codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

ALINORM 01/30A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-fourth Session
Geneva, Switzerland, 2-7 July 2001

REPORT OF THE NINTH SESSION OF THE CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Perth, Australia, 11-15 December 2000

Note: This report includes Codex Circular Letter CL 2001/2-FICS

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CX 4/70.2 **CL 2001/2-FICS**
January 2001

TO: - Codex Contact Points
- Interested International Organizations

FROM: Secretary, Joint FAO/WHO Food Standards Programme,
c/- FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: **Distribution of the Report of the Ninth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (ALINORM 01/30A)**

The attached report of the Ninth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems will be considered by the 24th Session of the Codex Alimentarius Commission (Geneva, Switzerland, 2 – 7 July 2001).

MATTERS FOR ADOPTION BY THE 24TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Draft and Proposed Draft Standards and Related Texts at Step 8 or 5/8

1. **Draft Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates (at Step 8)** (ALINORM 01/30, para. 30 and Appendix II).
2. **Proposed Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (at Step 5/8)** (ALINORM 01/30A, para. 89 and Appendix III).

Governments wishing to propose amendments or to comment on the above draft (Step 8) and proposed draft (Step 5/8) Guidelines should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (at Steps 5/8 or 8) (*Codex Alimentarius Procedural Manual*, Eleventh Edition, pages 19-23) to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (telefax: +39.06.5705.4593; e-mail: codex@fao.org) **not later than 1 May 2001**.

Proposed Draft Standards and Related Texts at Step 5

1. **Proposed Draft Guidelines for Food Import Control Systems (at Step 5)** (ALINORM 01/30A, para. 55 and Appendix IV).

Governments wishing to propose amendments or to comment regarding the implications which the above proposed draft Guidelines or any provisions thereof may have for their economic interests 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*, Eleventh Edition, pages 21-23) to the Secretary, Codex Alimentarius Commission, FAO, Viale Terme di Caracalla, 00100 Rome, Italy **not later than 1 May 2001**.

SUMMARY AND CONCLUSIONS

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

MATTERS FOR ADOPTION AND/OR CONSIDERATION BY THE 24TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

- Submitted the draft **Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates** to the Commission for adoption at Step 8 (para. 30);
- Agreed to advance the proposed draft **Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems** to Step 5 of the Procedure and recommended that the Commission adopt the text at Step 8 with the omission of Steps 6 and 7 (paras. 89 - 91);
- Forwarded the proposed draft **Guidelines for Food Import Control Systems** to the Commission for adoption at Step 5 (para. 55);
- Agreed to draft a revision of the **Codex Guidelines for the Exchange of Information in Food Control Emergency Situations** (CAC/GL 19-1995) for consideration at its next Session to include elements related to generic guidance and/or specific food emergency control plans, with the understanding that the revision of the Guidelines would be subject to approval as new work by the Commission (para. 105); and,
- Recommended that a short paper be prepared by the Secretariat for consideration by the Commission in order to obtain the Commission's guidance on **consideration of the concept of "traceability"** in relation to food import and export inspection and certification systems (para. 114).

MATTERS OF INTEREST TO THE 24TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES:

- Returned the proposed draft **Guidelines for the Utilization and Promotion of Quality Assurance Systems to Meet Requirements in Relation to Food** to Step 2 for further revision, comment and discussion at its next Session (para. 69);
- Returned the proposed draft **Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems** to Step 2 for further revision, comment and discussion at its next Session (para. 100); and,
- Decided not to pursue the elaboration of **Guidelines for Food Export Control Systems** at the current time, with the understanding that the elaboration of Guidelines could be considered at a future meeting if necessary (para. 109).

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INTRODUCTION

1. The Ninth Session of the Codex Committee on Food Import and Export Inspection and Certification and Inspection Systems (CCFICS) was held in Perth, Australia from 11-15 December 2000 at the kind invitation of the Government of the Commonwealth of Australia. The Session was chaired by Mr. Digby Gascoine, Technical Advisor, Australian Quarantine and Inspection Service, Department of Agriculture, Fisheries and Forestry – Australia. It was attended by 147 delegates, alternates and advisors from 42 member countries and observers from 11 international governmental and non-governmental organizations. A complete list of the participants at the Session is given in Appendix I to this report.

ADOPTION OF THE AGENDA[1] (Agenda Item 1)

2. The Committee agreed to discuss the matter of "Traceability" under Item 10 - Other Business as proposed by the Delegation of Japan. On this basis, the Committee adopted the Provisional Agenda as the Agenda for the Session.

MATTERS REFERRED FROM OTHER CODEX COMMITTEES[2] (Agenda Item 2)

3. The Committee was informed of matters arising from other Codex Committees, including the 47th Session of the Executive Committee of the Codex Alimentarius Commission. In addition to information provided on the consideration of "traceability" within the Codex *Ad Hoc* Intergovernmental Task Forces on Biotechnology[3] and on Animal Feeding[4], the Committee was also informed that the recently held 6th Session of the Codex Coordinating Committee for North America and the South West Pacific (CCNASWP) "noted that *traceability* was important in terms of food safety in general and may need to be considered more broadly by the Commission and its subsidiary bodies"[5].

DRAFT GUIDELINES FOR GENERIC OFFICIAL CERTIFICATE FORMATS AND THE PRODUCTION AND ISSUANCE OF CERTIFICATES[6] (Agenda Item 3)

4. The 8th Session of the Committee agreed to forward the proposed draft Guidelines to the 47th Session of the Executive Committee (CCEXEC) for adoption at Step 5. The Committee further agreed that a drafting group under the direction of Australia would review comments submitted during discussions at the 8th Session as well as comments submitted subsequent to adoption at Step 6 with a view towards the consideration of an amended text at the Committee's current meeting.[7] The 47th Session of the CCEXEC adopted the proposed draft Guidelines at Step 5 and comments were subsequently requested at Step 6 under CL 2000/15-GEN (July 2000) with a comment deadline of 15 September 2000. Several delegations noted that the Circular Letter had not come to their attention. No comments were received.

5. The Guidelines were revised by a drafting Group under the direction of Australia with the assistance of Canada, France, India, New Zealand, the Netherlands, South Africa, the United Kingdom, the USA and the European Commission. In redrafting the document, particular attention was given by the drafting group to written and verbal comments provided at the Committee's Eighth Session. The Delegation of France, speaking on behalf of the Members of the European Union present at the Session[8], expressed concern at the procedure used following adoption of the text at Step 6 because, the time available to the drafting group being short, some of the comments by members of the drafting group did not appear to have been considered. The Committee agreed to consider the document revised by the drafting group as the basis for its discussions at Step 7.

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1 CX/FICS 00/1 (August 2000)
2 CX/FICS 00/2 (October 2000)
3 ALINORM 01/34, paras. 13-38
4 ALINORM 01/38, paras. 31-32
5 ALINORM 01/32, paras. 62-69
6 CX/FICS 00/3 (November 2000) and comments submitted by Canada, United States, European Community (CRD 1), Brazil (CRD 9), United States (CRD 10) and Chile (CRD 11).
7 ALINORM 01/30, paras. 48-49 and Appendix II
8 On the basis of written comments approved by the fifteen Member countries of the European Commission.

6. The delegation of Australia, in introducing the document, emphasized that the Guidelines were written so as to apply only to official and officially recognized certificates and were intended to apply equally to both paper and electronic forms of certification.

TITLE

7. No change was made.

PREAMBLE

8. The Committee decided to make reference to third party certificates which, while not included in the guidelines were recognized as playing a trade facilitatory role.

SCOPE

9. The Committee agreed that throughout the text a reference to "certificates" would mean a reference to both "official and officially recognized" certificates and amended the text accordingly. It also noted the concerns of some countries about the difficulty of referring to "wholesomeness" as a declaration that could be subject to certification and agreed to use the term "suitability for consumption" based on the use of the expression in the *Recommended International Code of Practice – General Principles of Food Hygiene*[9].

10. It was agreed that matters of animal and plant health, although not normally addressed in the guidelines, should be considered when directly related to food quality and safety. The text was amended accordingly.

OBJECTIVES

11. No change was made.

DEFINITIONS

12. The Committee agreed to add a definition of "Certification", using the definition in the General Principles for Food Inspection and Certification[10]. It also agreed to amend the definition of "Certifying authorities" to "Certifying bodies", as this was the term used throughout the text. It was further agreed to link the recognition of these bodies with the requirements for Official Accreditation in Section 8 of the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems*[11].

PRINCIPLES

13. The Committee agreed to include in this Section a statement to the effect that government agencies having jurisdiction assume the responsibility for all certificates issued by official and officially recognized bodies.

14. Several delegations noted that the expression "competent authority" was used frequently throughout the text and proposed that a definition of this term be established. The Committee noted, however, that both terms had been used in previous texts adopted by the Commission and had been considered as self-explanatory.

15. The Committee also agreed to include a statement to the effect that multiple or redundant certificates should be avoided to the extent possible.

CRITERIA

Standard format

16. Several editorial changes were made to this section. The Committee deleted the reference to "paper that cannot be photocopied" as the document recognizes that further copies can be photocopies (paragraph 10). It also agreed that in cases where a certificate extended to two or more pages, each page should bear the unique identification number of the certificate in addition to other requirements to ensure integrity of the certificate (paragraph 11).

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9 CAC/RCP 1-1969, Rev.3 1997.
10 CAC/GL 20-1995.
11 CAC/GL 26-1997.

17. In regard to the situation when certificates were issued while the consignment was in transit, the Committee recognized that this was an exception to normal practice. Several alternative texts were proposed in the working paper and written comments. The Committee had an extended debate on this issue and agreed that although an exception to normal practice for certification, conditions could be established and agreed upon that would allow the issuing of certificates relating to consignments already in transit. The precondition to this taking place was the agreement between the relevant authorities in the importing and exporting countries on the appropriate systems to control the integrity of the certificate. Such agreements would allow, for example, the issuance of a certificate of analysis under such conditions. Paragraph 14 was amended accordingly.

