

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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ALINORM 99/30A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

23rd Session, FAO Headquarters, Rome, 28 June – 3 July 1999

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

Melbourne (Australia), 22 – 26 February 1999

LIST OF ABBREVIATIONS USED IN THIS REPORT:

ALINORM	Report of Codex Committees and other working papers submitted to the Codex Alimentarius Commission
CCFICS	Codex Committee on Food Export and Import Inspection and Certification Systems
CRD	Conference Room Document
CX/FICS	Working papers for the Codex Committee on Food Export and Import Inspection and Certification Systems
FAO	Food and Agriculture Organization of the United Nations
GATT	General Agreement on Tariffs and Trade
HACCP	Hazard Analysis and Critical Control Point (System)
IHR	International Health Regulations
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization and standards produced by this body
SPS	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
TBT	WTO Agreement on Technical Barriers to Trade
WHO	World Health Organization
WTO	World Trade Organization

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CL 1/1999-FICS

TO: Codex Contact Points
Interested International Organizations

FROM: Secretary, Codex Alimentarius Commission

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

DEADLINE: **30 April 1999**

ADDRESS FOR COMMENTS: Secretary, Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme
FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy
Fax: +39 (06) 5705.4593
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The Report of the Seventh Session of the Codex Committee on Food Import and Export Inspection and Certification Systems is attached. It will be considered at the Twenty-third Session of the Codex Alimentarius Commission, Rome, 28 June – 3 July 1999.

MATTERS FOR CONSIDERATION BY THE COMMISSION

TEXTS SUBMITTED TO THE COMMISSION FOR ADOPTION

The Committee advanced the *Draft Guidelines for the Development of Equivalence Agreements regarding Food Import and Export Inspection and Certification Systems* to Step 8 of the Uniform Procedure for the Elaboration of Standards and Related Texts (paragraph 30 and Appendix II). This text is now submitted to the Commission **for adoption**. Governments and Interested International Organizations wishing to comment on the may do so in conformity with the Uniform Procedure for the Elaboration of Standards and Related Texts: Guide to the Consideration of Standards at Step 8 of the Procedure (Procedural Manual of the Codex Alimentarius Commission, Tenth Edition, page 24). Comments should be sent to the Secretary of the Codex Alimentarius Commission at the address indicated above, not later than **30 April 1999**.

APPROVAL OF NEW WORK

The Commission is invited to approve the following new work at Step 1 of the Uniform Procedure for the Elaboration of Standards and Related Texts: Guide to the Consideration of Standards:

- Proposed Draft Guidelines for the Judgement of Equivalence of Sanitary Measures associated with Food Inspection and Certification Systems (*paragraph 81*)
- Proposed Draft Guidelines for the Utilization of and Promotion of Quality Assurance Systems (*paragraph 93*).

OTHER MATTERS REFERRED TO THE COMMISSION

The Committee requested the advice of the Executive Committee and the Commission on how to proceed on the matter of judgement of equivalence of technical regulations other than sanitary measures (*paragraph 84*).

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

Summary and Conclusions

MATTERS FOR CONSIDERATION BY THE CODEX ALIMENTARIUS COMMISSION

The Committee:

- advanced the Draft Guidelines for the Development of Equivalence Agreements regarding Food Import and Export Inspection and Certification Systems to Step 8 (paragraph 30 and Appendix II).
- requested the Commission to approve the following new work –
 - *Proposed Draft Guidelines for the Judgement of Equivalence of Sanitary Measures associated with Food Inspection and Certification Systems* (paragraph 81)
 - *Proposed Draft Guidelines for the Utilization of and Promotion of Quality Assurance Systems* (paragraph 93).

OTHER MATTERS REFERRED TO THE COMMISSION

The Committee:

- requested the advice of the Executive Committee and the Commission on how to proceed on the matter of judgement of equivalence of technical regulations other than sanitary measures (paragraph 84).

