ALINORM 03/30

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April 2002

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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

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-fifth Session
Rome, Italy, 30 June – 5 July 2003

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

Brisbane, Australia, 25 February – 1 March 2002

Note: This report includes Codex Circular Letter CL 2002/8-FICS

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CX 4/70.2 **CL 2002/8-FICS**
April 2002

TO: Codex Contact Points

Interested International Organizations

FROM: Secretary, Joint FAO/WHO Food Standards Programme, FAO

Viale delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: **Distribution of the Report of the Tenth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (ALINORM 03/30)**

The report of the Tenth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems will be considered by the 50th Session of the Executive Committee of the Codex Alimentarius Commission (Geneva, Switzerland, 26–28 June 2002) and the 25th Session of the Codex Alimentarius Commission (Rome, Italy, 30 June–05 July 2003).

PART A: MATTERS FOR ADOPTION BY THE 25TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Draft Standards and Related Texts at Step 8

Draft Guidelines for Food Import Control Systems (ALINORM 03/30, paras. 9-30 and Appendix II).

Governments wishing to propose amendments or to submit comments regarding the implications which the proposed draft Guidelines for Food Import Control Systems 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 8) (*Codex Alimentarius Procedural Manual*, Twelth Edition, pages 19-21) 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 15 October 2002**.

PART B: REQUEST FOR COMMENTS

Draft Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (ALINORM 03/30, paras. 31–52 and Appendix III)

The Committee agreed to request comments on the *Draft Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems*. Governments and interested international organizations are therefore invited to provide their comments on the above subject matter and should do so in writing to Codex Australia; Product Integrity and Animal and Plant Health; Agriculture, Fisheries and Forestry – Australia; GPO Box 858 Canberra ACT 2601; Australia , (email: codex.contact@affa.gouv.au or Fax: +61.2.6272.3103) with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (e-mail: codex@fao.org or fax: +39 06570.54593) before **30th June 2002.**

SUMMARY AND CONCLUSIONS

The Tenth 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 25TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

- Submitted the draft **Guidelines for Food Import Control Systems** to the Commission for final adoption at Step 8 (para. 30 and Appendix II).

MATTERS FOR CONSIDERATION BY THE 25TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES.

- Returned the draft **Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems** for revision, circulation, comment and further consideration at its next meeting (see paras. 50-52);
- Returned the proposed draft **Guidelines for the Utilization and Promotion of Quality Assurance Systems to Meet Requirements in Relation to Food** to Step 2 in order to be reformulated by a drafting group to reflect appropriate principles for circulation, comment and discussion at its next meeting (see para. 84);
- Returned the proposed draft **Guidelines for the Exchange of Information in Food Control Emergency Situations** to Step 2 for further revision, comment and discussion at its next meeting, and (see para. 94);
- Agreed to defer for the time being further drafting of the proposed **Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems** within the context of the Codex step procedure and **agreed** that a drafting group would prepare a **discussion paper** on the need for the further elaboration of the Guidelines for circulation, comment and consideration at its next meeting (see paras 73-75); and,
- Agreed that a working group would prepare a discussion paper on "**traceability**" for circulation, comment and further consideration at its next meeting (see paras 67-68).

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

Brisbane, Australia, 25 February– 1 March 2002

OPENING OF THE SESSION

1. The tenth session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) was held in Brisbane, Australia from 25 February – 1 March 2002 at the kind invitation of the Government of the Commonwealth of Australia. The session was chaired by Mr Gregory Read, Executive Manager, Australian Quarantine and Inspection Service, Department of Agriculture, Fisheries and Forestry– Australia. It was attended by 161 representatives from 43 Member Countries and 6 international organizations. A complete list of participants is attached at Appendix I.

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

2. The Committee noted that no written proposals had been received for revisions or amendments to the Provisional Agenda.

3. However, in accordance with Rule V.5 of the Rules of Procedure of the Codex Alimentarius Commission, the Joint FAO/IAEA/WHO International Consultative Group on Food Irradiation (ICGFI) proposed the inclusion of an Information Paper on Requirements in International Trade for Certificates for Foods Irradiated for Non-Phytosanitary Purposes[2]. The Committee agreed to consider the document under Other Business and Future Work (see Agenda Item 8).

4. The Australian Secretariat also proposed the inclusion of a document on Traceability in the Context of Inspection and Certification Systems[3] and in view of the importance of this issue for the future work of the CCFICS, the Committee agreed to consider the document immediately after Agenda Item 4 (Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems) as a new Agenda Item 4bis.

5. The Committee also agreed to consider Agenda Item 6 (Proposed Draft Guidelines for the Utilization and Promotion of Quality Assurance Systems to Meet Requirements in Relation to Food) immediately prior to Agenda Item 5 (Proposed Draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems).

6. The Committee adopted the Provisional Agenda, with the aforementioned amendment, as the Agenda for the Session.

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1 CX/FICS 02/1

2 CX/FICS 02/INF.1

3 CX/FICS 02/INF.2

MATTERS REFERRED FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 2)[4]

7. The Committee noted matters arising from the 24th Session of the Codex Alimentarius Commission and other Codex committees, including the 49th Session of the Executive Committee, the 34th Session of the Codex Committee on Food Hygiene and the forthcoming 17th Session of the Codex Committee on General Principles. These issues included the Consideration of the Draft Strategic Framework, Proposed Draft Medium-Term Plan 2003-2007 and the Chairperson's Action Plan; Consideration of Draft and Proposed Draft Standards and Related Texts; Consideration of New Work Proposals; Food Safety Objectives; and, the Proposed Draft Revision to the Revised Code of Ethics for International Trade in Foods.

8. As discussed during the Adoption of the Agenda (Agenda Item 1), the Committee noted that background information concerning Traceability would be presented under Agenda Item 4bis.

DRAFT GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS (Agenda Item 3)[5]

9. The 9th Session of the CCFICS forwarded the proposed draft Guidelines for Food Import Control Systems to the 24th Session of the Codex Alimentarius Commission for adoption at Step 5. [6] The extraordinary 49th Session of the Executive Committee of the Codex Alimentarius Commission[7] adopted the proposed draft Guidelines at Step 5 and subsequent to the CCEXEC, comments were requested at Step 6 under CL 2001/25-FICS. The Committee considered the proposed draft Guidelines (ALINORM 01/30A, Appendix IV) preliminarily adopted at Step 5 by the Executive Committee as the basis for its discussions at Step 7.

SECTION 2 – DEFINITIONS

10. The Committee agreed to add the term and definition for *"Appropriate Level of Protection (ALOP)"* in square brackets on the basis of the draft definition under development in the draft *Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (see Agenda Item 4) and with the understanding that a final definition would need to be agreed upon prior to the document's final adoption. As the remaining terms and definitions in this Section were derived from other adopted Codex texts, the Committee retained the remaining terms and definitions as proposed.

SECTION 3 – GENERAL CHARACTERISTICS OF FOOD IMPORT CONTROL SYSTEMS

11. For reasons of consistency within the text, the Committee changed the phrase "imported food control authority or authorities" to "competent authority (authorities)" in bullet 2 of paragraph 2 of this Section and as a consequential change in the remainder of the text. It was also clarified that the responsibilities were in regard to the competent authority "involved in the procedures". The Committee also confirmed that the term "competent authority" was self-evident and therefore, no definition was required. The Committee deleted the term "regulations" when used in conjunction with the term "legislation" from bullet 3 of paragraph 2 and throughout the text as legislation included regulations as defined.