Details of the consignment

18. The Committee recognized the practice and usefulness of including information on relevant transport and handling requirements including temperature control, for example in the case of frozen, quick frozen or chilled foods. A statement was added to this effect.

Statement of origin

19. No changes were made.

Attestations

20. The Committee agreed that the health status of the exporting country as it may affect the safety of the food could be subject to an attestation. It also agreed that attestations as to conformity to requirements should be extended to include standards, production and processing requirements.

Responsibilities of the certifying body

21. Editorial changes were made.

Responsibilities of certifying officers

22. The Committee agreed that a certifying officer could also certify in respect of known circumstances including conformity with production requirements and any other specified requirements applicable between the production of the food and the date of certification, as well as the circumstances at the time of signing the document. The text was amended accordingly.

Presentation of original certificates

23. No changes were made.

Instructions for completing paper certificates

24. In addition to editorial changes, the Committee agreed to delete reference to “Duplicate” certificates while retaining the reference to “Copies” so as to avoid confusion of terms. It was also agreed that alterations to certificates should be initialed and, where required by the importing country, stamped as this reflected current practice. In view of its earlier consideration regarding photocopies, it was agreed to delete reference to the use of a colour of ink “that does not readily photocopy”.

25. The Committee decided that the date borne by the certificate should be expressed unambiguously, but did not specify a date format.

26. The Committee also agreed that a certifying officer should ensure that each page of multi-page certificates bore the unique certification number as indicated above (see para. 16 above).

Instructions for completing electronic certificates

27. No changes were made.

Replacement certificates

28. It was agreed that loss as well as damage would constitute a reason for the issuance of a replacement certificate.

Revocation of a certificate

29. It was agreed that the exporter (or their agent) should be notified as soon as possible of the revocation of a certificate either in hard copy or by electronic means. It was agreed that the appropriate control authority of the importing country need only to be notified of this act in cases where the export of the consignment had occurred since in such cases the consignment was no longer under control of the exporting country.

STATUS OF THE DRAFT GUIDELINES FOR GENERIC OFFICIAL CERTIFICATE FORMATS AND THE PRODUCTION AND ISSUANCE OF CERTIFICATES

30. The Committee noted that the draft guidelines had been developed in the course of several sessions and that all points of disagreement had been resolved. It agreed therefore to submit the revised draft Guidelines as contained in Appendix II to this report for adoption by the Commission at Step 8 of the Procedure.

PROPOSED DRAFT GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS[12] (Agenda Item 4)

31. The 8th Session of the CCFICS agreed that the first draft of the proposed draft Guidelines for Food Import Control Systems would initially be prepared by the Secretariat for subsequent consideration by a drafting group consisting of Australia, Canada, France, India, Japan, Mexico, Morocco, the United Kingdom and the United States. The Committee further agreed that after consideration by the drafting group, the proposed draft Guidelines would be circulated for comment at Step 3 and further consideration at its current meeting.[13]

32. In introducing the document on behalf of the drafting group, the delegation of Australia noted that the proposed draft Guidelines took account of discussions and written comments submitted at the 8th Session of the CCFICS. It was further noted that the current document consisted of four principal sections, namely: Scope, Definitions, General Characteristics of Food Import Control Systems, and Implementation of the Control System. The Committee agreed to consider the document revised by the drafting group as the basis for its discussions at Step 4.

GENERAL COMMENTS

33. The Committee thanked the drafting group for its efforts in improving the text, and generally agreed that the document should be advanced in the Codex Step Procedure. It was suggested, however, that the document as currently drafted went beyond the intended scope in that the conditions proposed regarding food import control systems were also in some cases related to exporting countries.

34. The Committee agreed that the document should be totally re-numbered in future revisions for consistency with other texts related to food inspection and certification systems adopted by the Commission.

GENERAL CHARACTERISTICS OF FOOD IMPORT CONTROL SYSTEMS

35. The Committee agreed that the fourth bullet in the Section should be clarified to indicate that food import control systems should give "precedence to the protection of consumers over economic and trade considerations". The Committee also agreed that the seventh bullet point and other references in the text to "outcomes/objectives" of food control systems as related to those for domestic food should stipulate that "levels of protection" are ensured between import and domestic food control systems.

REQUIREMENTS FOR IMPORTED FOOD THAT ARE EQUIVALENT WITH REQUIREMENTS FOR DOMESTIC FOOD

36. As the Committee was of the opinion that the term "equivalence" was not applicable to specific food requirements, the term was replaced with "consistent" in order to align the title of the section with language used in the section addressing general requirements for food import control systems. The Committee agreed to combine the first two paragraphs of this Section and to include reference to the role of auditing of systems.

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12 Document CX/FICS 00/4 (August 2000) and comments submitted by Canada, Czech Republic, India, New Zealand, Republic of Korea, Turkey, the United States (CX/FICS 00/4-Add. 1); Spain, European Community (CRD 2); Thailand (CRD 8); Brazil (CRD 9); the United States (CRD 10); and, Chile (CRD 11).

13 ALINORM 01/30, paras. 30-32.

37. The Committee decided to delete entirely the paragraph describing the special case of zero tolerances related to pesticide or veterinary drug residues as being only one particular case out of many that had to be taken into consideration.

CLEARLY DEFINED RESPONSIBILITIES OF IMPORTED FOOD CONTROL AUTHORITY OR AUTHORITIES

38. It was suggested that the Section might be further clarified by the drafting group to define more precisely the role of bodies responsible for issuing and/or verifying the accuracy of certificates. The delegation of France, speaking on behalf of the Members of the European Union present at the Session[14], provided additional text in writing relevant to this topic, and the Committee agreed that the drafting group would consider the text.

CLEARLY DEFINED AND TRANSPARENT LEGISLATION/REGULATIONS AND OPERATING PROCEDURES

39. The Committee agreed with the general content of this section. The Committee decided to move the bullet related to the development of certification arrangements to the paragraph dealing with legal frameworks. The Committee agreed that the bulleted provision in paragraph 10 related to the powers of competent authorities concerning the disposition of imported products should be expanded to reflect the power of such authorities to order the destruction, reconditioning, re-export or designation of foods to alternative, non-food uses.

PRIORITY FOCUS ON THE HEALTH PROTECTION OF CONSUMERS

40. The Committee clarified the title and the text in this section to indicate that when designing and implementing food import control systems, precedence should be given to protecting the health of consumers and ensuring fair practices in food trade over economic and other trade considerations.

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

41. The Committee reaffirmed that the Guidelines were directed to food import control systems. However, the section was clarified to indicate that such systems could include provisions for the recognition of requirements stipulated in food control systems applied by exporting countries where appropriate and further agreed to delete reference to distribution of food products. It was also agreed that future revisions to the text should address unilateral recognition agreements.

CONSISTENT NATIONAL IMPLEMENTATION

42. The Committee changed the title to the Section to read "Uniform Nationwide Implementation".

IMPLEMENTATION OF THE CONTROL SYSTEM

43. It was suggested that the first sentence of the paragraph be deleted as redundant to the remainder of the section.

POINT OF CONTROL

44. The Committee added the provision "transport and distribution" to the bulleted list of import control points and to consider other potential control points in future revisions to the text inter alia, audit of the importers' auto control.

45. The Committee agreed to refer to the drafting group a paragraph submitted by the United States on the avoidance of multiple or redundant certificates.

INFORMATION ABOUT INCOMING FOOD

46. The Committee noted several suggestions for amendments to the draft text of this Section, which would be further considered by the drafting group.

FREQUENCY AND TYPES OF INSPECTION

47. The Committee agreed to consider the testing of imported foods, including history of conformance and past history of health hazards, as potential future additions to the text.

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[14] On the basis of written comments approved by the fifteen Member countries of the European Commission.

SAMPLING AND ANALYSIS

48. It was agreed that official analyses should be performed in official or officially accredited laboratories.

DECISION CRITERIA

49. The Committee transferred the paragraph on the interpretation of results from the previous section to the section on "Decision Criteria", as it was considered to be more appropriate in this section. The Committee agreed that the future revisions to the text should consider the inclusion of an appeal mechanism or review of rejections of consignments and clear time frames for these.

DEALING WITH EMERGENCIES

50. The Committee changed the title of the Section to "Dealing with Emergency Situations", and agreed that the text should be in accordance with the *Guidelines for the Exchange of Information in Food Control Emergency Situations"* (CAC/GL 19-1995) and the *Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food* (CAC/GL 25-1997).

RECOGNITION OF EXPORT CONTROLS

51. The Committee rearranged the final paragraph of this Section to clarify that certification agreements with exporting country official certification bodies may be of particular value where there is limited access to sophisticated facilities in the importing country.

OTHER CONSIDERATIONS

52. The Committee agreed that future revisions to the text should consider that when recognition is given to the control system of an exporting country, an audit of systems of the exporting country might be required rather than routine inspections.

DOCUMENTING THE SYSTEM

53. The Committee agreed to amend bullet 3 in paragraph 40 to "operating procedures, including methods of sampling, inspection and testing".

SYSTEM VERIFICATION

54. The Committee agreed that future revisions to the text should incorporate relevant provisions from Section 9 of the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997).

STATUS OF THE PROPOSED DRAFT GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS

55. In view of the progress made in its consideration of the text, the Committee forwarded the proposed draft Guidelines for Food Import Control Systems (see Appendix IV) to the 24th Session of the Codex Alimentarius Commission for adoption at Step 5.

56. The Committee also agreed that the drafting group[15] would immediately revise the Guidelines after adoption by the Commission on the basis of current discussions, written comments submitted for the present session and written comments to be submitted at Step 6. The revised text would then be circulated for additional comments and further consideration at the 10th Session of the CCFICS.