OTHER MATTERS

The Committee:

- agreed that the *Proposed Draft Guidelines/Recommendations for Food Import Control Systems* should be redrafted and restructured prior to being circulated for comment at Step 3 (paragraph 53);
- agreed that the *Proposed Draft Guidelines and Criteria for Official Certificate Formats and Rules relating to the Production and Issuance of Certificates* be revised with a view towards circulating the text formally for comments at Step 3 of the Codex Procedure (paragraph 68);
- agreed that all relevant Codex Committees would be informed of the current status of the *Proposed Draft Guidelines for the Judgement of Equivalence of Sanitary Measures associated with Food Inspection and Certification Systems*, bearing in mind that the Guidelines could have implications for their current and future work programmes (paragraph 83);
- requested the advice of Legal Counsel as to whether the activities proposed in the *Discussion Paper on Guidelines for the Establishment of a Database on Importing Country Legislation* fell within the mandate of the Codex Alimentarius Commission and the Terms of Reference of the Committee (paragraph 99); and
- requested the opinion of the Codex Committee on General Principles on the status of the activities proposed in the *Discussion Paper on Guidelines for the Establishment of a Database on Importing Country Legislation* in relation to the ongoing work of revising the Codex Acceptance/Notification Procedure (paragraph 99).

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

Melbourne (Australia), 22-26 February 1999

INTRODUCTION

1. The Seventh Session of the Codex Committee on Food Import and Export Inspection and Certification Systems was held in Melbourne, Australia from 22 to 26 February 1999, at the kind invitation of the Government of the Commonwealth of Australia. Mr. Digby Gascoine, Director, Policy and International Division, Australian Quarantine and Inspection Service chaired the Session. It was attended by 186 participants representing 45 Members of the Commission, 1 Observer country and 18 international organizations. A complete list of participants, including the Secretariat, is given in Appendix I.

2. The Honourable Senator Judith Troeth, Parliamentary Secretary to the Minister for Agriculture, Fisheries and Forestry in officially welcoming delegates to the meeting, reflected on the Committee's performance record in dealing with contemporary and frequently conceptually and technically difficult issues associated with food inspection and certification systems. The Senator noted that there had been a change to the culture behind food law and to the culture within food producing industries; the fundamentals for this change included: increasing consumer demands for safe food; the emergence of new and more virulent hazards capable of being conveyed in food; and the need to secure adequate food and nutrition for all of the world's population. She noted the enormity of the task for governments in responding to the changing environment that required food regulation to be flexible and adaptive in responding to developments such as the discovery of new food-borne pathogens, new behaviours of pathogens, and new technologies like genetic modification. Governments at the meeting were encouraged to work together, to take every opportunity to collectively examine ways to achieve an international response that will contribute to a global food supply that is safe and abundant, and that contributes to the economic stability of nations.

3. Mr. John R. Lupien, Director, Food and Nutrition Division, FAO responded on behalf of the Directors-General of FAO and WHO and thanked Senator Troeth for her remarks and the Government of Australia for its kind hospitality. He drew attention to the critical importance of the work of the Committee which was aimed at allowing Codex member countries in their programmes to assure effectively the quality and safety of their food imports and exports and foods in domestic markets. He noted that protecting the health and well-being of consumers had wider quality aspects since many food related health or economic risks were virtually impossible for consumers to detect. These could only be controlled by proper food production, storage, processing and marketing systems that started at the point of production and ensured proper inputs and practices throughout any food chain.

4. Mr. Lupien recalled the Conference held in Rome in March 1991 on *Food Standards, Chemicals in Food and International Trade* to examine the likely impact of the GATT Uruguay Round discussions on Sanitary and Phytosanitary Measures and on Technical Barriers to Trade. In light of the new round of WTO discussions to begin soon, FAO was convening a new inter-governmental Conference on *Food Trade Beyond the Year 2000: Science-Based Decisions, Harmonization, Equivalence and Mutual Recognition*, in cooperation with WHO and WTO. Mr. Lupien announced that thanks to the kind hospitality of the Commonwealth of Australia, the State of Victoria and the City of Melbourne that this Conference will be held in Melbourne in October 1999.

ADOPTION OF THE AGENDA (AGENDA ITEM 1)

5. The Committee adopted the Provisional Agenda¹ as the Agenda for the Session.

MATTERS REFERRED FROM CODEX COMMITTEES (AGENDA ITEM 2)²

6. The Committee was informed of the response of the Chair of the SPS Committee with regard to the request made by the 22nd Session of the Commission to obtain clarification on how the Committee would “differentiate standards, guidelines and other recommendations” in response to the SPS Agreement. The Committee noted the opinion of the Executive Committee (June 1998).