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4 CX/FICS 02/2

5 ALINORM 01/30A, Appendix IV and comments submitted in response to CL 2001/25-FICS by Canada, Mexico, New Zealand (CX/FICS 02/3), United States, European Community (CX/FICS 02/3-Add. 1), India (CRD3), Thailand (CRD 4) and Brazil (CRD 6).

6 ALINORM 01/30A, para. 55.

7 ALINORM 03/3, Appendix II.

Requirements for Imported Food That are Consistent with Requirements for Domestic Foods

12. The Committee agreed to delete and reorganize the existing paragraphs 3 and 4 into new paragraphs 3, 4 and 5 to more accurately and separately reflect the notions of imported and domestic requirements. The three new paragraphs were also strengthened to include examples of end-point standards and to specify that risk may vary due to various factors, including specific situations in the region of origin. The Committee also added a footnote to paragraph 5 to provide a reference to paragraph 54 of the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997),* which contained additional information on the assessment and verification of inspection and certification systems between exporting and importing countries.

13. The Committee confirmed that the Guidelines addressed the development and operation of an import control system to protect consumers and facilitate fair practices in the food trade and therefore, did not accept a suggestion to restrict requirements in such systems to food safety.

Clearly Defined Responsibilities of Imported Food Control Authority or Authorities

14. As previously decided, the Committee changed the title of this sub-section to read as Clearly Defined Responsibilities of Competent Authority or Authorities. In consideration that the terms "agency" or "agencies" could be interpreted differently among Codex member countries, the Committee deleted these terms and phrases containing these terms from paragraph 5. The Committee also agreed to change the term "shipment" to the term "consignment" in paragraph 7 and as a consequential change throughout the text.

Clearly Defined and Transparent Legislation/Regulations and Operating Procedures

15. As previously decided, the Committee changed the title of this sub-section to read as *Clearly Defined and Transparent Legislation and Operating Procedures.* The Committee clarified bullet 5 of paragraph 9 to specify that legislation should provide the competent authority with the ability to apply risk based sampling plans which took account of the compliance history of the particular food and other relevant information. Bullet 8 was also revised to indicate that legislation should provide the competent authority with the ability to reject, order reconditioning, processing or return to country of export of non-complying food and to implement administrative and/or judicial measures when the specific requirements were not satisfied.

Provision for Recognition of the Food Control System Applied by an Exporting Country's Competent Authority

16. The Committee changed the title of this sub-section to read Provision of the Importing Country for Recognition of the Food Control System Applied by an Exporting Country's Competent Authority.

17. The Committee also added a phrase to indicate that "unilateral recognition" was also a means for importing countries to recognize the food safety controls of an exporting country in paragraph 12.

Implementation that Ensures the Levels of Protection Achieved are Consistent with those for Domestic Food

18. The phrase stating that "the objectives of the import controls are the same as those applied to domestically produced food" was revised to indicate that differences in approach were justifiable provided they were necessary to ensure that the level of protection achieved was consistent with that of domestic food.

SECTION 4 – IMPLEMENTATION OF THE CONTROL SYSTEM

19. In view of previous discussions that the scope of the Guidelines covered food safety and the facilitation of trade, the Committee deleted the specific reference to "food safety" and replaced it with the general term "requirements" in paragraph 15. The Committee also clarified that the possibility of recognizing guarantees at origin included the implementation of controls in exporting countries.

Point of Control

20. The Committee added the bullet "origin, where agreed upon with the exporting country" to paragraph 16 as another point for the control of imported food by the importing country. In view of the difficulty in arriving at the same outcome regardless of the point of control or assessment (e.g., contaminants, microbiological load) the Committee deleted paragraph 17 in its entirety. In regard to pre-shipment clearance, the Committee also clarified that such clearance should be based on the results of the documentary check of the consignments.

Information about Incoming Food

21. The Committee changed the title to read as *Information About Food to be Imported.* The Committee strengthened the bullet points in paragraph 21 to provide additional examples of details of consignments that may be obtained, including product description, means of preservation, country of dispatch, seal identification numbers and name and address of producer, including establishment registration number.

Frequency of Inspection and Testing of Imported Food

22. The bulleted text in paragraph 22 of this Section was amended to reflect that the frequency and testing of imported foods included controls to take account of various factors, including the history of conformity of producers, processors, manufacturers, exporters, importers and distributors.

23. Paragraph 23 was completely redrafted to reflect that checks of imported product might also be conducted on product intended for re-exportation or on the basis of requirements of the country of final destination. The delegation of Switzerland objected to this revision as it was not always possible to control the requirements for products at their final destination. Paragraph 24 was also strengthened to stress that sampling frequency of products with a poor compliance history might be set at a higher rate than products with a good compliance history provided that it was shown through transparent and objective criteria. It was also clarified that the importer might be required to prove the fitness of each consignment through laboratories, including official laboratories, which were recognized, accredited and/or listed by the competent authority.

Sampling and Analysis

24. The Committee clarified paragraph 25 to indicate that in the absence of Codex sampling plans, internationally accepted or scientifically based sampling plans were required.

Decision Criteria

25. The title was revised to read as "Decisions". An additional sentence was added to the end of paragraph 29 to allow for the possibility to consider withdrawal of a rejected consignment when food that meets international standards is rejected because it fails to meet the national standards of the importing country. The Committee did not accept the proposal of Thailand to also apply this option to consignments that also met national standards of the exporting country.

Recognition of Export Controls

26. The delegation of Japan noted its reservation to the concept of the development of certification agreements with officially recognized certification bodies of the exporting country.

Information Exchange

27. The Committee clarified paragraph 34 to stress that food import control systems involve information exchange between the competent authorities of exporting and importing countries. It was also clarified in bullet 4 that such information included specific details of rejected food such as destruction, processing, reconditioning or redirection of consignments for non-human food uses.

Documenting the System

28. In view of the difficulty in providing job descriptions of all personnel involved in imported food control, the Committee clarified the second bullet in paragraph 40 to indicate that an indication of job function, as appropriate, would be adequate.

Trained Inspectorate

29. The Committee clarified paragraph 42 to indicate that when third parties are officially recognized by the competent authority of the importing country to perform specific inspection work, the qualifications of such staff should at least be the same as the inspection staff of the competent authority that carry out similar tasks.

Status of the Draft Guidelines for Food Import Control Systems

30. The Committee forwarded the draft Guidelines for Food Import Control Systems (see Appendix II) to the 25th Session of the Commission for final adoption at Step 8.

DRAFT GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS (Agenda Item 4)[8]

31. The 9th session of the CCFICS advanced the proposed draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems to the 24th Session of the Codex Alimentarius Commission for adoption at Steps 5 and 8, with the omission of Steps 6 and 7.[9]

32. In discussing the proposed draft Guidelines, the Commission noted[10] that the intention of the text was to assist countries, and especially developing countries, in the application of provisions concerning equivalence in the WTO SPS Agreement, insofar as food import and export inspection and certification systems were concerned. The Executive Committee had accorded high priority to this work. The representative of the WTO participating at the Commission noted that one of the concerns raised by developing countries in the SPS Committee was the difficulties faced in having the equivalence of their exported products recognized in terms of health protection, and they had stressed the need for clear guidance in this area. It was noted that such guidance was urgently needed to expand developing country export markets.

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8 ALINORM 01/30A, Appendix III and comments submitted in response to CL 2001/25-FICS by Argentina, Canada, Mexico, New Zealand, United States, IACFO (CX/FICS 02/4), EC (CX/FICS 02/4-Add. 1) and India (CRD 3).