PROPOSED DRAFT GUIDELINES FOR THE UTILIZATION AND PROMOTION OF QUALITY ASSURANCE SYSTEMS TO MEET REQUIREMENTS IN RELATION TO FOOD[16] (Agenda Item 5)

57. The Delegation of Australia, in introducing the working document, noted that the Guideline was being developed in response to the mandate set out by the Commission in the Committee's Terms of

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15 Lead by Australia, with the assistance of Canada, France, India, Japan, Republic of Korea, Mexico, Morocco, the United Kingdom and the United States.

16 CX/FICS 00/5 (August 2000) and comments of Canada, New Zealand, United States, (CX/FICS 00/5-Add.1 November 2000), Spain, European Community (CRD 3), Thailand (CRD 8), Brazil (CRD 9) and Chile (CRD 11).

Reference. The Delegation noted that the drafting group had attempted to indicate the way in which quality assurance systems used by commercial enterprises could also be used by the competent authorities in the process of food inspection and certification, while delineating elements of quality assurance systems which should be considered by industry and how HACCP could be integrated into such systems. It was noted that written comments suggested that the approach followed may not have given appropriate emphasis to matters of concern to governments and this aspect should be a focus of discussions for the Committee.

58. The Delegation of the United States stated that the document as drafted contained a considerable amount of material directed to industry, particularly Sections 5 and 6, which was not appropriate. This material should therefore be placed in an Annex. The Delegation stated that, if the Guidelines were to be of use to governments and official bodies, they must have a clear and narrow scope. It also expressed concern at the proposals contained in the proposed draft guidelines regarding the use of industry experts to carry out official audits.

59. The Delegation of France, speaking on behalf of the Members of the European Union present at the Session[17], stated that too much emphasis had been placed on the systems of quality assurance considered as an end in themselves and not as a tool for the competent authorities who remain responsible for food control in international trade. In the opinion of the Delegation the text required clarification and should concentrate of three points:

- the use of quality assurance by enterprises to meet requirements with regard to food safety and fair trade practices;
- procedures to be used by government officials in relation to inspection of quality assurance systems used by the food industry; and
- promotion of quality assurance to facilitate trade.

60. The Delegation of New Zealand stated that the sections dealing with the elements of quality assurance systems, their implementation and maintenance, would be better placed elsewhere, perhaps in an annex to the document. The text related to the application of HACCP principles within a quality assurance system could also be minimized by using a footnote reference to the Codex HACCP Guidelines. The section on official assessment and certification required expansion.

61. The Delegation of Canada expressed concern at problems in the use of terminology and stated that the emphasis on HACCP masked the provisions of the guidelines on the use of quality assurance by importing food industries.

62. The Delegation of Brazil stated that it could agree to the continued development of the guidelines for use on a voluntary basis; that the terminology should be harmonized with internationally accepted terms; and, that the quality assurance systems applied should be internationally recognized.

63. The Delegation of India noted that HACCP was only one of several food safety systems that could be used under the Codex General Principles of Food Hygiene and that this fact was not reflected in the Guidelines. In general, there was too much emphasis on HACCP.

64. The Delegation of Thailand, supported by those of China and Malaysia, reiterated the reservation made at previous sessions of the Committee. It stated that the introduction of good manufacturing practices and HACCP allowed enterprises to meet the ALOP and was concerned that the guidelines could be interpreted in a manner that would make the use of quality assurance systems compulsory. The Delegation noted that food-exporting countries may decide to use any world-wide recognized quality control systems in their production processes as they deem appropriate.

65. The Delegation of Japan asked whether there might be linkages between the contents of this document and the issue of “traceability” to be discussed under Item 10. The delegation of Japan also enquired as to how traceability related to the work of other Codex committees.

66. The Delegation of Germany noted that the ISO 9000 standards for quality assurance were under revision.

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[17] On the basis of written comments approved by the fifteen Member countries of the European Commission.

67. The Committee noted that the objective of the guidelines was to provide advice to governments and their official and officially-recognized inspection and certification bodies in the case that an enterprise had established a quality assurance system. It further noted the views expressed above, as well as those submitted in writing, and decided that the Proposed Draft Guidelines required further work. It requested the drafting group to revise the Proposed Draft Guidelines in the light of the above discussion.

68. The drafting group led by Australia was reconstituted to include Canada, Denmark, France, India, Japan, Morocco, the Netherlands, New Zealand, South Africa, Switzerland, United States and European Commission.

STATUS OF THE PROPOSED DRAFT GUIDELINES FOR THE UTILIZATION AND PROMOTION OF QUALITY ASSURANCE SYSTEMS TO MEET REQUIREMENTS IN RELATION TO FOOD

69. The Committee returned the Proposed Draft Guidelines to Step 2 for further revision, comment, and discussion at its next session.

PROPOSED DRAFT GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS[18] (Agenda Item 6)

70. The Eighth Session of the CCFICS had requested[19] a drafting group under the direction of New Zealand to proceed with the development of proposed draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems for circulation and comment at Step 3 prior to its current meeting. In approving the elaboration of the Guidelines as new work, the 47th Session of the CCEXEC indicated that the document should emphasize systems requirements. The CCEXEC also recognized the need to develop guidelines for determining equivalence of food control systems covering not only safety, but also quality and conformity.[20]

71. The Guidelines were revised by a drafting group under the direction of New Zealand with the assistance of Argentina, Australia, Canada, France, Japan, the United States and the European Commission. In redrafting the document, particular attention was given by the drafting group to written and verbal comments provided at the 8th Session of the CCFICS. The Committee agreed to consider the document revised by the drafting group as the basis for its discussions at Step 4.

72. The Committee noted that the intention of the Guidelines was to give application to the Articles on Equivalence in the WTO SPS Agreement insofar as they concerned food import and export inspection and certification systems. It was noted that the Executive Committee had accorded a high priority to this work. It was further noted that these guidelines could provide the basis for work for other Codex Committees, especially the Committee on Food Hygiene in relation to the risk analysis of microbiological hazards in foods, and were of general interest to consumers and civil society.

PREAMBLE

73. Although the Committee noted that not all Members of the Codex Alimentarius Commission were members of the World Trade Organization, the reference to the WTO SPS Agreement was strengthened in view of this important linkage.

SCOPE

74. This Section was amended to reflect the wish of the Executive Committee that the guidelines should emphasize sanitary measures associated with food import and export inspection systems rather than measures per se.

DEFINITIONS

75. The Committee agreed that the definitions in this section should be either those already adopted by the Codex Alimentarius Commission in relation to risk analysis, or derived from the corresponding

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18 CX/FICS 00/6 (August 2000); Comments of Canada, Czech Republic, India, New Zealand, United States, International Association of Consumer Food Organizations (CX/FICS 00/6-Add.1); European Community (CRD 4); Thailand (CRD 8); Brazil (CRD 9); and, Chile (CRD 11).

19 ALINORM 01/30, paras. 62-65.

20 ALINORM 01/3, paras. 26, 43 and Appendix III.

definitions of the WTO SPS Agreement amended to address food-related sanitary measures only. On this basis, the definition of Sanitary Measure was broadened to take into account diseases that may be carried by foods. Some delegations also suggested that the definition of sanitary measures should be based on the term "hazard". Delegations stated that the definition of sanitary measure required further careful consideration at national level, and had to be considered in relation to the Scope of the Guidelines.

76. It was also noted that Codex had a significant existing body of work in relation to hazards transmitted through feedstuffs. The Committee therefore agreed to retain the reference to these matters within the context of the draft Guidelines.

77. The Codex definition of "Risk" was added and the definition of "Risk management" deleted, as the latter term was not used in the document.

78. The Committee noted that the determination of the Appropriate Level of Sanitary Protection (ALOP) by a country was essentially a value judgement rather than a scientific determination. Sanitary measures intended to achieve the ALOP should, however, be based on scientific principles. Attention was drawn to the applicable Articles 2, 3, 5 and 7 of the WTO SPS Agreement that indicated how such measures were to be established or maintained by WTO Members. It was further expressed by the delegation of India that this aspect may need to be suitably brought out in the definition of ALOP and the subject may require further reflection. Reference was also made to the Guidelines to Further the Practical Implementation of Article 5.5 (of the SPS Agreement), recently adopted by the WTO Committee on SPS Measures[21]. For the purpose of clarity in the Guidelines, it was agreed that reference to the Appropriate Level of Sanitary Protection would be indicated by the standard abbreviation "ALOP".

SANITARY MEASURES AND THE DETERMINATION OF EQUIVALENCE

79. The Committee amended the Title of this Section.

80. In relation to the examples of sanitary measures and their partial categorization (paragraph 7), the Committee noted that the examples cited were consistent with those cited in the WTO SPS Agreement whereas the categorization was the basis for the further elaboration of the present document. Some delegations noted that not all of the examples cited had been included in the partial categorization. The Committee agreed to maintain the text as drafted but added references to transport infrastructures (paragraph 7a) and methods of sampling and inspection (paragraph 7c).

81. The Committee decided to strengthen the reference to the concept of a scientific basis for the comparison of sanitary measures including the use of a risk assessment where appropriate (paragraph 9d).

GENERAL PRINCIPLES FOR THE DETERMINATION OF EQUIVALENCE

82. The Committee stressed that countries retained their sovereign right to establish their own ALOP, and noted that the ALOP may be stated in either quantitative or qualitative terms (paragraph 10.1). It was recalled that in establishing an ALOP, the rights and obligations of WTO Members were stated in the WTO SPS Agreement and that the WTO Committee on Sanitary and Phytosanitary Measures had established Guidelines for this purpose.[22]

83. The Committee also agreed to strengthen the provision dealing with transparency, by calling for consultations with all interested parties to the extent practicable and reasonable when judging equivalence.

GUIDELINES FOR THE DETERMINATION OF EQUIVALENCE

84. The Committee agreed to insert text regarding the exchange of information on the importing country's sanitary measures and the review of this information by the exporting country (paragraph 11). The new text combined several themes under this section and as a result some paragraphs were deleted.

