed Guidelines on Food Import Control Systems which would complement and not duplicate other initiatives undertaken by the Committee or other parties.

31. The Committee agreed that a discussion paper on this subject would be developed under the direction of the Codex Secretariat, in cooperation with Mexico, for consideration at its 5th Session, where a decision could be taken as to the possible future elaboration of Guidelines on Food Import Control Systems.

### **DATE AND PLACE OF NEXT SESSION (Agenda Item 10)**

32. The Committee was informed that its 5th Session would be held in Australia in approximately one year's time, with the date and place to be determined between the Codex and Australian Secretariats.

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<sup>16</sup> CX/FICS 96/9.

<sup>17</sup> ALINORM 97/23, para. 23.

**CODEX COMMITTEE ON FOOD IMPORT AND EXPORT CERTIFICATION  
AND INSPECTION SYSTEMS**

**CURRENT STATUS OF WORK**

<b>SUBJECT</b>	<b>STEP</b>	<b>FOR ACTION BY:</b>	<b>DOCUMENT REFERENCE</b>
Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food	8	22nd CAC	ALINORM 97/30, Appendix 2
Proposed Draft Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems	5	43rd CCEXEC Governments 5th CCFICS	ALINORM 97/30, Appendix 3
Proposed Draft Guidelines on the Principle Elements in an Electronic Documentation System	2/3	Australia Governments 5th CCFICS	ALINORM 97/30, paras. 10 - 13
Proposed Draft Guidelines on the Application of the ISO 9000 Series to Food Inspection and Certification Systems	2/3	CX Sect/FRA Governments 5th CCFICS	ALINORM 97/30, paras. 14 - 18
Proposed Draft Guidelines for the Development of Agreements Regarding Food Import and Export Inspection and Certification Systems	2/3	United States Governments 5th CCFICS	ALINORM 97/30 paras. 19 - 20
Guidelines and Criteria for a Generic Official Certificate Format	----	AUL Sect 5th CCFICS	ALINORM 97/30, para. 24
Implications of the phrase "or risk of contamination"	----	5th CCFICS	ALINORM 97/30, paras. 25 - 26
Guidelines on Food Import Control Systems	----	CX Sect/MEX 5th CCFICS	ALINORM 97/30, paras. 30 - 31

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**REVISED DRAFT GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN  
COUNTRIES ON REJECTIONS OF IMPORTED FOOD<sup>1</sup>**  
**(Advanced to Step 8 of the Procedure)**

**Preamble**

1. The following guidelines provide the basis for structured information exchange on import rejections. The most important information elements to be considered in such guidelines are shown in the Annex and each category is discussed in more detail below. The guidelines are intended to cover all types of food.
2. These guidelines deal only with import rejections caused by failure to comply with importing country requirements. Information exchange in food control emergency situations is dealt with in the Guidelines for the Exchange of Information in Food Control Emergency Situations (CAC/GL 19-1995)<sup>2</sup>.
3. The use of these Guidelines for the Exchange of Information on Rejections of Imported Food is intended to assist countries to conform with the Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995), in particular the transparency provisions contained in paragraph 14 of the Principles.

**General Considerations**

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

5. When the rejection of the consignment arises from

- evidence of a serious food safety or public health problem in the exporting country; or
- evidence of serious misrepresentation or consumer fraud; or
- evidence of a serious failure in the inspection or control system in the exporting country;

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

6. Upon receipt of such a communication, the food control authorities in the exporting country should undertake the necessary investigation to determine the cause of any problem that has led to the rejection of the consignment. The food control authority in the exporting country, if requested,

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

<sup>2</sup> Codex Alimentarius, Volume 1A, *General Requirements*, FAO/WHO, Rome, 1995.

should provide the authorities in the importing country with information on the outcome of the necessary investigation, if available. Bilateral discussions should take place as necessary.