9 ALINORM 01/30A, para. 89 and Appendix III.

10 ALINORM 01/41, paras. 185-188.

33. Several delegations at the Commission were of the view that more time was needed to scrutinize the document in detail and therefore suggested that the Guidelines be adopted at Step 5 only. It was also suggested that the document should be considered in parallel with the CCFICS Guidelines on the Judgement of Technical Regulations Associated with Food Inspection and Certification Systems. It was noted that further consideration was required in the Scope section as well as in the definition for the equivalence of sanitary measures.

34. In view of the above concerns, the Commission adopted the Guidelines at Step 5 only so that they could be further considered by the CCFICS.

35. The Committee noted that Objective 1 (Promoting Sound Regulatory Frameworks) of the Commission's draft Medium-Term Plan 2003-2007 as related to Standards Development included the "Application of guidelines on the judgement of equivalence for specific purposes such as equivalence of measures to ensure food hygiene or measures to ensure conformity with essential quality requirements".

36. The Committee was also informed that a letter dated 3 December 2001 from the Chairman of the WTO Committee on Sanitary and Phytosanitary Measures (SPS) to the Chairman of the Codex Alimentarius Commission highlighted the WTO/SPS Committee Decision of the Implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures (G/SPS/19 of 26 October 2001). Among other things, the letter noted that the SPS Committee recognized the ongoing work of the Codex Alimentarius Commission on the issue of equivalence, and encouraged WTO Members to actively participate in this work. In addition, it was stated that the SPS Committee recognized the urgency for the development of guidance on the judgement of equivalence and the letter formally encouraged the Codex Alimentarius Commission to complete its work as expeditiously as possible. The letter also invited the Codex Alimentarius Commission to continue to keep the WTO/SPS Committee regularly informed regarding its activities related to equivalence.

37. The Committee considered the proposed draft Guidelines (ALINORM 01/30A, Appendix III) preliminarily adopted at Step 5 by the Executive Committee as the basis for its discussions at Step 7.

GENERAL COMMENTS

38. A large number of delegations were in general agreement with the text adopted by the Executive Committee at Step 5. These delegations noted that in view of the importance of the text to both importing and exporting countries and the extensive consideration of previous drafts, the Committee should support the advancement of the Guidelines to the Commission for final adoption at Step 8. These delegations noted that notwithstanding the importance and relevance of deliberations in the WTO/SPS Committee related to the implementation of Article 4 of the SPS Agreement, it was not necessary to restate the rights and obligations of WTO Members in the Codex Guidelines. It was stressed that the Codex text would not impose additional rights or obligations on the WTO Members but was only meant to facilitate the standardization objectives of Codex related to consumer protection and the facilitation of trade in foods.

39. The representative of the WTO stressed the high priority accorded to the continued elaboration of the Guidelines and stressed that coordination between national government agencies separately involved in the WTO and Codex debates needed to be enhanced. In this regard, the Representative noted that the WTO/SPS Committee would develop a specific programme to further the implementation of Article 4, with particular consideration of the problems encountered by developing Member countries.

40. Other delegations, while recognizing the importance of the Guidelines for the facilitation of exports from developing countries, recognized the ongoing work in the WTO/SPS Committee on the development of a specific programme to further the implementation of Article 4 of the SPS Agreement. These delegations noted that the WTO/SPS Committee deliberations should be considered in the context of the Codex Guidelines so that these guidelines could be further developed in an objective and transparent manner and so that they were equitable for both exporting and importing countries.

SECTION 1 – PREAMBLE

41. A delegation suggested that paragraph 2 be clarified to indicate that there was a need to determine the effectiveness of sanitary measures "associated with food safety". It was also suggested that it should be stipulated that the Guidelines would facilitate trade "while protecting the health of consumers".

42. The Committee noted that the text should refer to the establishment of an "equivalence determination" as opposed to "arrangement".

SECTION 2 - SCOPE

43. It was also suggested that paragraph 4 should be revised to indicate that the determination of equivalence included implementation, monitoring and "enforcement". In addition, the delegation of Argentina suggested the inclusion of two new paragraphs to clarify both the general and specific aims of equivalence agreements, namely, to facilitate the trade of products or groups of products that are subject to sanitary measures associated with food safety and to reduce the frequency of physical checks or other types of controls. Other delegations pointed out that the objective of the document was merely to provide guidance for the judgment of equivalence and these issues were covered by other Codex texts, e.g. CAC/GL 34-1999. It was also suggested that the text should better reflect that judgement of equivalence could be applied either to a single or set of sanitary measures or to the entire system so that the same needs were appropriately reflected.

SECTION 3 – DEFINITIONS

Sanitary measure

44. It was suggested that the definition be broadened to indicate that risks associated with sanitary measures arose "from hazards in foods".

Equivalence (of Sanitary Measures)

45. It was noted that the definition for equivalence of sanitary measures should be aligned with the Codex definition for Equivalence (CAC/GL 26-1997). However, it was noted that the definition for the term "sanitary measure" was aligned with Annex A of the SPS Agreement. If the scope of the term "sanitary measure" was broadened to include all food safety hazards, it would thereby include food safety measures that may be outside the scope of the SPS Agreement (e.g., measures to address allergens) and there would need to be a consequential change in the scope of the term "equivalence (of sanitary measures)". The Committee agreed that because of concerns expressed, the definitions for the terms "sanitary measure" and "equivalence (of sanitary measure)" would be subjected to further debate. The Committee also noted the suggestion to add a footnote reference to Article 2.3 of the WTO/SPS Agreement.

46. The Committee noted the request for the addition of the term *Determination of equivalence* and its associated definition although it was stated that this concept was in and of itself the purpose of the Guidelines.

SECTION 4 – SANITARY MEASURES AND THE DETERMINATION OF EQUIVALENCE

47. It was suggested to add the entire text of Article 3.3 of the SPS Agreement as a footnote to paragraph 6. It was also suggested that the first sentence of paragraph 8 be changed to read that "An equivalence determination can be made on a measure or measures related to a specific food product or category of food product, or on a system-wide basis, as agreed upon between the parties". It was also suggested that the text be clarified that an evaluation of safety components of the exporting country's food inspection and certification system was relevant to the measure for which determination of equivalence was sought.

48. The delegation of Argentina suggested that the entire bulleted text in paragraph 9 be rewritten to reflect the WTO/SPS Committee decision on equivalence but the Committee decided to subject this revision to further debate and left the text unchanged.

SECTION 5 – GENERAL PRINCIPLES FOR THE DETERMINATION OF EQUIVALENCE

49. A number of changes were suggested to paragraph 10 but the text was left unchanged.

Status of the Draft Guidelines for the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems

50. A consensus position could not be secured and therefore, the Committee decided to append the draft Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems, as originally presented and unchanged from the text adopted by the 24th Session of the Codex Alimentarius Commission, to its report (see Appendix III) for comments, with a comment deadline of 30 June 2002 (see Circular Letter to this report). The Committee agreed that a drafting group[11] would prepare a revised version of the draft Guidelines for circulation, additional comment at Step 6 and further consideration at its next meeting. In the interest of transparency and participation by all Codex member countries and international organizations, it was stressed that the revised version of the Guidelines would be circulated for additional comment no later than 30 September 2002.

51. The Committee stipulated that the draft revised Guidelines would be revised by the drafting group on the basis of the attached text (see Appendix III), the above discussions, written comments submitted at the current meeting[12] and additional comments to be submitted by the comment deadline of 30 June 2002. The Committee noted that these activities would be conducted in the first instance by electronic means and if possible, in a meeting to be organized, convened and funded (i.e., interpretation and facilities) by the United States.

52. The Committee requested the drafting group to ensure that the revised Guidelines should clearly identify the separate but complementary roles, responsibilities and mandates of the Codex Alimentarius Commission and the World Trade Organization, should develop Guidelines that are useful and fully understood by all parties and should seek to resolve all remaining differnces in the interpretation of the text so that the Guidelines might be advanced by the next CCFICS meetning for final adoption by the Commission.