85. The Committee had an extended discussion on the issues of modalities of resolution of differences of opinion over judgement of a submission, but agreed that consideration of such modalities were beyond the scope of the Guidelines.

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[21] WTO document G/SPS/15 – 18 July 2000.

[22] WTO document G/SPS/15.

86. The Committee agreed to remove from paragraph 12.3 reference to the dialogue on an objective basis for comparison having the purpose of reaching agreement.

87. The Flow Chart (Figure 1) was amended to reflect the amended Procedure for the Determination of Equivalence.

JUDGEMENT

88. The Committee agreed to restate the need for transparency in the analytical process on which a judgement is based and the need for consultation with all interested parties to the extent practicable and reasonable. It decided to simplify the remaining paragraphs of this Section and in particular decided to delete the examples of the types of information to be taken into account in making a judgement on the basis that the examples were either repetitious of other material or insufficiently detailed to provide adequate guidance in the matter. The Committee agreed that development of examples of the information to be taken into account when making judgements could perhaps be developed in the future as an Annex.

STATUS OF THE PROPOSED DRAFT GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS

89. The Committee noted that significant progress had been made in the consideration of the issues contained in the text and that all outstanding differences of opinion had been resolved. It therefore agreed to advance the proposed draft Guidelines to Step 5 of the Procedure and recommended that the 24th Session of the Commission omit Steps 6 and 7 and proceed to the adoption of the Guidelines at Step 8.

90. In view of extensive changes made to the document which was recently approved as new work at the 47th Session of the CCEXEC, the delegation of Malaysia was of the view that more time was needed to scrutinize the work through another round of comments at Step 6. It was suggested therefore that the document advance through the normal Codex step procedure. The delegation of India, supported by Brazil and Mexico, expressed the view that a number of new concepts and other changes had been introduced to the document. It was therefore necessary that the document be discussed with government and other interested parties in the country and therefore suggested that the document be progressed in the normal Codex step procedure. Brazil also proposed that the present Guidelines should be integrated with the proposed draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems. The delegation of Botswana raised concern that in light of the limited participation of African countries due to the costs involved in attending Committee sessions, it would prefer that the document be advanced in the normal step procedure in order to benefit from further discussions and contributions in other fora. The Delegations of Argentina, Cuba and Uruguay generally supported these views and also drew attention to divergences in the revised Spanish text when compared to the English Version. The delegation of the United Kingdom noted in particular its concern regarding the scope of the document and the definition of sanitary measures and that it did not have the opportunity to discuss the document with other interested parties, including consumer groups. The Delegation of France noted discrepancies in the French version of the text.

91. The Committee noted that the recommendation to the Commission to omit Steps 6 and 7 meant that the option of returning the text for a further round of comments was available to the Commission if the comments received at Step 5 suggested that this would be appropriate. If, on the other hand, the comments received at Step 5 favored the advancement of the text, the Commission had the option to proceed directly to Step 8.

92. The revised text is given in Appendix III to the present report.

PROPOSED DRAFT GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF TECHNICAL REGULATIONS ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS[23] (Agenda Item 7)

93. The Eighth Session of the Committee had agreed that the proposed draft Guidelines would be developed by a drafting group under the direction of Australia for circulation and comment at Step 3 and

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[23] CX/FICS 00/7 (August 2000) and comments of Canada, New Zealand, International Association of Consumer Food Organizations (CX/FICS 00/7 – Add.1 November 2000), European Community (CRD 5), Brazil (CRD 9), Chile (CRD 11).

further consideration at the present Session[24]. The revised text was introduced by the Delegation of Australia which noted that the guidelines presented a high degree of complexity due to the differences between "technical regulations" and "standards" as defined in the WTO Agreement on Technical Barriers to Trade (TBT Agreement). To allow a basis for comparison, the concept of "technical requirement" had been introduced. This also allowed a certain amount of correspondence with the Proposed Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (see previous Agenda Item).

94. The Delegation of France regretted not having been associated with the work of the drafting group, the deadline for reply being too short and coinciding with the European summer vacation.

95. There was general agreement that the revised text was a considerable improvement on the previous version, but that there were several outstanding issues to be resolved most notably the inconsistent use of terminology. Although some delegations were of the opinion that the text could be merged with the text on judgement of equivalence of sanitary measures, other delegations pointed out that the basis for the determination of equivalence in the SPS and TBT Agreements was different even though the processes were similar and that this could lead to confusion. The Committee agreed therefore that, at least for the time being, the two texts would be developed on a parallel but separate basis.

96. Several delegations drew attention to the concept of "technical requirements" introduced into the text and noted that this was not the same at "Technical Regulations" as defined in the TBT Agreement. One delegation questioned whether the requirements under this definition would be applied to contractual arrangements between buyer and seller.

97. The Committee agreed that the definition of "Equivalence (of technical requirements)" should be aligned with the corresponding text on sanitary measures and the definition of "technical requirement" would be re-worded for consistency with the TBT definition of "technical regulation".

98. In general and where appropriate, the text would be amended for consistency with the corresponding text on sanitary measures, including the provisions relating to transparency and the need for consultation with all interested parties. It was suggested that all judgements of equivalence should specify mechanisms by which the importing country could verify that the exporting country continued to administer and enforce the measures covered by the determination of equivalence.

STATUS OF THE PROPOSED DRAFT GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF TECHNICAL REGULATIONS ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS

99. The Committee expressed its appreciation to the members of the Drafting Group. It was of the opinion that the text as currently drafted was proceeding in the right direction but that it needed substantial revision in view of changes made to the corresponding text on sanitary measures. It requested the drafting group (Australia, France, South Africa, USA and the European Commission) to prepare a revised text on this basis that also took into account the oral comments and written comments provided at the present session. The revised text should be issued in ample time for comment by Members and interested international organizations. The comments should be circulated well in advance of the Committee's next Session. The Committee also suggested that the draft text should be accompanied by examples of the application of the guidelines to different types of technical requirements for further discussion by the Committee, in order to facilitate further development of the Guidelines.

100. The Committee noted that considerable work was required to finalize the document and therefore returned the text to Step 2 of the Procedure.

DISCUSSION PAPER ON RISK MANAGEMENT GUIDELINES FOR FOOD CONTROL EMERGENCY SITUATIONS INVOLVING INTERNATIONAL TRADE[25] (Agenda Item 8)

101. The 8th Session of the CCFICS accepted the offer of Australia to prepare a discussion paper for consideration at its current meeting which addressed the adequacy of relevant Codex texts as well as the issues involved regarding food control emergency situations.[26]

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[24] ALINORM 01/30, para. 69

[25] CX/FICS 00/8 (September 2000) and comments submitted by the European Community (CRD 6) Brazil (CRD 9).

102. In introducing the discussion paper, the delegation of Australia noted that the paper emphasized potential future work in the application of risk analysis to food emergency situations and information exchange; model food emergency response plans; levels (extent) of food distribution; re-export of food to third countries; and, communication between exporting and importing countries.

103. The Committee thanked the delegation of Australia for its efforts, and noted that Australia had proposed the development of a generic model for the management of food control emergency situations, including the exchange of information in such situations, through the expansion of the *Codex Guidelines for the Exchange of Information in Food Control Emergency Situations* (CAC/GL 19-1995) and/or the elaboration of companion guidelines addressing emergency response issues.

104. The Committee reached general agreement that the elaboration of guidelines for food control emergency situations involving international trade should be undertaken in the context of CAC/GL 19-1995. It was suggested that guidelines concerning food control emergency situations should include the consideration of:

- The development of a specific food emergency control plan or alternatively, generic guidance;
- The difficulty in applying sound risk management and risk communication practices to food control emergency situations due to the inherent lack of information and timely risk assessments;
- The need to expand on the application of risk communication, including a framework for feedback, in the process;
- differences and similarities between importing and exporting control measures to be taken;
- final disposition of food products, including the concept of traceability and third country exports;
- texts and other documentation elaborated by international governmental and non-governmental organizations, including the future elaboration of the FAO Rapid Alert System; and,
- a revised definition for food control emergency situations.

105. The Committee accepted the offer of Australia, with assistance provided by Japan, the Netherlands, the United States and the European Commission, to draft a revision of the *Codex Guidelines for the Exchange of Information in Food Control Emergency Situations* (CAC/GL 19-1995) for consideration at its next Session to include elements related to generic guidance and/or specific food emergency control plans on the basis of the Committee's discussions and written comments submitted. It was understood that the revision of the current *Codex Guidelines* would be subject to approval as new work by the 24th Session of the CAC.

DISCUSSION PAPER ON FOOD EXPORT CONTROL SYSTEMS[27] (Agenda Item 9)

106. The Eighth Session of the Committee had accepted the offer of Morocco to elaborate a discussion paper on the potential development of guidelines for food export control systems for consideration at its current meeting.[28]

107. In introducing the document, the Chairperson noted that the paper suggested the development of guidelines for food export control systems for balance with the elaboration of guidelines for food import control systems and in consideration of the Committee's mandate related to both food export and import control and inspection. The Chairperson suggested that the Committee might want to consider the adequacy of current Codex texts related to import control, as well as the programme of work of the Committee, when considering the potential elaboration of guidelines.

108. The Committee thanked Morocco for the development of the discussion paper. It was noted that food export control systems were normally applied by governments for purposes outside the mandate of Codex, e.g., for the promotion or expansion of markets. It was also stated that export control was normally

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26 ALINORM 01/30, para. 72.

27 CX/FICS 00/9 (September 2000) and comments submitted by the European Community (CRD 7) and Brazil (CRD 9).

28 ALINORM 01/30, para. 75.

an integral part of food import control systems and that food export control systems were already adequately addressed in the FAO Series of Manuals of Food Quality Control: Food for Export[29].