7. The Committee noted that the 22nd Session of the Codex Committee on Methods of Analysis and Sampling had agreed to refer “Criteria For Evaluating Methods of Analysis For Codex Purposes” (Annex of CX/FICS 99/2) which deals with trade dispute situations to this Committee for consideration. The Committee decided to discuss this matter under Other Business and Future Work (see paras. 100 - 102).

8. The Committee also noted that most of other items would be discussed under relevant agenda items.

9. The representative of WHO informed the Committee of the progress on the revision process of the International Health Regulation (IHR). The Committee was informed that the first version of the proposed revised International Health Regulation was distributed to WHO Member States in February 1998. The second revision would be circulated to WHO Members and other relevant international organizations for further consultation within 1999 taking into account the evaluation of pilot studies on the “Notification of Syndromes”.

DRAFT GUIDELINES FOR THE DEVELOPMENT OF EQUIVALENCE AGREEMENTS REGARDING FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (AT STEP 7)(AGENDA ITEM 3)³

10. The Committee noted that work on the Guidelines had been initiated following a proposal made by the Delegation of the USA at its Third Session (1995) and that the 21st Session of the Commission (1995) had approved the elaboration of the Guidelines. In introducing the document, the Delegation of the USA stated that the Guidelines described the nature and content of equivalence agreements for food import and export inspection and certification systems and set out a process whereby such agreements could be established between trading partners. The Representative of the WTO noted with satisfaction the progress that had been made to date on the Guidelines.

11. Several Spanish-speaking delegations noted problems in the Spanish version of the text and the Committee agreed that the Delegation of Argentina would act as rapporteur for the final version of the draft text in Spanish. Therefore, comments raised that related only to the Spanish text are not generally reported here.

TITLE

12. No changes were made.

SECTION I - SCOPE

13. It was noted that the English version of the text referring to “less formal” agreements was the correct interpretation of the meaning of this provision (rather than “informal”).

¹ CX/FICS 99/1

² CX/FICS 99/2

³ ALINORM 99/30, Appendix II; CL 1998/6-FICS (Request for comments at Step 5); CL 1998/20-FICS (Request for comments at Step 6); CX/FICS 99/3 (Comments of Egypt, Slovak Republic, USA, OECD); CRD 1 (Comments of Chile, Cuba, Malaysia, Spain, Thailand, Uruguay), CRD 4 (Comments of Japan); CRD 5 (Comments of EC); CRD 8 (Comments of India).

SECTION 2 - DEFINITIONS

14. The Committee decided to retain those definitions that had already been agreed to in other texts and that had been approved by the Commission. It also decided to retain the full text of these definitions rather than make cross-references to them, in order that the final text would be complete and self-contained. It was noted that the term “government agency” was equivalent to the term “government body” for the purpose of this document. The Delegation of Indonesia proposed that a definition of the term “competent authority” be included in the text.

SECTION 3 - PURPOSE OF AGREEMENTS

15. The Committee agreed to extend the purpose relating to the use of collective resources to indicate that these would be used “more efficiently and effectively”.

SECTION 4 – TYPES OF AGREEMENTS

16. The Committee agreed to change the title of this Section to “Scope and Types of Agreements” for clarity and consistency with the content of the Section. A paragraph (former paragraph 14) that dealt with consideration of the exporting country’s measures rather than with the type of agreement was transferred to the following Section.

17. The Committee agreed with the comments of several countries that the agreements to be covered by this text were those that dealt with the equivalence of systems rather than requirements *per se* and made the necessary changes to the text. In order to remove any ambiguity and to make a positive statement, it was agreed to reword the sentence that indicated that agreements “may be entered into where equivalence has been established in respect of some or all requirements”. This provided flexibility in cases where not all requirements were covered by the agreement.

SECTION 5 – CONSIDERATIONS BEFORE ENTERING INTO BILATERAL OR MULTILATERAL DISCUSSIONS

18. The Committee agreed to reword the paragraph dealing with the establishment of priorities for consultations dealing with the development of agreements. It also agreed to reword the paragraph dealing with the provision of technical assistance to indicate the appropriate relationship between importing developed countries and exporting developing countries.