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11 Led by New Zealand with the assistance of the Australian and Codex Secretariats and the participation of Argentina, Australia, Brazil, Canada, France, Germany, Japan, Malaysia, United States, IACFO, ICGMA and the EC.

12 CX/FICS 02/4, CX/FICS 02/4-Add. 1 and CRD 3.

TRACEABILITY IN THE CONTEXT OF FOOD INSPECTION AND CERTIFICATION SYSTEMS (Agenda Item 4bis)[13]

53. As previously decided (see para. 4), the Committee agreed to consider the information paper on Traceability in the Context of Inspection and Certification Systems prepared by the Australian Secretariat under Agenda Item 4bis.

54. The 49th Session of the Executive Committee noted[14] that the Codex Secretariat paper on Traceability[15] had been prepared at the specific request of the CCFICS but treated the issue as a general issue confronting Codex. The Executive Committee noted that the concept of traceability was not new to Codex but that it had not been treated in a systematic manner. The Executive Committee also supported the analysis and approach outlined in the Codex Secretariat paper, pointing out that any measures requiring traceability should be justified as either having a food safety objective (i.e., as an SPS measure) or as having a legitimate objective (i.e., as a TBT measure).

55. The Executive Committee recommended that the Codex Committee on General Principles consider these two aspects of traceability, although it was of the opinion that first consideration should be given to the use of traceability as a risk management option in the draft Working Principles for Risk Analysis. The Executive Committee also noted in particular the role of the CCFICS in relation to the development of procedures for the application of traceability in food import and export inspection and certification systems. The Executive Committee agreed that relevant Codex Committees[16] should undertake work, as they deemed appropriate, within their respective mandates. In this regard, the Committee noted the opinion expressed by the CCFH at its 34th Session that specific work on traceability as related to food hygiene was premature[17]. The Executive Committee also welcomed the suggestion that the Chairpersons of the Committees concerned and the Secretariat should coordinate work so as to avoid a divergence of approach and asked to be kept informed of progress in this work.

56. The Committee noted that the forthcoming Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology would be considering comments on traceability in the context of their work in response to CL 2001/27-FBT. The Committee was also informed of the recent decision of ISO to undertake new work on the elaboration of Traceability System in the Agriculture Food Chain – General principles for Design and Development (ISO/AWI 22519).

57. The Committee noted that the concept of "traceability" was already included in many Codex texts and was linked in most cases to product identification and recall procedures. The Committee also noted that Codex texts generally did not apply traceability to the origin of foods and ingredients although Country of Origin provisions included traceability requirements in at least two Codex texts[18].

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13 CX/FICS 02/INF.2 and comments submitted by the USA (CRD 8).

14 ALINORM 03/3, paras. 29-33.

15 ALINORM 01/21, Part IV–Add.1

16 Including the Codex Committees on General Principles, Food Labelling, Food Hygiene and Food Import and Export Inspection and Certification Systems.

17 ALINORM 03/13, Para. 100.

18 General Codex Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985 Rev.1-1991 (amended 2001)) and Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999, Rev.1-2001) .

58. The Committee noted that traceability might also be used to ensure fair practices as it correlated to the prevention of deceptive practices (e.g., organically produced food) as a legitimate objective described by the WTO Agreement on Technical Barriers to Trade. Within the Australian Secretariat's paper, traceability was described as a means to preserve the identity of the food product and according to several definitions adopted by the Commission, the concept of traceability might be considered to be included as a requirement[19].

59. The Committee was invited by the Australian Secretariat's paper to consider three different issues relating to traceability and inspection/certification systems:

- Whether the existing Codex norms originating in CCFICS were adequate in relation to their applicability to traceability;
- Whether any work currently underway needed to be re-oriented; and,
- Whether any new projects needed to be initiated in order to cover the issue of traceability.

60. Therefore, the Committee was invited to consider different scenarios to address traceability in the context of its mandate such as to acknowledge the fact that inspection and certification may be in some situations be the most efficacious means of implementing a requirement for food to be traceable; to attempt to codify the circumstances in which traceability should be applied as a requirement; and, to note that aspects of traceability were specifically referenced in two texts[20] already adopted by the CCFICS and the Codex Alimentarius Commission.

61. Many delegations expressed their support for CCFICS to consider the development of the concept of traceability in the context of food import and export inspection and certification systems in parallel to work undertaken in other Codex Committees such as the CCGP. The delegation of the USA presented a Conference Room Document supporting the initiation of work on traceability with respect to food safety. Other delegations expressed the view that in consideration of the on-going discussions on traceability in the context of the Working Principles for Risk Analysis, the CCGP should define the overall Codex framework on traceability prior to any work being initiated by other Codex Committees such as the CCFICS.

62. Several delegations stressed the importance of evaluating the cost-benefit of traceability as a requirement when applied to foods, food ingredients and composite foods throughout the entire food chain. It was proposed that the Committee consider practical issues related to traceability such as consignment records, point of application in the food chain, paper records versus electronic records and product markers and the technical and economic costs and benefits of such issues.

63. Several delegations stressed the need for CCFICS to focus its priorities on the application of traceability to food import and export inspection and certification systems in relation to food safety issues, since it was considered as an appropriate tool to trace-back products and would facilitate recall procedures in case of emergency situations. While some delegations recognised the importance of traceability in relation to other legitimate factors, other delegations believed that discussion on traceability in relation to other legitimate factors by the CCFICS was not appropriate at this stage. Other delegations pointed out that it was not desirable to separate the two aspects of traceability as traceability was a means to achieve both food safety objectives but also to promote fair trade practices in food, consistent within the mandate of the Codex Alimentarius Commission.

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19 CX/FICS 02/INF. 2, Para.16-25

20 *Guidelines for the Exchange of Information in Food Control Emergency Situations* (CAC/GL 19-1995) and *Guidelines for the Exchange of Information Between Countries on Rejections of Imported Foods* (CAC/GL 25-1997).

64. The importance in establishing a comprehensive traceability system in order to trace-back and withdraw products from the market, which were susceptible in provoking harmful effects to the health of consumers, e.g. BSE, Dioxin, was stressed. However, considering that traceability should be addressed in a coherent and uniform manner at the Codex level it was recommended by some countries that any new work should be delayed pending the development of clear principles by the CCGP.

65. The importance of addressing cost implications, and the possible denial of market access related to the implementation of traceability, including the subsequent economic impact on production systems for developing countries, and especially the least-developed ones, was also noted.

66. However, it was noted that traceability could lead to economic benefits in certain circumstances and that the costs of the absence of traceability should also be taken into account. In particular, the absence of traceability systems in the production chain and food businesses might actually lead to a lack of control in food-borne disease outbreaks and/or the withdrawal of unsafe foods from the market in emergency situations.