109. The Committee decided not to pursue the elaboration of guidelines for food export control systems at the current time, especially in view of other completed Codex work that addressed the issue and also in view of its current heavy programme of work. It was agreed that the elaboration of guidelines could be considered at a future meeting if necessary.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 10)

TRACEABILITY

110. The Delegation of Japan introduced a brief paper on the matter of traceability[30] in which it noted that this issue had been referred to, or was currently being discussed by various Codex Committees including CCFICS, Committee on Fish and Fishery Products, Task Force on Animal Feeding, and the Task Force on Foods Derived from Biotechnology. It stated that the concept of traceability cut across a wide range of food issues. It further noted that, as yet, there had not been a forum under the Codex Alimentarius Commission in which a comprehensive discussion had taken place on the issue and that Codex had not yet defined the purpose and framework of this concept. The Delegation was of the opinion that due to the importance of this concept in relation to food import and export inspection and certification systems it would be an appropriate matter for the Committee to discuss. The Committee expressed its appreciation to the Delegation of Japan for raising the issue and agreed that the points raised needed to be addressed within the Codex framework.

111. At the request of the Chairperson, the Secretariat noted that different Codex Committees and Task Forces had undertaken either prior or current work related to traceability including the Committees on Food Hygiene, Food Labelling, and Food Additives and Contaminants in addition to the subsidiary bodies mentioned by Japan. The Secretariat noted that the modalities required for systems of traceability seemed to fall within the terms of reference of CCFICS whereas consideration of a Codex-wide definition of the concept would logically fall within the work of the Committee on General Principles.

112. The Representative of the European Commission stated that traceability was an instrument of risk management and as such should be considered by the Committee on General Principles. Moreover, in the opinion of the Representative, the issue was not exclusively related to food safety. For example in the area of organic foods or food claimed to be "GMO-free" it was a matter of ensuring the integrity of the product in relation to consumer confidence. Because it was such a general concept, the Representative recommended that the Committee on General Principles should establish a definition and establish general orientations.

113. The Delegation of Canada, supported by several other delegations, stated that there was a need for a general discussion paper on the status and use of the concept in which the problems, challenges and opportunities to Codex would be highlighted. The Delegation of the Republic of Korea stated that this was an important issue for food safety systems involved in international trade. The Representative of the International Association of Consumer Food Organizations proposed that consideration could be given to a "bottom up" approach, allowing a more general definition to be derived from the practical application of the concept by individual committees within their terms of reference. The Delegation of the United States was of the opinion that emphasis should be placed on the purpose and application of the concept rather than a definition. The Delegation of New Zealand was of the opinion that contemporary experience in the use of the concept at the national level should be identified and examples included in any discussion paper.

114. The Committee agreed that within its Terms of Reference it had a responsibility to consider work in this area and that there was need for a substantive discussion of the issue at its next meeting. In view of the system-wide interest and involvement in the issue, the Committee recommended that a short paper be prepared by the Secretariat for consideration by the Codex Alimentarius Commission at its next Session in order to obtain the Commission's guidance in this matter. In the meantime, the other relevant Committees and Task Forces, including the Committee on General Principles, would be informed of this recommendation.

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29 FAO Food and Nutrition Paper Volume 14 – Part 6.

30 CRD. 12

DATE AND PLACE OF NEXT SESSION (Agenda Item 11)

115. The Committee noted that its Tenth Session was tentatively scheduled to be held in Australia from 25 February to 1 March 2002, subject to further discussion between the Codex and Australian Secretariats.

SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE (ALINORM 01/30A)
Draft Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates	8	24th CAC	Paras. 4 – 30 and Appendix II
Proposed Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems	5/8	24th CAC	Paras. 70 – 92 and Appendix III
Proposed Draft Guidelines for Food Import Control Systems	5	24th CAC Governments 10th CCFICS	Paras. 31 – 56 and Appendix IV
Proposed Draft Guidelines for the Utilization and Promotion of Quality Assurance Systems to Meet Requirements in Relation to Food	2/3	Drafting Group Governments 10th CCFICS	Paras. 57 – 69
Proposed Draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems	2/3	Drafting Group Governments 10th CCFICS	Paras. 93 - 100
Proposed Draft Revision to the Codex Guidelines for the Exchange of Information in Food Control Emergency Situations	1/2/3	24th CAC Drafting Group 10th CCFICS	Paras. 101 - 105
Consideration of the Concept of Traceability in Relation to Food Import and Export Inspection and Certification Systems	-----	Secretariat 24th CAC 10th CCFICS	Paras. 110 - 114

ALINORM 01/30A
Appendix I

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ALINORM 01/30A
Appendix II

DRAFT GUIDELINES FOR GENERIC OFFICIAL CERTIFICATE FORMATS AND THE PRODUCTION AND ISSUANCE OF CERTIFICATES
(Advanced to Step 8 of the Codex Procedure)

SECTION 1 - PREAMBLE

1. These guidelines recognize that importing country authorities may, as a condition of clearance of consignments, require importers to present certification issued by, or with the authority of, exporting country authorities. These guidelines do not mandate a need to use such certification or in any way diminish the trade facilitatory role of commercial or other types of certificates, including third party certificates, not issued by, or with the authority of, exporting country authorities. These guidelines are based on the presumption that the commercial parties engaged in international trade in food are responsible for complying with the regulatory requirements of the exporting and importing country.

SECTION 2 - SCOPE

2. These guidelines concern the design and use of official and officially recognized certificates that attest to attributes of food presented for international trade. Hereafter, in these Guidelines, the term "certificates" means official and officially recognized certificates. Certificates should be required only where declarations are necessary relating to product safety or suitability for consumption, or to otherwise facilitate fair trade.

3. These guidelines do not deal with matters of animal and plant health unless directly related to food quality or safety. However, it is recognized that, in practice, a single certificate may contain information relevant to several matters.

4. These guidelines are equally applicable to the use of paper or electronic forms of certification.

SECTION 3 -OBJECTIVES

5. Certificates should contain essential information relating to food safety and the facilitation of trade. The level of information required should be adequate for the importing country's purpose and not impose unnecessary burdens on the exporting country or exporter, nor should there be a requirement for the disclosure of information that is commercial-in-confidence unless it is of relevance to public health.

SECTION 4 - DEFINITIONS

Certificates are those paper or electronic documents which describe and attest to attributes of consignments of food moving in international trade.

Certification is the procedure by which official certification bodies or officially recognized certification bodies provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products.[31]

Official certificates are certificates issued by an official certification body of an exporting country, in accordance with the requirements of an importing or exporting country.

Officially recognized certificates are certificates issued by an officially recognized certification body of an exporting country, in accordance with the conditions of that recognition and in accordance with the requirements of an importing or exporting country.

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

Certifying bodies are official certification bodies and officially recognized certification bodies[32].

Certifying officers are employees of certifying bodies authorized to complete and issue certificates.

SECTION 5 - PRINCIPLES

6. Certificates should be required only where declarations are necessary to provide information about product safety or suitability for consumption, or to otherwise facilitate fair trade. Multiple or redundant certificates should be avoided to the extent possible. The rationale and requirements for certification should be communicated in a transparent manner and consistently implemented in a non-discriminatory manner. Certificates should be designed and used in a manner that:

- meets requirements in respect of food safety, suitability for consumption and the facilitation of fair trade in food;
- simplifies and expedites the certification process;
- clarifies the responsibility of all parties;
- satisfies compulsory trade description requirements;
- provides for accurate identification of the consignment being certified;
- minimizes the risk of fraud.

The government agency having jurisdiction shall take responsibility for any certificate issued by a certifying body.

SECTION 6 - CRITERIA

STANDARD FORMAT

7. Each certificate should contain a declaration by the official, or officially recognized certification body which relates to the consignment described on that certificate. The certificate should clearly identify the certifying body with letterhead and/or logo.

8. Each certificate should have a unique identification number and be presented in an unambiguous style in a language, or languages, fully understood by the certifying officers and by the receiving authority. A record of unique identification numbers assigned to certificates should be maintained by the competent authority and be able to be related to the distribution of the certificates.

9. Where certificates are produced as a paper document, the original certificate should be uniquely identifiable and be printed with at least one copy for the use of the certifying body and retention by that authority for an appropriate period of time. Further copies may be officially printed copies or photocopies. In all cases the status of the certificate should be clear, for example, marked “original” or “copy”, as appropriate.

10. Certificates should be designed so as to minimize the risk of fraud (for example, use of watermark paper, or other security measures for paper certificates; use of secure lines and systems for electronic certificates.)

11. Where certificates are produced in a physical form, they should occupy one sheet of paper or, where more than one page is required, in such a form that any two or more pages are part of an integrated whole and indivisible sheet of paper. Where this is not possible, each individual sheet should be separately initialed by the certifying officer and/or numbered so as to indicate it is a particular page in a finite sequence (for example page 2 of 4 pages) and should contain the unique identification number for that certificate.

12. The certificate should clearly describe the commodity and consignment to which it uniquely relates.

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

13. Certificates should contain a clear reference to any requirements to which the certified product is required to conform.

14. Certificates should be issued prior to the consignment, to which the certificate relates, leaving the control of the certifying body. Certificates may be issued while consignments are in transit to the country of destination only when appropriate systems of control are agreed by the competent authorities of the importing and exporting countries.

15. The use of electronic means for the issue or transfer of certificates should be accepted where the integrity of the certification system has been assured to the satisfaction of the relevant authorities of both the importing and exporting country. A hard copy form of an electronic certificate should be made available by the issuing authority on request of the importing country's authorities. When electronic certificates are used, the importing country's inspectors should have electronic access to the certification details.

DETAILS OF THE CONSIGNMENT

(NOTE: These details are not specific to food, as they constitute the normal field of information contained in any Bill of Lading for transport vessels carrying product between countries. The shipping data on the official certification documentation provides a means of verifying details about the product.)

16. The details of the product being certified should be clearly documented on the certificate, which should at least contain the following information:

- nature of the food;
- name of product;
- quantity, in the appropriate units;
- lot identifier or date coding;
- identity and, as appropriate, the location of the production establishment;
- name and contact details of the importer or consignee;
- name and contact details of the exporter or consignor;
- country of dispatch; and
- country of destination.