SECTION 6 – INITIATING DISCUSSIONS TOWARDS AN EQUIVALENCE AGREEMENT

19. The Committee noted that the text provided for cases where the importing country would have difficulty in responding to requests for the establishment of an agreement. It was noted that the SPS Agreement obliged WTO Members to enter into consultations if requested to do so (Article 4.2). However, the Committee noted that the Guidelines were applicable also to provisions covered by the TBT Agreement where no such obligation was mentioned and were for use by all countries, not only WTO Members. The relevant paragraphs were amended to take these matters into consideration in a way that did not affect either the rights or obligations of WTO Members under the SPS Agreement. It was also agreed that responses to requests for consultations should be made in a timely manner. A paragraph relating to the provision of relevant information needed for the consultative process was deleted as the required details had been set out in another Section of the Guidelines.

SECTION 7 – CONSULTATIVE PROCESS FOR EQUIVALENCE AGREEMENTS

20. The Committee agreed to a number of improvements to the text of this Section in the use of the terms “risk” and “hazard” and to emphasize that the agreements covered by the Guidelines referred to control measures and not to requirements *per se*. It was agreed to retain the separate references to equivalence agreements for food safety (sanitary) control measures and to equivalence agreements for other relevant requirements for food. The text dealing with the first of these references was amended for consistency with the SPS Agreement.

21. The Committee noted several references to “participating competent authorities” and recalled that the roles and responsibilities of “competent authority(ies)” were covered by the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and*

*Certification Systems*⁴, adopted by the Commission in 1997, especially the Section dealing with Inspection and Certification System Infrastructure. However, it agreed to replace reference to “competent authorities” with a reference to “participants in the agreements” where possible, this being more correct in the context of this Section of the Guidelines.

22. The Committee agreed to include a provision for the development of procedures to allow the importing country to reexamine products to verify that an exporting country had corrected deficiencies.

23. The Committee debated the provision relating to the enhancement of public confidence in the agreement. Several delegations were of the opinion that the negotiating process was primarily a matter of government-to-government relations and that non-governmental participation in this process was a matter for individual governments to decide in accordance with national legislative and regulatory processes. These delegations were of the view that the text as written was too prescriptive and preferred to use the word “may” as the operational verb in this sentence. Other delegations and the observers from IFOAM, Consumers International and WTO drew attention to the transparency provisions of the adopted *Codex Principles for Food Export Inspection and Certification* and the general approach of the Commission towards transparency. These delegations preferred to use the word “should” as the operational verb in this sentence.

24. The Committee agreed to modify the paragraph by introducing a phrase to protect legitimate confidentiality, consistent with the transparency provisions of the *Codex Principles for Food Export Inspection and Certification*. The Committee also decided to retain the use of the word “should”. The Delegations of Egypt, Malaysia, Singapore, Uruguay and Vietnam reserved their positions in relation to this decision on the use of the word “should”.

25. In the same paragraph, the Committee also agreed to change the word “basis” in the original text to “content”. Several delegations stated that they preferred to use the broader term “basis”.

SECTION 8 – PILOT STUDIES

26. Some Delegations questioned the need for this Section and its practical application in the development of equivalence agreements. The delegations of Australia and Botswana noted that in their experience, pilot studies had proved to be practical and useful and that in any case the provisions of this Section were entirely optional. The Committee agreed to retain the text.

SECTION 9 – DRAFTING THE AGREEMENT

27. No changes were made to this Section.

SECTION 10 – IMPLEMENTING THE AGREEMENT

28. The Committee agreed that proposals for new or revised measures that pertain to the agreement should be notified instead of the finalized measures, in order to be consistent with the obligations of WTO Members under the SPS and TBT Agreements.

APPENDIX A – CONTENTS OF EQUIVALENCE AGREEMENTS

29. The Committee agreed to the contents of the Appendix with small changes to the *château* and to the paragraph on *Sample Collection*. Separate provisions were made regarding *Entry into Force* and for the *Review, Modification and Termination of the Agreement*, primarily for clarity. The paragraph dealing with *Signatures* on the Agreement was also modified for the sake of clarity.

STATUS OF THE DRAFT GUIDELINES FOR THE DEVELOPMENT OF EQUIVALENCE AGREEMENTS REGARDING FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

30. The Committee agreed to advance the *Draft Guidelines for the Development of Equivalence Agreements regarding Food Import and Export Inspection and Certification Systems* to Step 8 for

⁴ Reference to be included.

consideration by the 23rd Session of the Commission. The revised text of the Draft Guidelines is attached as Appendix II to this report.