Status of the Consideration of Traceability in the Context of Food Inspection and Certification Systems

67. Considering the relevance of this issue for CCFICS and consistent with the mandate provided by the CCEXEC to identify specific areas for the application of traceability to inspection and certification systems in relation to food safety issues, the Committee decided that a working group led by Switzerland, with the assistance of Argentina, Australia, Bolivia, Brazil, Canada, Chile, France, Germany, India, Ireland, Italy, Japan, Kenya, Korea, Netherlands, Norway, Paraguay, Peru, Philippines, Sweden, Thailand, United Kingdom, United States, the European Commission, Biotechnology Industry Organization (BIO), Confédération des industries agro-alimentaires de l'UE (CIAA), Consumers International (CI), Council for Responsible Nutrition (CRN), Croplife International (GCPF), and International Council of Grocery Manufacturers Associations (ICGMA) and International Federation for Animal Health (IFAH)[21], should draft a discussion paper for circulation, comment and further consideration at its next meeting. The Committee agreed that the discussion paper should specifically address:

- the adequacy and applicability of traceability in existing or pending texts under elaboration by the CCFICS;
- on the basis of the above review, the appropriateness for CCFICS to develop specific guidance on the practical implementation of traceability with respect to food import and export inspection and certification systems, with priorities to be developed in the light of its above discussion;
- the outcome of the Chairpersons meeting[22] from the relevant Codex Committees that was scheduled to meet prior to the 17th session of the CCGP on traceability;
- a time-frame for any new work that CCFICS could undertake with the understanding that this work should not duplicate the work being undertaken by other Committees.

68. The Committee noted that if possible, the document would be discussed at an informal meeting immediately prior to the next CCFICS session, subject to further discussions between the Codex and Australian Secretariats.

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21 Other members can indicate their interest to participate in writing directly to the Codex Secretariat

22 In regard to the Chairperson's Coordination and Advisory Group to facilitate more efficient consideration and finalization of draft standards, the Commission noted that Chairpersons of Codex Committees and Task Forces had been meeting on an informal basis in the margins of some Codex meetings. The Commission agreed that this group should continue to meet, as required, on an informal basis to provide a coordinating role but without the power to take decisions or make recommendations to the Commission (see the Report of the 24th Session of the Codex Alimentarius Commission, ALINORM 01/41, para. 57).

PROPOSED DRAFT GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF TECHNICAL REGULATIONS ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS (Agenda Item 5)[23]

69. The 9th Session of the CCFICS requested a drafting group led by Australia to prepare a revised text on the basis of oral and written comments presented at the meeting for circulation and comment at Step 3 and further consideration at its next session[24]. The Committee was informed that the Guidelines were intimately linked to the on-going discussion on the Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (see agenda item 4).

70. The Committee suggested that the document be further clarified as to its practical scope, purpose and application. It was generally felt that such a text should better focus on judgment of equivalence of procedures and rules to establish technical regulations and the mutual recognition of single measures rather than giving harmonized guidance on the judgement of equivalence of single technical regulations *per se*. It was noted that the inclusion of concrete examples where equivalence between two technical regulations was reached could assist in its application and that an examination of the variations in determination of equivalence in different countries was required. Several delegations were concerned that these guidelines may lead to confusion in regard to the application and status of Codex standards.

71. The Committee agreed that in any case international harmonization on technical regulations was already taking place in other Codex Committees by virtue of their standardization work and that decisions were commonly agreed upon by consensus. The Committee also noted that Objective 1 (Promoting Sound Regulatory Frameworks) of the Commission's draft Medium-Term Plan 2003-2007 as related to Standards Development included the "Application of guidelines on the judgement of equivalence for specific purposes such as equivalence of measures to ensure food hygiene or measures to ensure conformity with essential quality requirements".

72. The Committee agreed that priority should be given to the further elaboration of the draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems for the time being.

Status of the Proposed Draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems

73. The Committee agreed to defer for the time being further drafting of the proposed draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems within the context of the Codex step procedure.

74. The Committee agreed that a drafting group led by Australia, with the assistance of Canada, France, Norway, Papua New Guinea, United States and the European Commission, should prepare a discussion paper for circulation, comment and further consideration at its next meeting, taking into account the above discussions and written comments submitted.

75. The Committee agreed that the paper should examine the need for the elaboration of guidelines on the judgement of equivalence of technical regulations to ensure conformity with essential quality requirements, and presenting pertinent examples for consideration and recommendations relating to the elements for inclusion in a draft guideline.

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23 CX/FICS 02/5 and comments submitted by Argentina, Brazil, Canada, Czech Republic, France, New Zealand, United States (CX/FICS 02/5 Add.1), Mexico (CRD 1), Papua New Guinea (CRD 5) and the European Commission (CRD 9).

24 ALINORM 01/30A, para. 99

PROPOSED DRAFT GUIDELINES FOR THE UTILIZATION AND PROMOTION OF QUALITY ASSURANCE SYSTEMS TO MEET REQUIREMENTS IN RELATION TO FOOD (Agenda Item 6)[25]

76. The 9th Session of the CCFICS requested a drafting group lead by Australia to prepare a revised version of the Guidelines for circulation and comment at Step 3 prior to the current meeting.[26] The Committee considered the proposed draft Guidelines as presented in document CX/FICS 02/6 as the basis for its discussions.

77. The Committee noted that the ISO had recently published Guidelines on the Application of ISO 9001:2000 for the Food and Drink Industry and had also initiated work for the development of ISO 22000 – Food Safety Management Systems – Requirements. The potential development of a related Agricultural Quality System Standard (AG 9000) based on ISO 9000 was also highlighted.

GENERAL COMMENTS

78. The Committee supported the continued elaboration of the Guidelines in principle. However, several delegations suggested that the document should be refocused. This might be done by first drawing up a list of principles to be reflected in the guidelines. Some delegations proposed that the voluntary nature of quality assurance systems should be stressed in that it was the responsibility of the food industry to produce safe food and the responsibility of the competent authorities to ensure the application and enforcement of requirements within this context.

79. Other delegations felt that notwithstanding the notion that the use of quality assurance systems should be promoted, such systems would need to be officially recognized and that private systems should not be considered as equivalent to official controls. It was further noted that international standardization activities did not utilize the concept of quality assurance systems as opposed to the management of such systems. The difficulties in the application of quality assurance systems along with HACCP principles was also noted as a specific problem in developing countries and in this regard, the Codex Committee on Food Hygiene was considering the application of HACCP in small and less developed businesses.

SECTION 1 – SCOPE

80. It was suggested that the Title of the Guidelines should be changed to read as Guidelines for the Utilization and Assessment of Quality Assurance Systems to Meet Requirements in Relation to Foods. It was also noted that the Scope of the Guidelines should be restricted to the official recognition of the requirements in and of themselves as opposed to the quality assurance system in its entirety. In this regard, it was suggested that the notion that the guidelines did not mandate nor promote the use of a particular system needed to be emphasized and that the underlying principle of the specific Codex Principles related to HACCP needed to be stressed.

SECTION 3 – DEFINITIONS

81. The Committee noted the suggestion that the addition of a term and definition for *quality assurance system* was required.

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25 CX/FICS 02/6 and comments submitted by Argentina, Canada, Colombia, New Zealand, United States, European Community (CX/FICS 02/6 – Add. 1), Mexico (CRD 2), India (CRD 3), Thailand (CRD 4), Brazil (CRD 6) and Bolivia (CRD 7).

26 ALINORM 01/30A, paras. 68-69.

SECTION 6 – BENEFITS OF OFFICIALLY RECOGNIZED QUALITY ASSURANCE SYSTEMS

82. It was noted that quality assurance systems did not necessarily ensure that requirements were met and that such systems must contain specific elements to ensure such guarantees. It was further noted that while the official recognition of QA systems might allow competent authorities to modify inspection methods used, this was not a general rule and such benefits were not limited to systems that were officially recognized. They should contain specific elements which help achieve compliance with requirements. It was also suggested that examples illustrating how competent authorities have or could benefit from the use of officially recognized systems would be helpful.

ANNEX I – SUGGESTED ELEMENTS OF A QA SYSTEM FOR FOOD PRODUCTION AND THE IMPLEMENTATION AND MAINTENANCE OF A QA SYSTEM

ANNEX II – HACCP PRINCIPLES AND THE STEPS OF HACCP

83. It was suggested that both Annexes be deleted as elements contained therein were already contained or referenced in other Codex texts.