Certificates may also contain information on relevant transport and handling requirements, including appropriate temperature controls.

STATEMENT OF ORIGIN

17. Where, in exceptional cases justified by immediate public health concern, the importing country requires a statement as to the origin of ingredients in a product, the certificate should specify the origin of ingredients sourced outside the exporting country.

ATTESTATIONS

18. The particular attestations to be included in a certificate will be determined by the requirements of the importing or exporting country. They should be clearly identified in the text of the certificate. Such attestations may include, but are not limited to:

- health status as it may affect the safety of the food;
- product conformity with particular standards, production or processing requirements;
- the status (e.g. licensing details) of production, processing and/or packaging establishment in the exporting country; and,
- reference to any associated bilateral/multilateral agreement.

RESPONSIBILITIES OF THE CERTIFYING BODY

19. The certifying body should be designated and adequately empowered by national legislation or regulation in a transparent manner to provide the particular attestations required in a certificate or officially recognized certificate. Such designation/ empowerment should be recognized as sufficient by governments, alleviating requirements for further identity or authority.

20. The certifying bodies should ensure that their procedures allow for the issue of the certificate in a timely manner so as to avoid unnecessary disruptions to trade.

21. The certifying bodies should have in place an effective system to prevent, to the extent practicable, the fraudulent use of official and officially recognized certificates.

RESPONSIBILITIES OF CERTIFYING OFFICERS

22. Information and guidance notes to facilitate the correct completion of certificates should be available to all certifying officers and to the parties responsible for providing details for inclusion in a certificate.

23. The certifying officers should:

- be appropriately designated by the certifying body;
- have no conflict of interest in the commercial aspects of the consignment and be independent from the commercial parties;
- be fully conversant with the requirements to which they are attesting;
- have access to a copy of regulations or requirements that are referred to on the certificate or clear information and guidance notes issued by the competent authority explaining the criteria that the product must meet before being certified;
- only certify matters which are within their own knowledge (or which have been separately attested to by another competent party); and
- only certify in respect of the circumstances known at the time of signing the document including conformity with production requirements and any other specified requirements between production and date of certification.

PRESENTATION OF ORIGINAL CERTIFICATES

24. The importer or consignee is responsible for ensuring that the product is presented to the importing country's authorities with the original certificate in accordance with the importing country's requirements. In the case of electronic certificates the consignee should supply the importing country authority with sufficient details concerning the consignment to allow the identity of goods to be established against the details contained in the certificate.

INSTRUCTIONS FOR COMPLETING PAPER CERTIFICATES

25. Certificates should always be issued and presented, to the exporter or their agent, as the original certificate (i.e., this is an original printed paper form of the original certificate issued once only).

26. A copy of the original certificate (clearly marked as such) should be kept by the certifying body in the exporting country and be provided to the competent authority in the importing country, on request.

27. When signing a certificate, the officer should ensure that:

- the certificate contains no deletions other than those required by the text of the certificate;
- any alterations of the certified information are initialed and, as required by the importing country, stamped by the certifying officer using the official stamp of the certifying body;
- when the certificate occupies more than one sheet of paper, each individual sheet is separately initialed by the certifying officer and numbered with the respective unique certificate number;

- the certificate bears his/her signature, his/her name and official position of the certifying officer in clear lettering and, where appropriate, his/her qualifications;
- the certificate bears the date expressed unambiguously on which the certificate was signed and issued and, where appropriate, the time for which the certificate will remain valid;
- after signature by the certifying officer, no portion of the certificate is left blank in a manner that would allow it to be amended.

INSTRUCTIONS FOR COMPLETING ELECTRONIC CERTIFICATES

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

29. Before authorizing an electronic certificate, the certifying officer should ensure that all steps and checks established for the secure operation of the electronic system have been satisfactorily completed.

REPLACEMENT CERTIFICATES

30. Where, for any good and sufficient reason (such as loss of or damage to the certificate in transit), a replacement certificate is issued by the certifying officer it must be clearly marked "REPLACEMENT" before being issued. A replacement certificate should reference the number of the original certificate that it supercedes.

REVOCATION OF A CERTIFICATE

31. When for good and sufficient reason there is cause to revoke a certificate, the certifying body should revoke the original certificate as soon as possible and notify the exporter or their agent in hard copy or by electronic means of the revocation. The notice should reference the number of the original certificate to which the revocation refers and provide all particulars regarding the consignment and the reason(s) for the revocation. A copy of the revocation should be provided to the appropriate food control authority of the importing country if the export of the consignment has occurred.

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Appendix III

PROPOSED DRAFT GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS
(Advanced to Step 5/8 of the Codex Procedure)

SECTION 1 - PREAMBLE

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

2. In such circumstances, and in order to facilitate trade, there is a need to determine the effectiveness of sanitary measures of the exporting country in achieving the appropriate level of sanitary protection of the importing country. This has led to recognition of the principle of equivalence as provided for in the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement).

3. Application of the principle of equivalence has mutual benefits for both exporting and importing countries.

SECTION 2 - SCOPE

4. This document provides guidelines on the judgement of the equivalence of sanitary measures associated with food inspection and certification systems. For the purpose of determining equivalence, these measures can be broadly characterized as: infrastructure; programme design, implementation and monitoring; and/or specific requirements (refer paragraph 7).

SECTION 3 - DEFINITIONS

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

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

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.[33]

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.[1]

Risk Assessment**:** A scientifically-based process consisting of the following steps: (i) hazard identification; (ii) hazard characterisation; (iii) exposure assessment; and (iv) risk characterisation.[1]

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

Equivalence (of sanitary measures)[34]: Equivalence is the state wherein sanitary measures applied in an exporting country, though different from the measures applied in an importing

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[33] Codex Alimentarius Commission: Procedural Manual (11th Edition), pages 48-49.

[34] Equivalence is defined in CAC/GL 26-1997: "*Equivalence* is the capability of different inspection and certification systems to meet the same objectives".

country, achieve, as demonstrated by the exporting country, the importing country's appropriate level of sanitary protection.

SECTION 4 - SANITARY MEASURES AND THE DETERMINATION OF EQUIVALENCE

6. To facilitate judgement of equivalence between countries and promote harmonisation of food safety standards, Codex members should base their sanitary measures on Codex standards and related texts.[35]

7. Sanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety. For the purposes of determining equivalence, the sanitary measures associated with a food inspection and certification system can be broadly categorised as:

a) infrastructure; including the legislative base (e.g., food and enforcement law), and administrative systems (e.g., organisation of national and regional authorities);

b) programme design, implementation and monitoring; including documentation of systems, monitoring, performance, decision criteria and action, laboratory capability, transportation infrastructure and provisions for certification and audit; and/or

c) specific requirements; including individual facilities (e.g., premises design), equipment (e.g., design of food contact machinery), processes (e.g., HACCP plans), procedures (e.g., ante- and post-mortem inspection), tests (e.g., laboratory tests for microbiological and chemical hazards) and methods of sampling and inspection.

8. A sanitary measure proposed for determination of equivalence may fall into one or more of these categories, which are not mutually exclusive. A single measure, however, on which an equivalence determination may be made, cannot be considered in a vacuum. In other words, whether the importing country's ALOP is likely to be achieved can only be determined in most cases through an evaluation of all relevant components of an exporting country's food inspection and certification system. For example, a determination of equivalence for a specific sanitary measure at the programme design, implementation and monitoring level will require in most cases a prior determination of an equivalent infrastructure. A determination of equivalence for a specific sanitary measure at the specific requirements level will require in most cases a prior determination of an equivalent infrastructure and equivalent programme design, implementation, and monitoring.

9. An objective basis for comparison of sanitary measures must be established to allow an equivalence determination to be made, and this may include the following elements:

a) the reason/purpose for the sanitary measure;

b) the relationship of the sanitary measure to the ALOP, i.e., how the sanitary measure achieves or contributes to the achievement of the ALOP;

c) where appropriate, an expression of the level of control of the hazard in a food that is achieved by the sanitary measure;

d) the scientific basis for the sanitary measure under consideration, including risk assessment where appropriate.

SECTION 5 - GENERAL PRINCIPLES FOR THE DETERMINATION OF EQUIVALENCE

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

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

10.1 An importing country has the sovereign right to set a level of sanitary protection it deems appropriate in relation to the protection of human life and health.[36] The ALOP may be expressed in qualitative or quantitative terms.

10.2 An importing country should be able to describe how its sanitary measure achieves, or contributes to the achievement of, its ALOP.

10.3 An importing country should recognize that sanitary measures different from its own may be capable of achieving its ALOP, and can therefore be found to be equivalent.

10.4 The sanitary measures applied by the exporting country must achieve the importing country's ALOP.

10.5 Countries should, upon request, enter into consultations with the aim of achieving bilateral or multilateral recognition of the equivalence of specified sanitary measures[37].

10.6 It is the responsibility of the exporting country to demonstrate that its sanitary measures can achieve the importing country's ALOP.

10.7 The comparison of countries' sanitary measures should be carried out in an objective manner.

10.8 Where risk assessment is used in the demonstration of equivalence, countries should strive to achieve consistency in the techniques applied so as to ensure that findings can be objectively compared.

10.9 When judging the equivalence of sanitary measures, the importing country should take into account any knowledge it has of the food inspection and certification systems in the exporting country and of the performance of those systems.

10.10 The exporting country should provide access to enable the inspection and certification systems which are the subject of the equivalence determination to be examined and evaluated upon request of the food control authorities of the importing country.

10.11 Countries should ensure transparency in both the demonstration and judgement of equivalence, consulting all interested parties to the extent practicable and reasonable.

SECTION 6 - PROCEDURE FOR THE DETERMINATION OF EQUIVALENCE

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

12. The determination of equivalence is facilitated by both exporting and importing countries following a sequence of steps, such as those described below and illustrated in Figure 1:

12.1 The exporting country identifies the sanitary measure of the importing country for which it wishes to apply a different measure, and requests the reason/purpose for the measure.