31. The Delegation of Chile expressed its reservation with regard to the integrity of the new version of the Spanish text, in particular with the procedure followed whereby not only were comments translated, but the entire text had been re-translated. This had resulted in the new Spanish text differing from the previous text in paragraphs where no decision had been made by the Committee to make amendments. The Delegation of Spain expressed the same reservation.

32. The Delegation of Argentina clarified that the reservation expressed by Chile was unrelated to the responsibility given to it by the Committee (see para. 11 above).

PROPOSED DRAFT GUIDELINES/RECOMMENDATIONS FOR FOOD IMPORT CONTROL SYSTEMS (AGENDA ITEM 4)⁵

33. The Committee noted the background of the document and the fact that the 45th Session of the Executive Committee (June 1998) had approved the elaboration of the proposed draft Guidelines/Recommendations as new work at Step 1.⁶ The Delegation of Mexico introduced the paper and emphasized that the guidelines/recommendations should guarantee the safety of food and rapid entry into the country of destination. The Committee was informed that the text prepared incorporated the comments received from Germany, Australia, Egypt, United States and the Netherlands and the principles of FAO Manual of Food Quality Control. Imported Food Inspection (Food and Nutrition Paper 14/15, 1993) and WHO Manual for Inspection of Imported Food (1992) were applied.

34. The Committee agreed to receive the views of participating delegations on the document taking into account the fact that the text had not been formally circulated to governments and interested international organizations for comments. The Committee discussed Annex 1 to the working document containing the proposed draft *Guidelines/Recommendations for Imported Food Control Systems* section by section.

GENERAL ISSUES

35. The Committee thanked the delegation of Mexico for the paper, which received wide support from the delegations. Several delegations expressed their intention to move forward while some delegations were generally of the opinion that further elaboration of the paper should be made and the work in this area should proceed carefully and gradually.

36. The Delegation of Germany speaking on behalf of the Member States of the European Union present at the Session⁷, expressed its concern that the text presented only one possible model and that there were different ways of achieving the same results (such as systems of “self-checking”). The representative stated that the text should be developed only as an Information Paper and the heading of the text should be changed as such, although it was noted that such texts had not been published in the Codex Alimentarius. These views were supported by the Delegation of Switzerland. The Delegation of Malaysia wished the text to remain as an information paper and not as a guideline in view of the problems faced by many developing countries in setting up infrastructure such as communication systems and the application of risk assessment. The Delegation of the Republic of Korea supported this view.

37. Several delegations stated that the paper should take into account the relative responsibilities of the importing and exporting countries. It was pointed out that it was the responsibility of the producers, exporters and importers to comply with the regulatory requirements established by the importing

⁵ CX/FICS 99/4; CRD 5 (Comments of EC); CRD 8 (Comments of India)

⁶ See ALINORM 99/3, Appendix 3.

⁷ Except where otherwise indicated throughout this report, the Delegation of Germany spoke on behalf of the Member States of the European Union present at the Session.

country and that it was the responsibility of the governments to show that these requirements had been met.

38. Several delegations stated that the structure of the proposed guidelines needed to be changed so as to be more consistent with operations rather than following a series of principles. It was noted that this would require a very substantial redrafting of the document.

39. A question was asked about the difference between guidelines and recommendations under the WTO Agreements. The Committee noted the opinion of the 45th Session of the Executive Committee on this matter and the comments of the Chairman of the WTO SPS Committee⁸.

SCOPE

40. Several delegations expressed their opinion that the scope of the paper should be extended to cover consumer protection issues such as fraud as well as food safety. Some delegations recommended deletion of the reference to the determination of equivalence.

DEFINITIONS

41. The Committee noted that the definitions conform to those of the Procedural Manual and other texts adopted by the Commission.

SECTION 3 - TRANSPARENT SYSTEM WITH DOCUMENTED PROCEDURES AND STANDARDS

42. It was suggested that this section should refer to *Food Import Control Inspection Systems*, rather than *Food Import Control Systems*. It was also suggested that reference should be made to the **timeliness** of communication and dissemination of information on regulations, policies and guidelines applied by an importing country.

SECTION 4 - CLEARLY DEFINED AUTHORITY FOR LEGISLATION, REGULATION AND OFFICIAL INSPECTION SYSTEM

43. The Committee agreed to delete reference to the possible extension of sovereignty of a country to food production controls in other countries.