Status of the Proposed Draft Guidelines for the Utilization and Promotion of Quality Assurance Systems to Meet Requirements in Relation to Food

84. The Committee returned the proposed draft Guidelines to Step 2 so that the document could be reformulated by the drafting group to reflect appropriate principles. The drafting group would be led by Australia, with the assistance of Canada, Denmark, France, India, Japan, the Netherlands, New Zealand, Papua New Guinea, South Africa, Switzerland, United States and the European Commission.

PROPOSED DRAFT REVISION OF THE CODEX GUIDELINES FOR THE EXCHANGE OF INFORMATION IN FOOD CONTROL EMERGENCY SITUATIONS (Agenda Item 7)[27]

85. The 9th Session of the CCFICS requested a drafting group led by Australia 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 with the understanding that this revision was subject to approval as new work by the 24th session of the Codex Alimentarius Commission.[28] The extraordinary 49th session of the Executive Committee of the Codex Alimentarius Commission approved the revision to these Guidelines as new work[29]. The Committee utilized document CX/FICS 02/7 as a basis for its discussions.

86. The Committee was informed that the scope of the revised proposed draft guidelines had been broadened to include issues such as the importance of risk analysis in food emergency situations at various stages of food distribution as well as to include an expanded section on the specific responsibilities of exporting and importing countries. The Committee also noted the proposal for changing the title of *Food Control Emergency Situation* into *Food Safety Emergency Situation* to better reflect the broadened scope of the guidelines. The Committee was also invited to further discuss the revised provisions on the appropriateness, or otherwise, of destruction of lots of food by the importing country, where being identified as having potential adverse effects to the health of the consumers.

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27 CX/FICS 02/7 and comments submitted by Canada, Japan, Mexico and the European Commission (CX/FICS 02/7 Add.1)

28 ALINORM 01/30A, Para. 105

29 ALINORM 03/3, Para. 24 and Appendix III

87. Although it was recognised that the revised text accurately reflected discussions held at its 9th session, the Committee considered proposals related to the reorganization of those sections addressing risk analysis in order to clarify and avoid repetition within the text. The Committee also noted the need to reorganize the different notification procedures as well as the proposed introduction of a specific section on End-of-Emergency Notification. The Committee also noted that in order to better reflect the title of the Guidelines as related to its content, it was proposed to modify the title to read as "Guidelines for Food Safety Emergencies Involving International Trade".

88. In paragraph 2, it was suggested to replace the phrase "clearly identified" with "reason to believe" so as to reflect that management decisions in emergency situations may be based on incomplete results of a risk assessment.

89. In paragraph 6, concerns were expressed that the term "significant" was not appropriate and this should be replaced by "relevant" or other wording to reflect that when scientific uncertainty prevailed, risk management measures may be applied provisionally as set out in Article 5.7 of the WTO SPS Agreement.

90. A complete rewording of paragraph 22 was proposed so as to reflect that "Affected products should either be dealt with by the importing country or returned to the sender. No products should be re-exported to a third country unless the competent authority in that country is fully informed of the nature of the food emergency and has agreed to accept the food."

91. In paragraph 22, the first sentence raised serious concerns vis a vis a possible contradiction with section 4.2 of the *Code of Ethics for International Trade in Food* (CAC/GL 20). It was also proposed that the responsibility of the importing country in taking decisions to re-export food subject to an emergency situation should be further considered.

92. In paragraph 23, it was requested that appropriate specific information on the role that FAO and WHO and other international organizations played in the case of food safety emergency situations should be included.

93. Several delegations expressed their reservation to paragraph 29 in regard to whether the purpose of the guidelines was to define national food emergency plans to be applied by governments or to establish principles for the exchange of information between countries in the case of food safety emergency situations.

Status of the Proposed Draft Revision of the Codex Guidelines for the Exchange of Information in Food Control Emergency Situations

94. The Committee agreed to return the proposed draft *Guidelines for the Exchange of Information in Food Control Emergency Situations* to Step 2 for revision by a drafting group led by Australia and with the assistance of Germany, Japan, Netherlands, Papua New Guinea, the United States and the European Commission. The Committee agreed that the text would be redrafted based on the above discussions and written comments submitted and would take account of the revision currently being undertaken on the Codex Code of Ethics for International Trade in Foods. It was concluded that the revised document would be circulated for comment and further consideration at its next meeting.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 8)

INFORMATION PAPER ON REQUIREMENTS IN INTERNATIONAL TRADE FOR CERTIFICATES FOR FOODS IRRADIATED FOR NON-PHYTOSANITARY PURPOSES [30]

95. The Committee was informed that that the Guideline for the Certification of Foods Irradiated Other than for Phytosanitary Purposes was most recently considered at the 18th Meeting of the Joint FAO/WHO/IAEA International Consultative Group on Food Irradiation (ICGFI) in October 2001, whereby it was decided that the text would be further harmonised with the Codex Guidelines for Generic Official Certificate Formats and the Production and Issuance for Certificates[31] adopted by the 24th Session of the Codex Alimentarius Commission[32].

96. The Committee noted that the CCFICS had not elaborated guidelines for certificates applicable to specific commodities. Certificates applicable to specific commodities were currently being considered by the Codex Committee on Fish and Fishery Products[33] and the Codex Committee on Milk and Milk Products[34]. The Committee also noted that the Codex Committee on Food Additives and Contaminants had been undertaking work related to revisions of the *Codex General Standard for Irradiated Foods* and the *Recommended International Code of Practice for the Radiation Processing of Food.*

97. The Representative of the IAEA informed the Committee that the Guidelines for the Certification of Foods Irradiated Other Than For Phytosanitary Purposes developed by ICGFI were appended to CX/FICS 02/INF.1 and were brought to the attention of the Committee for information only. The IAEA representative indicated that the ICGFI would continue its consistent approach to food safety issues in relation to Codex work.

98. Views were expressed on the importance of food irradiation treatments as an efficient means to ensure food safety. It was also recommended that further work was required in order to achieve a improved consistency between the body of the text and the preamble.

99. The Delegation of Spain, speaking on behalf of the 15 Member States of the European Union, informed the Committee that the requirements established in the ICGFI Guidelines did not meet compliance with the food safety requirements of the EU legislation for irradiated foods since individual premises required approval by the EC and inspection/certification by officials from the individual Member states.

100. It was noted by one delegation and confirmed by the Codex Secretariat that the ICGFI Guidelines had no standing within Codex.

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30 CX/FICS 02/INF.1

31 ALINORM 01/30A, Appendix II

32 ALINORM 01/41, para. 143

33 ALINORM 01/18, paras. 136-140 and Appendix VIII

34 ALINORM 01/11, paras. 129-130

DATE AND PLACE OF NEXT SESSION (Agenda Item 9)

101. The Committee noted that its 11th Session was tentatively scheduled to be held in Australia from 1-5 December 2003. However, in view of the importance of finalizing ongoing work so that it might be considered and adopted by the 25th Session of the Commission in July 2003, the Committee requested that its 11th Session be held in Australia from 24 – 28 February 2003, subject to further discussions between the Codex and Australian Secretariats.

SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE IN ALINORM 03/30
Draft Guidelines for Food Import Control Systems	8	Comments 25th Session of the CAC	Paras. 9-30 and Appendix II
Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems	5-6	Comments Drafting Group Comments 11th CCFICS	Paras. 31-52 and Appendix III
Proposed Draft Guidelines for the Exchange of Information in Food Control Emergency Situations	2-3	Drafting Group Comments 11th CCFICS	Paras. 85-94
Proposed Draft Guidelines for the Utilization and Promotion of Quality Assurance Systems to meet Requirements in Relation to Food	2	Drafting Group Comments 11th CCFICS	Paras. 76-84
Draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems	---	Drafting Group Comments 11th CCFICS	Paras. 69-75
Traceability in the Context of Food Import and Export Inspection and Certification Systems	---	Working Group Comments 11th CCFICS	Paras. 53-68

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APPENDIX II

PROPOSED DRAFT GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS
(Advanced to Step 8)

SECTION 1 -SCOPE

1. This document provides a framework for the development and operation of an import control system to protect consumers and facilitate fair practices in food trade while ensuring unjustified technical barriers to trade are not introduced. The Guideline is consistent with the Codex *Principles for Food Import and Export Inspection and Certification*[1] and provides specific information about imported food control that is an adjunct to the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems*[2].

SECTION 2 – DEFINITIONS [3]

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

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

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

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

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

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

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

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

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

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

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

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1 *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995)

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

3 Definitions drawn from the *Guidelines for the Design, Operation , Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997) are marked with *. Definitions drawn from Codex Alimentarius Commission, Procedural Manual (12th edition) are marked with **.

SECTION 3 - GENERAL CHARACTERISTICS OF FOOD IMPORT CONTROL SYSTEMS

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

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

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

3. Requirements are commonly expressed as end-point standards with specific limits and complementary sampling regimes. These requirements may consist of standards, provisions for sampling, process controls, conditions of production, transport, storage, or a combination of these.

4. The extent and stringency of requirements applied in specific circumstances should be proportionate to risk, noting that risk may vary from one source to another because of factors such as specific and/or similar situations in the region of origin, technology employed, compliance history, etc. and/or examination of relevant attributes of a sample of products at import.

5. As far as possible, requirements should be applied equally to domestically produced and imported food. Where domestic requirements include process controls such as good manufacturing practices, compliance may be determined or equivalence confirmed by auditing the relevant inspection and certification systems and, as appropriate, the facilities and procedures in the exporting country[4].

CLEARLY DEFINED RESPONSIBILITIES OF COMPETENT AUTHORITY OR AUTHORITIES.

6. The competent authority(ies) involved in any of the imported food inspection functions at the point or points of entry, during storage and distribution and/or at point of sale, should have clearly defined responsibilities and authority. Multiple inspection and duplicative testing for the same analyte(s) on the same consignment should be avoided to the extent possible.

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

8. Where the competent authorities of an importing country use third party providers as officially recognised inspection bodies and/or officially recognized certification bodies to implement controls, such arrangements should be conducted in the manner discussed in CAC/GL 26-1997, Section 8, Official Accreditation. The functions that can be conducted by such providers may include:

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[4] *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997), Para. 54.

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

CLEARLY DEFINED AND TRANSPARENT LEGISLATION AND OPERATING PROCEDURES

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

10. Legislation should provide the competent authority with the ability to:

- appoint authorised officers;
- require prior notification of the importation of a consignment of a foodstuff;
- require documentation;
- inspect, including the authority to enter premises within the importing country, physically examine the food and its packaging; collect samples and initiate analytical testing; inspection of documentation provided by an exporting country authority, exporter or importer; and verification of product identity against documentary attestations;
- apply risk-based sampling plans, taking into consideration the compliance history of the particular food, the validity of accompanying certification, and other relevant information;
- charge fees for the inspection of consignments and sample analysis;
- recognize accredited or accredit laboratories;
- accept; reject; detain; destroy; order to destroy; order reconditioning, processing, or re-export; return to country of export; designate as non-food use;
- recall consignments following importation;
- retain control over consignments in transit during intra-national transport or during storage prior to import clearance; and,
- implement administrative and/or judicial measures when the specific requirements are not satisfied.

11. In addition, the legislation may make provisions for:

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

PRECEDENCE TO THE PROTECTION OF CONSUMERS

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

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

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

production, manufacture, importation, processing, storage, and transportation of the food products, and verification of the export food control system applied.

UNIFORM NATION-WIDE IMPLEMENTATION

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

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

15. As an importing country has no direct jurisdiction over process controls applied to food manufactured in another country, there may be a variation in approach to the compliance monitoring of domestic and imported food. Such differences in approach are justifiable provided they are necessary to ensure that the level of protection achieved is consistent with that of domestically produced food.

SECTION 4 - IMPLEMENTATION OF THE CONTROL SYSTEM

16. Operational procedures should be developed and implemented to minimize undue delay at the point or points of entry without jeopardizing effectiveness of controls to meet requirements. Implementation should take into account the factors listed in this section and the possibility of recognizing guarantees at origin that includes implementation of controls in the exporting countries.

POINT OF CONTROL

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

- origin, where agreed upon with the exporting country;
- entry to the country of destination;
- further processing;
- transport and distribution;
- storage; and,
- sale, (retail or wholesale).

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

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

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

INFORMATION ABOUT FOOD TO BE IMPORTED [5]

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

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

- date and point of entry;
- mode of transport;
- comprehensive description of the commodity (including for example product description, amount, means of preservation, country of origin and/or of dispatch, identifying marks such as lot identifier or seal identification numbers etc);
- exporter's and importer's name and address;
- manufacturer and/or producer, including establishment registration number;
- destination; and,
- other information.

FREQUENCY OF INSPECTION AND TESTING OF IMPORTED FOOD

22. The nature and frequency of inspection, sampling and testing of imported foods should be based on the risk to human health and safety presented by the product, its origin and the history of conformance to requirements and other relevant information. Control should be designed to account for factors such as:

- the risk to human health posed by the product or its packaging;
- the likelihood of non-compliance with requirements;
- the target consumer group;
- the extent and nature of any further processing of the product;
- food inspection and certification system in the exporting country and existence of any equivalence, mutual recognition agreements or other trade agreements; and,
- history of conformity of producers, processors, manufacturers, exporters, importers and distributors.

23. Physical checks of imported product, preferably using statistically based sampling plans, should represent valid methods for the verification of compliance with requirements by the product as established by the importing country, or in the case of importing a product for the purposes of re-exportation, verification should be made on the requirements of the country of final destination and said requirements should be specified in the certificate of re-exportation. Inspection procedures should be developed to include defined sampling frequencies or inspection intensities, including for re-exported product.

24. Sampling frequency of products supplied from a source for which there is no or known poor compliance history may be set at a higher rate than for products with a good compliance history provided this is shown through transparent and objective criteria. The sampling process enables a compliance history to be created. Similarly, food from suppliers or imported by parties with a known poor compliance history should be sampled at higher intensity. In these cases, every consignment may need to be physically inspected, until a defined number of consecutive consignments meets requirements. Alternatively the inspection procedures can be developed to automatically detain product from suppliers with a known poor compliance history and the importer may be required to prove the fitness of each consignment through use of a laboratory (including official laboratory) recognized, accredited and/or listed by the competent authority until a satisfactory compliance rate is achieved.

SAMPLING AND ANALYSIS

25. The inspection system should be based on Codex sampling plans for the particular commodity/contaminant combination where available. In the absence of Codex sampling plans, reference should be made to internationally accepted or scientifically based sampling plans.

26. Internationally validated standard methods of analysis or methods validated through international protocols should be used where available. Analysis should be conducted in official or officially accredited laboratories.

DECISIONS

27. Decision criteria (without prejudice to the application of customs procedures) should be developed that determine whether consignments are given:

- acceptance;
- entry if cleared upon inspection or verification of conformance;
- release of non-conforming product after re-conditioning and/or corrective measures have been taken;
- rejection notice, with redirecting product for uses other than human consumption;
- rejection notice, with re-exportation option or return to country of export option at exporter expense;
- rejection notice with destruction order.