12.2 The importing country provides the reason/purpose for the identified sanitary measure.

12.3 On the initiative of the exporting country, the importing and exporting countries should enter into a dialogue concerning an objective basis for comparison.

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[36] The SPS Agreement sets out the rights and obligations of WTO Members in relation to the determination of an appropriate level of sanitary protection.

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

12.4 The exporting country develops the submission to demonstrate that the application of the different sanitary measure achieves or contributes to the achievement of the ALOP of the importing country, and presents it to the importing country.[38]

12.5 The importing country determines whether the exporting country's measure achieves the importing country's ALOP.

12.6 If the importing country has any concerns with the submission as presented, it should notify them to the exporting country at the earliest opportunity and should detail the reasons for concern. If possible, the importing country should suggest how the concerns might be addressed.

12.7 The exporting country should respond to such concerns by providing further information as appropriate.

12.8 The importing country notifies the exporting country of its judgement within a reasonable period of time and provides the reasoning for its decision, should the judgement be that the sanitary measure(s) is not equivalent.

12.9 An attempt should be made to resolve any differences of opinion over judgement of a submission, either interim or final.

SECTION 7 - JUDGEMENT

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

14. Experience and detailed knowledge of an exporting country's food inspection and certification systems may in itself be sufficient to allow an objective judgement of equivalence by the importing country. For example, a sanitary measure categorized as a specific requirement (refer paragraph 7) may be able to be judged equivalent without consideration of the supporting programme design, implementation and monitoring, and infrastructure.

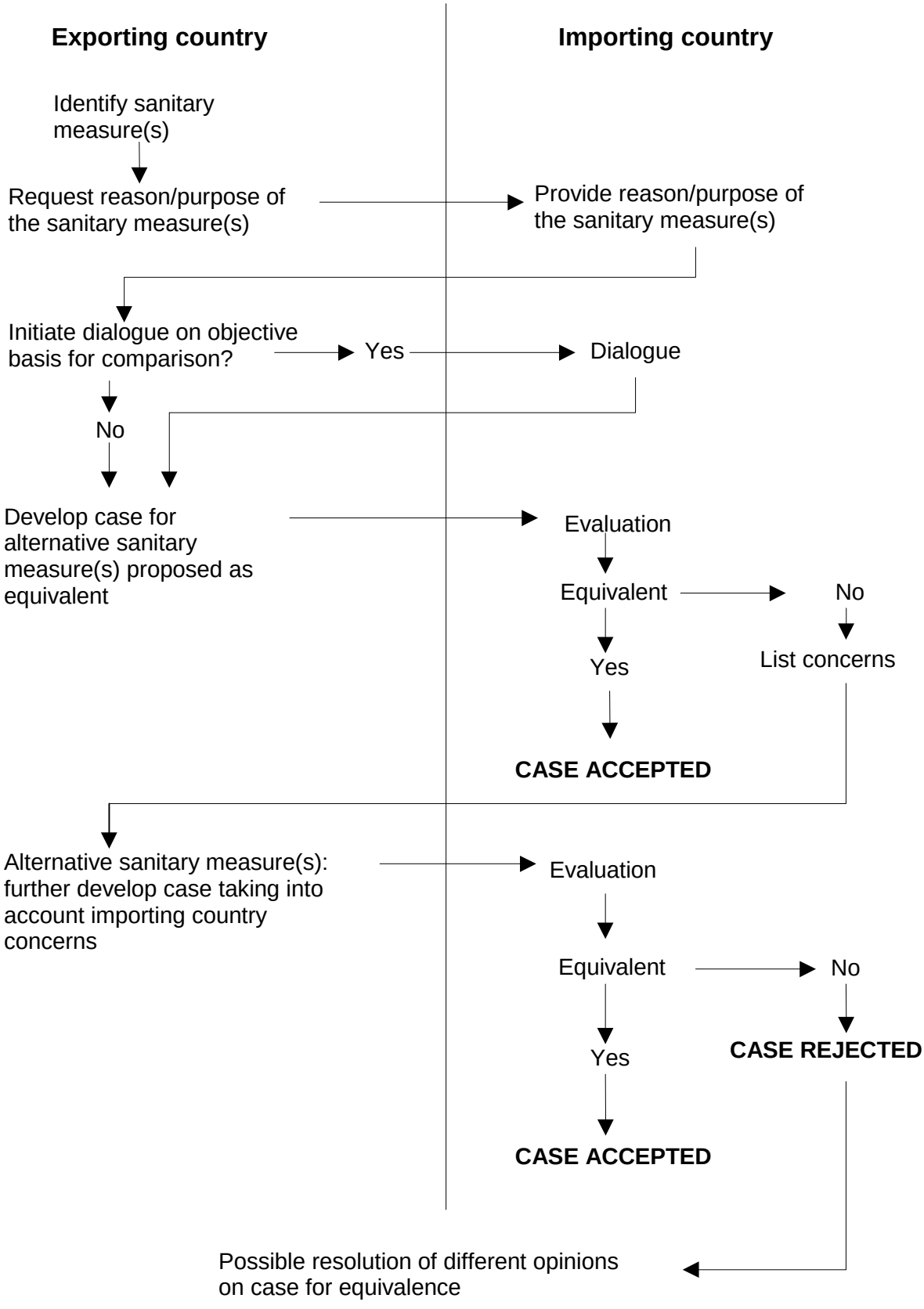
15. Where countries have no previous history of significant trading in foods or detailed knowledge of each other's food inspection and certification systems, the determination of equivalence may require a detailed side-by-side comparison of all relevant sanitary measures.

16. Judgement of equivalence should take into account those Codex texts relevant to the food safety matters under consideration.

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

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

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



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Appendix IV

PROPOSED DRAFT GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS (Advanced to Step 5 of the Codex Procedure)

SECTION 1 -SCOPE

1. This document provides a framework for the development and operation of an import control system to protect consumers and facilitate fair practices in food trade while ensuring unjustified technical barriers to trade are not introduced. The Guideline is consistent with the Codex *Principles for Food Import and Export Inspection and Certification*[39] and provides specific information about imported food control that is an adjunct to the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems*[40].

SECTION 2 - DEFINITIONS[41]

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

*Certification** is the procedure by which official certification bodies and officially recognized bodies provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products.

*Inspection** is the examination of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify that they conform to requirements.

*Legislation** includes acts, regulations, requirements or procedures, issued by public authorities, related to foods and covering the protection of public health, the protection of consumers and conditions of fair trading.

*Official accreditation** is the procedure by which a government agency having jurisdiction formally recognizes the competence of an inspection and/or certification body to provide inspection and certification services.

*Official inspection systems and official certification systems** are systems administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function or both.

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

*Requirements** are the criteria set down by the competent authorities relating to trade in foodstuffs covering the protection of public health, the protection of consumers and conditions of fair trading.

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39 CAC/GL 20-1995 *Principles for Food Import and Export Inspection and Certification*

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

41 Definitions drawn from the *Guidelines for the Design, Operation , Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997) are marked with *. Definitions drawn from Codex Alimentarius Commission, Procedural Manual (11th edition) are marked with **.

*Risk assessment*** A scientifically based process consisting of the following steps (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment, and (iv) risk characterisation.

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

SECTION 3 - GENERAL CHARACTERISTICS OF FOOD IMPORT CONTROL SYSTEMS

2. Food import control systems should have the following main characteristics:

- requirements for imported food that are consistent with requirements for domestic foods;
- clearly defined responsibilities of the imported food control authority or authorities;
- clearly defined and transparent legislation/regulations and operating procedures;
- precedence to the protection of consumers over economic and trade considerations;
- provision for recognition of the food controls applied by an exporting country's competent authority or authorities
- uniform nationwide implementation by the importing country of its requirements;
- implementation that ensures the levels of protection achieved are consistent with those for domestic food.

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

3. Requirements are commonly expressed as end-point or limit value standards with complementary sampling regimes etc, or provisions concerning process controls, or a combination of these. In general, requirements should be applied equally to domestically produced and imported food. The extent and stringency of requirements applied in specific circumstances should be proportionate to risk, noting that risk may vary from one source to another because of factors such as technology employed, compliance history, etc. and /or examination of relevant attributes of a sample of products at import. .

4. Where domestic requirements include process controls such as good manufacturing practice, compliance may be determined by auditing as appropriate, the systems, facilities and procedures in the exporting country.

CLEARLY DEFINED RESPONSIBILITIES OF IMPORTED FOOD CONTROL AUTHORITY OR AUTHORITIES.

5. The competent authority(ies) involved in any of the imported food inspection functions at the point or points of entry, during storage and distribution and/or at point of sale, should have clearly defined responsibilities and authority. When responsibility for determining compliance with requirements is shared among agencies of the importing country, multiple inspection and duplicative testing for the same analyte(s) on the same consignment by the different agencies should be avoided to the extent possible. In such situations, agencies having jurisdiction should share inspection, testing, and other information on the consignment.

6. Some countries, for example those that are part of a regional economic grouping, may rely on import controls implemented by another country. In such cases, the functions, responsibilities, and operating procedures undertaken by the country which conducts the imported food control should be clearly defined and accessible to authorities in the country or countries of final destination with the aim of delivering an efficient and transparent import control system that provides the appropriate level of protection.

7. Where the competent authorities of an importing country use third party providers as officially recognised inspection bodies and/or officially recognized certification bodies to implement controls,

such arrangements should be conducted in the manner discussed in CAC/GL 26-1997, Section 8, Official Accreditation. The functions that can be conducted by such providers may include:

- sampling of target food shipments;
- analysis of samples;
- compliance evaluation of relevant parts or all of a quality assurance system that may be operated by importers in order to comply with official requirements.