44. Several delegations expressed the need to further elaborate the issues related to use of third party organizations for inspection, testing and analysis, and certification. The representative of WTO explained that the SPS and TBT Agreements did allow the use of third party inspections. It was also noted that such “officially recognized systems” were included in the Codex Principles for Import and Export Inspection and Certification.

45. The Delegation of Germany speaking on behalf of the Member States of the European Union present at the Session requested that reference to “pre-authorization acceptance” of imported foods be deleted.

SECTION 5 - APPLICATION OF RISK ANALYSIS

46. Several delegations questioned the statement that resources should determine priorities in regard to risk analysis, and stated that priorities should be determined on the basis of risks to public health. Delegations also expressed concern at the emphasis on lot-by-lot inspection in this section, stating that such a procedure was unusual and very burdensome. It was requested that the term “history of compliance” be qualified.

47. There was considerable concern about the proposal that exporting countries should collect and disseminate epidemiological data on food-borne illnesses. A number of delegations requested that this provision be deleted from the guidelines or else be placed in a framework where there was equivalent responsibilities between the importing and exporting countries. The Representative of Consumers International supported retention of the provision. It was noted that such information was being collected and disseminated within the context of other programmes.

⁸ CX/FICS 99/2

SECTION 6 – A FOOD IMPORT CONTROL SYSTEM SHOULD BE CONSISTENTLY IMPLEMENTED AND PROVIDE FOR PARITY WITH DOMESTIC CONTROL

48. A number of delegations drew attention to the fact that it was not always possible to apply the same requirements to imported foods as apply to domestic products. The Observer from the WTO clarified that the WTO SPS and TBT Agreements did not require this, but required that imported goods received no less favorable treatment than domestic goods, bearing in mind the objectives of the relevant requirements.

49. Questions were raised about some of the obligations implied in the proposal that Food Import Inspection Systems should be fully documented, and what this would mean for those developing countries that had inadequate infrastructures. It was suggested that specific, quantifiable criteria might need to be established in order to meet the obligations of this requirement.

50. Several delegations referred to the need to defining the point of entry. It was also suggested that provision should be made for inspection of food in transit from one country to another and also via a third country.

SECTION 7 – RECOGNITION OF FOOD SAFETY CONTROLS IN THE EXPORTING COUNTRY

51. As noted above, it was suggested that this section should be expanded to cover other requirements, not only food safety controls. It was also suggested to include the concept that developed importing countries should provide assistance to developing countries to assist them to establish control systems and standards that would meet the level of protection desired by the importing country.

SECTION 8 – ADHERENCE TO THE CODEX “CODE OF ETHICS FOR INTERNATIONAL TRADE IN FOODS”

52. It was suggested that this section should be brought into line with the relevant Codex documents quoted and that the responsibilities of the importing and exporting parties and authorities be better defined. It was suggested that this section should contain a provision for feedback of information to the exporting country in order to improve the future level of compliance with import requirements.

STATUS OF THE PROPOSED DRAFT GUIDELINES/RECOMMENDATIONS FOR FOOD IMPORT CONTROL SYSTEMS

53. The Committee agreed that the Proposed Draft Guidelines/Recommendations should be redrafted and restructured prior to being circulated for comment at Step 3. The Committee appointed a drafting group consisting of Australia, Canada, France, Germany, Japan, Netherlands, South Africa and the USA to undertake the revision. The Delegation of Mexico and the Australian Secretariat would coordinate this work.

PROPOSED DRAFT GUIDELINES AND CRITERIA FOR OFFICIAL CERTIFICATE FORMATS AND RULES RELATING TO THE PRODUCTION AND ISSUANCE OF CERTIFICATES (AGENDA ITEM 5)⁹

54. The Committee noted the background to the document and the fact that the 45th Session of the Executive Committee had approved the development of the draft guidelines as new work at Step 1 of the Procedure¹⁰. The paper was introduced by the delegations of United Kingdom and Australia, the author countries. As the text had not been formally circulated to governments and interested international organizations for comment, the Committee agreed to receive the views of participating delegations on the document. The debate focussed on the Annex to the working document containing the proposed draft *Guideline and Criteria for a Generic Official Certificate Format*.