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

29. The system should include formal means to communicate decisions regarding clearance and status of consignments.[6] There should be an appeal mechanism and/or opportunity for review of official decisions on consignments.[7] When food is rejected because it fails to meet national standards of the importing country but conforms to international standards, the option of withdrawing the rejected consignment should be considered.

DEALING WITH EMERGENCY SITUATIONS

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

31. If the food control authorities in importing countries detect problems during import control of foodstuffs which they consider to be so serious as to indicate a food control emergency situation, they should inform the exporting country promptly by telecommunication.[8]

RECOGNITION OF EXPORT CONTROLS

32. Consistent with paragraph 12 of these guidelines, the importing country should establish mechanisms to accept control systems in an exporting country where these systems achieve the same level of protection required by the importing country. In this regard, the importing country should:

- develop procedures to conduct assessment of the exporting country systems consistent with the Annex of the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997);
- take into account the scope of the arrangement, for example, whether it covers all foods or is restricted to certain commodities or certain manufacturers;
- develop clearance procedures that achieve its appropriate level of protection if arrangements developed with an exporting country are limited in scope;

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6 Paragraph 4 of the *Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food* (CAC/GL 25-1997) should be consulted in this regard.

7 Paragraph 6 of the *Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food* (CAC/GL 25-1997) should be consulted in this regard.

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

- provide recognition of export controls through, for example, exemption from routine import inspection;
- conduct verification procedures for example, occasional random sampling and analysis of products upon arrival. (Section 5 and Annex of CAC/GL 26-1997 deal with the provision and verification of systems that provide certification for food in trade);
- recognize that arrangements need not rely on the presentation of certificates or documentation with individual consignments, when such an approach is acceptable to both parties.

33. The competent authority of the importing country may, develop certification agreements with exporting country official certification bodies or officially recognized certification bodies, with the aim of ensuring requirements are met. Such agreements may be of particular value where, for example, there is limited access to specific facilities such as laboratories and consignment tracking systems.[9]

INFORMATION EXCHANGE

34. Food import control systems involve information exchange between competent authorities of exporting and importing countries. The information may include:

- requirements of food control systems;
- "hard copy" certificates attesting to conformity with requirements of the particular consignment;
- electronic data or certificates where accepted by the parties involved;
- details about rejected food consignment, such as destruction, re-exportation, processing, re-conditioning or redirection of consignment for uses other than human consumption;
- list of establishments or facilities that conform to importing country requirements.

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

OTHER CONSIDERATIONS

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

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

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 food import control systems should include:

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

- an organizational chart of the official inspection system, including geographical location and the roles of each level in the hierarchy;
- job functions as appropriate;
- operating procedures including methods of sampling, inspection and testing;
- relevant legislation and requirements that should be met by imported food;
- important contacts;
- relevant information about food contamination and food inspection; and,
- relevant information on staff training.

TRAINED INSPECTORATE

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

42. Where third parties are officially recognised by the competent authority of the importing country to perform specified inspection work, the qualifications of the inspection staff should be at least the same as inspection staff of the competent authority who may carry out similar tasks.

43. The competent authority of the importing country responsible for conducting assessment of food control systems of exporting countries should engage personnel with appropriate qualifications, experience and training required of personnel assessing domestic food controls.

SYSTEM VERIFICATION

44. Verification should be carried out on the basis of Section 9 of the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997) and the food import control system should be independently assessed on a regular basis.

SECTION 5 - FURTHER INFORMATION

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

APPENDIX III

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

(at Step 5)

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.[1]

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

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

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

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.[3]

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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[3] 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.[4] 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[5].

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.

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.[6]

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

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

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.

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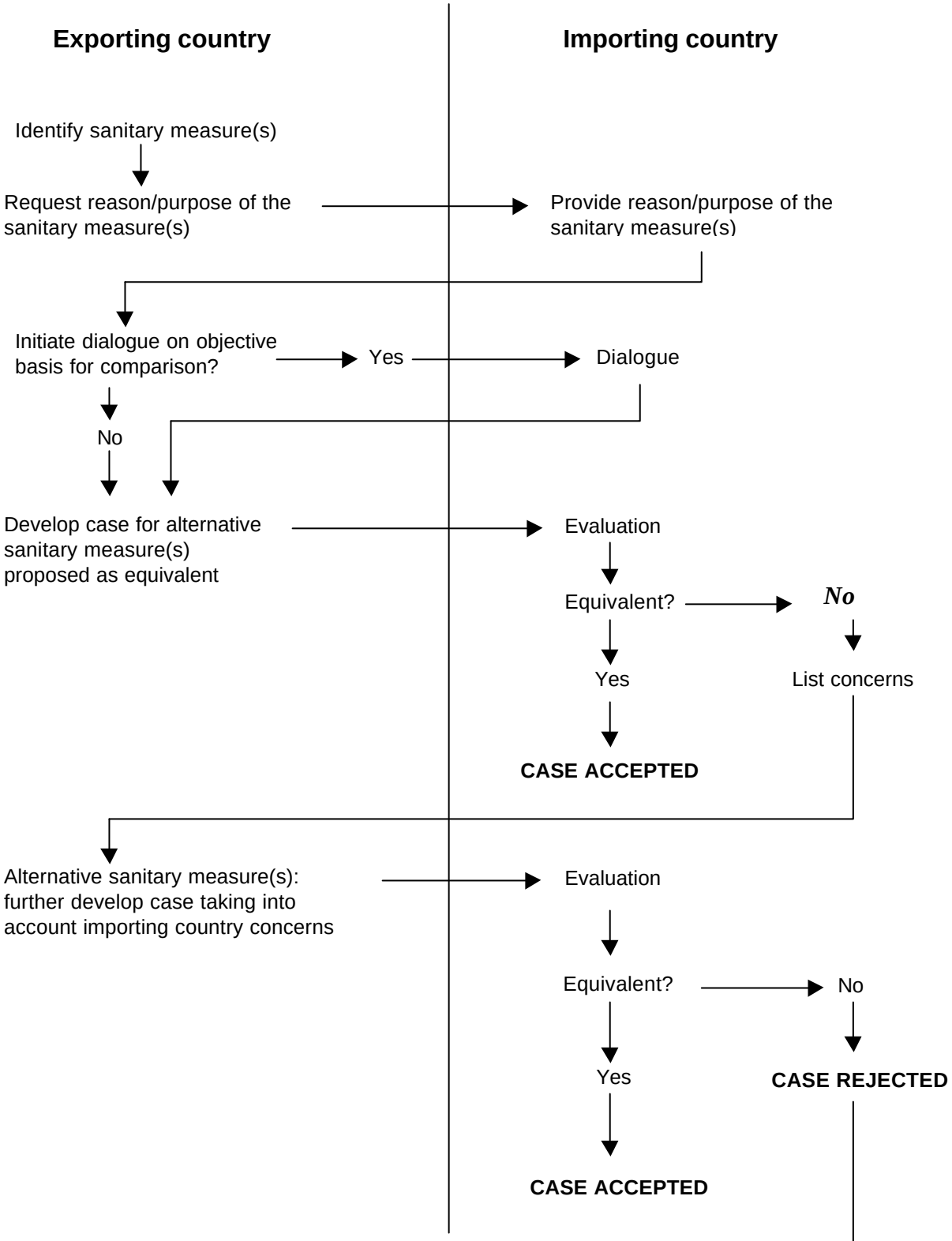
[6] Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems; CAC/GL 34-1999.

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



(a) Possible resolution of different opinions on case for equivalence