CLEARLY DEFINED AND TRANSPARENT LEGISLATION/REGULATIONS AND OPERATING PROCEDURES

8. The object of legislation/regulations is to provide the basis and the authority for operating a food import control system. The legal framework allows for the establishment of the competent authority(ies) and the processes and procedures required to verify the conformity of imported products against requirements.

9. Legislation/regulations should provide the competent authority with the ability to:

- appoint authorised officers;
- require prior notification of the importation of a consignment of a foodstuff;
- require documentation;
- inspect, including the authority to enter premises within the importing country, physically examine the food and its packaging; collect samples and initiate analytical testing; inspection of documentation provided by an exporting country authority, exporter or importer; and verification of product identity against documentary attestations;
- apply differential sampling plans depending on risk posed by the particular food, its compliance history and the validity of accompanying certification;
- charge fees for the inspection of consignments and sample analysis;
- accredit laboratories for the examination of samples;
- accept, refuse entry, detain, destroy or order to destroy, order reconditioning or re-export, or designate alternative uses;
- recall consignments following importation;
- retain bond over consignments during intra-national transport or during storage prior to import clearance;
- implement administrative and legal sanctions when the specific requirements are not satisfied; and

10. In addition the legal framework may make provisions for:

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

PRECEDENCE TO THE PROTECTION OF CONSUMERS

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

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

12. Food import control systems should include provisions for recognition as appropriate of the food control system applied by an exporting country's competent authority. Importing countries can recognise the food safety controls of an exporting country in a number of ways that facilitate the entry of goods, including the use of memoranda of understanding, mutual recognition agreements and equivalence agreements. Such recognition should, as appropriate, include controls applied during the production, manufacture, importation, processing, storage, and transportation of the food products, and verification of the export food control system applied.

UNIFORM NATION-WIDE IMPLEMENTATION

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

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

14. As an importing country has no direct jurisdiction over process controls applied to food manufactured in another country, there may be a variation in approach to the compliance monitoring of domestic and imported food. Such differences in approach are justifiable on the basis that the objectives of the import controls are the same as those applied to domestically produced food.

SECTION 4 - IMPLEMENTATION OF THE CONTROL SYSTEM

15. Operational procedures should be developed and implemented to minimize undue delay at the point or points of entry without jeopardizing effectiveness of controls to ensure food safety. Implementation should take into account the factors listed in this section.

POINT OF CONTROL

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

- entry to the country of destination;
- further processing;
- transport and distribution;
- storage; and,
- sale, (retail or wholesale).

17. The system should be structured to deliver the same outcomes regardless of the point or points of control.

18. The importing country can recognize controls implemented by the exporting country. The application of controls by the exporting country, during production, manufacture and subsequent transit should be encouraged, with the aim of identifying and correcting problems when and where they occur, and preferably before costly recalls of food already in distribution are required.

19. Pre-shipment clearance is a possible mechanism for ensuring compliance with requirements of, for example, valuable bulk packed products that if opened and sampled upon entry, would be seriously compromised, or for products that require rapid clearance to maintain safety and quality.

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

INFORMATION ABOUT INCOMING FOOD

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

- date and point of entry;
- mode of transport;
- description of the commodity (including commodity, amount, country of origin, identifying marks such as lot identifier etc);
- exporter or importer;
- manufacturer (if possible); and
- destination.

FREQUENCY OF INSPECTION AND TESTING OF IMPORTED FOODS

22. The nature and frequency of inspection and testing of imported foods should be based on the risk to health presented by the product and the history of conformance to requirements. Control should be designed to account for factors such as:

- the risk to human health posed by the product;
- the risk of non-compliance with requirements;
- the target consumer group;
- the extent and nature of any further processing of the product;
- factors relating to the food inspection and certification system in the exporting country and existence of any equivalence, mutual recognition agreements or other trade agreements.

23. Physical checks on imported product, using random statistically based sampling plans, are valid means of checking product compliance. Inspection procedures should be developed to include defined sampling frequencies or inspection intensities. The frequency of sampling should be proportionate to the assessed risk, which may take into account evidence of, or confirmed non-conformity for a particular product, processor, importer or country.

24. Sampling frequency of products supplied from a source for which there is no compliance history, should be set at a higher rate than for products from other sources. The sampling process enables a compliance history to be created. Similarly, food from suppliers or imported by parties with a known poor compliance history should be sampled at higher intensity. In these cases, every shipment may need to be physically inspected, until a defined number of consecutive shipments meets requirements. Alternatively the inspection procedures can be developed to automatically detain product from suppliers with a known poor compliance history and the importer may be required to prove the fitness of each consignment through use of an accredited laboratory until a satisfactory compliance rate is achieved.

SAMPLING AND ANALYSIS

25. The inspection system should have defined sampling procedures based on Codex sampling plans for the particular commodity/contaminant combination where available.

26. Where samples are selected for analysis standard methods of analysis, or methods validated through appropriate protocols, should be used. Analysis should be conducted in official or officially accredited laboratory facilities.

DECISION CRITERIA

27. Decision criteria should be developed that determine whether shipments are given

- free entry;
- entry if cleared upon inspection or verification of conformance;
- entry of non-conforming product after corrective measures have been taken, or redirecting product for uses other than human consumption;
- rejection notice, with re-exportation option;
- rejection notice with destruction order

28. Results of inspection and, if required, laboratory analysis, should be carefully interpreted in making decisions relating to acceptance or rejection of a consignment. The inspection program should include decision-making rules for situations where results are borderline, or sampling indicates that only some lots within the consignment comply with requirements. Procedures may include further testing and examination of previous compliance history.

29. The system should include formal means to communicate decisions about results of analysis, clearance and status of shipments. Advice on decisions should be provided to importers without delay. There should be an appeal mechanism for review of rejections of consignments.

DEALING WITH EMERGENCY SITUATIONS

30. The responsible authority should have procedures that can respond appropriately to emergency situations. This will include holding suspect product upon arrival and recall procedures for suspect product already cleared and, if relevant, rapid notification of the problem to international authorities.

31. If the food control authorities in importing countries detect problems during import control of foodstuffs which they consider to be so serious as to indicate a food control emergency situation, they should inform the exporting country promptly by telecommunication.[42]

RECOGNITION OF EXPORT CONTROLS

32. Consistent with paragraph 11 of this guideline, the importing country should establish mechanisms to accept control systems in an exporting country where these system achieve the same level of protection required by the importing country. In this regard, the importing country should:

- develop procedures to conduct assessment of the exporting country systems consistent with the Annex of the Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997);
- take into account the scope of the arrangement, for example, whether it covers all foods or is restricted to certain commodities or certain manufacturers;

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[42] CAC/GL 19-1995 *Guidelines for the Exchange of Information in Food Control Emergency Situations*

- develop clearance procedures that provide an appropriate level of protection if arrangement developed with an exporting country are limited in scope;
- provide recognition of export controls through, for example, exemption from routine import inspection;
- conduct verification procedures for example, occasional random sampling and analysis of products upon arrival. (Section 5 and Annex of CAC/GL 26-1997 deal with the provision and verification of systems that provide certification for food in trade);
- recognise that arrangements need not rely on the presentation of certificates or documentation with individual shipments, when such an approach is acceptable to both parties.

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

INFORMATION EXCHANGE

34. Imported food control systems involve information exchange between competent authorities and countries that are trading partners. The information may include:

- requirements of food control systems;
- "hard copy" certificates attesting to conformity with requirements of the particular shipment;
- electronic data or certificates where accepted by the parties involved;
- details about rejected food shipments;
- list of establishments or facilities that conform to importing country requirements.

35. Any changes to import protocols, which may affect trade, should be promptly communicated to trading partners, allowing a reasonable interval between the publication of regulations and their application taking into account the risk to the consumer and the urgency of the measure.

OTHER CONSIDERATIONS

36. The authority may consider developing alternative arrangements in lieu of routine inspection. This may include agreements where the inspection authority assesses the controls that importers implement over suppliers and the procedures that are in place to verify compliance of suppliers. Alternative arrangements may include some sampling of product by the authority as an audit, rather than routine inspection.

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

38. If a product registration system exists or is implemented, a clear rationale for such product registration (e.g. specific and documented food safety concerns) should exist. Such product registrations should treat imported and domestic product in the same or equivalent manner.

DOCUMENTING THE SYSTEM

39. A food import control system should be fully documented, including a description of its scope and operation, responsibilities and actions for staff, in order that all parties involved know precisely what is expected of them.

40. Documentation of an imported food control system should include

- an organizational chart of the official inspection system, including the roles of each level in the hierarchy;
- job descriptions of all personnel;
- operating procedures including methods of sampling, inspection and testing;
- relevant legislation and requirements that should be met by imported food;
- important contacts; and,
- reference information about food contamination and food inspection.

TRAINED INSPECTORATE

41. It is fundamental to have adequate, reliable, well trained and organised inspection staff, with supporting infrastructure, to deliver the imported food control system. Training, communication, and supervisory elements should be organised to provide consistent implementation of requirements by the inspectorate throughout the food import control system.

42. Where third parties are officially recognised to perform inspection work, or there are alternative arrangements in place, such as a quality assurance arrangement with the importing company, the qualifications of the auditors, or company inspection staff, should be at least the same for inspection staff of the competent authority.

43. The authority responsible for conducting assessment of food control systems of exporting countries should engage personnel with the qualifications and training expected of personnel assessing domestic food controls.

SYSTEM VERIFICATION

44. Consistent with Section 9 of the Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification System (CAC/GL 26-1997) an imported food control system should be independently assessed on a regular basis.

SECTION 5 - FURTHER INFORMATION

45. The Food and Agriculture Organization of the United Nations *Manual of Food Quality Control. Imported Food Inspection* (Food and Nutrition Paper 14/15, 1993) and World Health Organization/Western Pacific Regional Center for the Promotion of Environmental Planning and Applied Science (PEPAS): *Manual for the Inspection of Imported Food* (1992) contribute valuable information for those engaged in the design and re-design of imported food control systems.