7. In other circumstances, for example:

- where there is evidence of repeated failures of a correctable nature (eg labelling errors, mislaying of documents); or
- where there is evidence of systematic failures in handling, storage or transport subsequent to inspection/certification by the authorities in the exporting countries,

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

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

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

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

### **Detailed Information**

#### *Identification of the food concerned*

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

#### *Importation details*

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

#### *Rejection decision*

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

*Reasons for rejection*

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

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

16. When the level of a contaminant in a food has been found to be above the maximum permitted level, the contaminant should be specified, together with the level found and the maximum permitted level. In the case of biological contamination or contamination by biological toxins, where no maximum level has been fixed, the identity of the organism or toxin concerned should be given as specifically as possible, and as appropriate, the level of contamination found. Similarly, contraventions of regulations on food additive or compositional standards should be specified. Some countries accept certain foods (eg fresh meat) only from specifically approved establishments in the exporting country. If such foods are refused entry because evidence that they come from such an establishment is lacking or incomplete, this should be stated.

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

*Action taken*

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

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

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

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

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

Identification of the food concerned

Description and quantity of product

Type and size of package

Lot identification (number, production date, etc.)

Container number, bill of lading or similar transportation details

Other identification stamps, marks or numbers

Certificate number

Name and address of manufacturer, producer, seller and/or exporter, establishment number, as appropriate

Importation details

Port or other point of entry

Name and address of importer

Date presented for entry

Details of rejection decision

Whole/part of (specify) consignment rejected

Name and address of food control authority making decision to reject

Date of decision

Name and address of food control authority which can provide more information on reason for rejection

Reason(s) for rejection

Biological/microbiological contamination

Chemical contamination (pesticide or veterinary drug residues, heavy metals, etc.)

Radionuclide contamination

Incorrect or misleading labelling

Compositional defect

Non-conformity with food additive requirements

Organoleptic quality unacceptable

Technical or physical defects (e.g., packaging damage)

Incomplete or incorrect certification

Does not come from an approved country, region or establishment

Other reasons

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

**Action taken**

Food destroyed

Food held pending reconditioning/rectification of deficiencies in documentation

Food held pending final judgement

Place where food is held

Import granted for use other than human consumption

Re-export granted under certain conditions, e.g. to specified informed countries

Importer notified

Embassy/food control authorities of exporting country notified

Authorities in other likely destination countries notified

Other



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

(Advanced to Step 5 of the Procedure)

**SECTION I - SCOPE 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* (CAC/GL 20-1995).
2. These guidelines are intended to assist countries in the application of requirements for trade in foodstuffs and in determining equivalency in order to protect consumers and facilitate fair trade.
3. 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).
4. Application 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 to facilitate trade.

**SECTION 2 - DEFINITIONS**

*Audit* is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.<sup>1</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 inspection, auditing of quality assurance systems, and examination of finished products.<sup>1</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>1</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.

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<sup>1</sup> (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.<sup>1</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>1</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>1</sup>

*Risk Assessment* is the evaluation of the likelihood and severity of adverse effects on public health arising, for example, from the presence in foodstuffs of additives, contaminants, residues, toxins or disease-causing organisms.<sup>2</sup>

### **SECTION 3 - RISK ANALYSIS**

5. The use of scientifically based risk analysis including risk assessment will increase confidence in food safety and will facilitate international trade by increasing confidence in the inspection results of trading partners.

6. Risk analysis should be applied to all segments of the food production and distribution chain, including agricultural inputs and pre-harvest procedures, to enable inspection resources to be targeted effectively on hazards to public health.

7. The principles of Hazard Analysis Critical Control Point (HACCP) developed by the Codex Committee on Food Hygiene<sup>3</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 recognised by governments as a fundamental tool for improving the safety of foodstuffs.

### **SECTION 4 - QUALITY ASSURANCE**

8. The voluntary utilisation 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.

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

10. The degree to which industry 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**

11. 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>2</sup> Consistent with the Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995) but subject to consideration by the Commission.

<sup>3</sup> Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) System; CAC/GL 18-1993.

12. For the determination of equivalence, governments should recognise 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.

13. 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 can be considered to 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.

14. 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 other relevant inspections already validly carried out by self-evaluation or by competent third-party evaluations in the exporting country.

15. Evaluations of inspection and certification carried out 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**

16. 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.

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

- the legislative framework, control programs 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, eg., exchange of information on hazards and monitoring and surveillance.

18. 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**

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

20. 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.

21. 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 recognise a sub-national competent authority for purposes of inspection or certification where this arrangement is acceptable to the national authorities concerned.

### **Legislative Framework**

22. 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.

23. 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.

24. 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, coding requirements and charging of fees.

25. 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. Inspectors must be capable, appropriately trained and must be able to take the necessary measures in cases of non-conformity, to prevent recurrence and to protect public health.

### **Control programmes and operations**

26. 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.

27. In particular, countries should require or encourage the use of a HACCP approach by food establishments and, for this reason, should provide training on HACCP for official inspectors. Where programmes include the taking 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.

28. The elements of a control program 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.

29. 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.

30. 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.

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

#### **Decision criteria and action**

32. The controls program 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.

33. 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. An exporting country may take into account risk and the controls implemented by a producer when identifying the appropriate level of inspection for export.

34. 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.

35. 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.

36. 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. Additionally, the following matters should be taken into consideration:

- 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.

37. Where an imported product is found not to be in conformity, the resulting measures should be applied according to the criteria stated in paragraph 37 above. Such measures may be cumulative if necessary.

*In respect of the product not in conformity measures may include:*

- 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 measures may include:*

- 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 30 and 31);
- on-site visits;
- in the most serious or persistent cases, imports from establishments or countries may be suspended;
- control programmes implemented by the importer to ensure problems do not re-occur.

38. 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.

39. 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* (ALINORM 97/30, Appendix 2).

#### **Facilities, Equipment, Transportation and Communications**

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

41. 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.

42. 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**

43. Inspection services should utilize laboratories that are evaluated and/or accredited under officially recognized programs 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.

44. Inspection systems' laboratories should apply the principles of internationally accepted quality assurance techniques to ensure the reliability of analytical results<sup>4</sup>.

### **Personnel**

45. Inspection services should have, or have access to, a sufficient number of qualified personnel as appropriate in the following areas: food science and technology, chemistry, microbiology, veterinary science, human medicine, epidemiology, audit and law.

## **SECTION 7 - CERTIFICATION SYSTEMS**

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

47. 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.

48. 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.

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<sup>4</sup> The Codex Committee on Methods of Analysis and Sampling is studying a series of internationally recommended documentation on quality assurance systems for laboratories. The complete reference will be included in the final version of these guidelines.

49. 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.

50. 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 programs. 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 - COMPETENCE OF NATIONAL INSPECTION AND CERTIFICATION BODIES AND OFFICIAL ACCREDITATION<sup>5</sup>**

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

52. 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.

53. 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**

54. 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

55. 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.

56. The areas to be covered should include the entire process of the inspection and certification system as outlined in Sections 6 and 7 (above).

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<sup>5</sup> A list of international documentation related to objective criteria for the assessment of the competence of inspection bodies involved in the official import and export control of foods is available from the Codex Contact Point for Australia, Australian Quarantine and Inspection Service, GPO Box 858, Canberra, ACT, Australia; facsimile number 61 6 272 3103.



57. A prospective importing country may undertake a review with the approval 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.

58. 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.

59. 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.

60. Guidelines on procedures for conducting an assessment and verification of the systems of an exporting country by an importing country are outlined in Appendix 1.

## **SECTION 10 - TRANSPARENCY**

61. Consistent with the principles on transparency contained in the *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995), 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.

## **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 programs. 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 will 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

5.1 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 programs. 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.