⁹ CX/FICS 99/5; CRD 2 (Comments of USA); CRD 5 (Comments of EC); CRD 7 (Draft Model Certificate for Fish and Fishery Products, prepared by Canada and Norway on behalf of the Codex Committee on Fish and Fishery Products); CRD 8 (Comments of India).

¹⁰ See ALINORM 99/3, Appendix 3.

GENERAL ISSUES

55. Several delegations stressed the urgency of finalizing work on the Guidelines in order to provide a framework for the development of certificates for specific commodities by Codex Commodity Committees. Nevertheless, there was a general opinion that the document needed to be redrafted to take into account a number of related issues, including many that were raised in the debate reported below. It was also suggested that the document should deal with the proper attestation of certificates following consignments that were split before final destination.

TITLE

56. Most of the comments supported the use of an expanded title consistent with the title of the text as approved by the Executive Committee or the full title as indicated in the present Agenda Item. It was noted, however, that the Committee had the right to propose changes to this title as might be required during the subsequent elaboration of the text.

OBJECTIVES

57. Several Delegations stressed the need to include a consideration of the principles or rationale behind the use of certificates that would contain in particular a statement to the effect that certification was non-mandatory and that other procedures such as mutual recognition agreements could be used in place of certificates. It was also indicated that the guidelines should cover the development of certificates and their management and that the actual format of and content of certificates should be developed by individual Codex Commodity Committees or other parties for areas not covered by Codex work. The need to make provisions for electronic forms of certificates was highlighted by several delegations.

GENERAL FORMAT OF CERTIFICATE

Standard Format

58. Several delegations noted that this sub-section did not deal with matters concerning the Standard Format and therefore a re-organization or re-ordering of the paragraphs would be required. It was suggested that the headings "General Format of Certificate" and "Criteria" be exchanged. It was suggested that there was a need for the text to be more explicit or more detail provided in relation to the identification and/or nature of the product. It was also pointed out that the document did not seem to cover all available forms of certificates and their type and characteristics (sanitary or quality certificates; certificates covering mixed consignments; multiple but connected pages to single certificates; etc.). It was further stressed that the text should specify that there should be one Original certificate regardless of the number of copies and that one copy of the certificate as well as the identification number should be retained by the certifying authority.

59. In addition it was proposed that any change in the circumstances of the certifying authority be communicated promptly to the importing country. Some delegations recommended that some of the terms used in the text (attestation, seal, approved stamp, etc.) should be defined and that the period of validity of the certificate should bear an appropriate relationship with the life of the product.

60. In regard to the languages to be used in certificates, it was proposed that certificates should be in a language comprehensible to the certifying officer and in at least one of the official languages of the country of destination.

Responsibilities of Certifying Officers

61. Some delegations suggested that this section should be deleted since it was not consistent with the purpose of the document. A number of delegations were of the opinion that this section should describe the obligations and responsibilities of certifying authorities and certifying officers and should make reference to issues such as;

- certifying officers should have due authority to issue certificates;
- linkages to the Codex *Principles of Food Import and Export Inspection and Certification*;

- the independence of certifying officers.

62. Several delegations drew attention to the conceptual and practical problems inherent in certifying information ascertained by a person other than the certifying officer. They were of the opinion that this provision required further elaboration to provide for, *inter alia*, attestations in writing, information derived from other competent authorities, and information obtained from official or officially recognized food quality and safety programmes or systems.

Instructions for Completing the Form

63. It was noted that this sub-section contained provisions related to completing and issuing of certificates and should therefore be re-titled. It was also pointed out that there was no provision for electronic forms of certification. Several delegations requested clarification of the persons and/or authorities to which the original and copies of the certificate should be provided.

64. Several delegations were of the opinion that the rules for the issuance of “Duplicate” certificates should be expanded and should indicate that such certificates were issued as full replacements for original certificates that were then no longer valid.

65. It was pointed out that several of the details contained in this sub-section were either not essential or were not practical, such as the provision that certificates should not be capable of being photocopied.

CRITERIA

66. Several delegations questioned the specific criteria proposed for inclusion in certificates. In particular, it was suggested that “consignee” or “port of entry” should replace the term “product destination” and that reference should also be made to the “consignor”. Many delegations questioned the provision requiring the certificate to specify the country of origin of ingredients, stating that this would be either impossible or at least very difficult and some delegations suggested deleting this provision. It was proposed that there be a definition of “country of origin” that would take into account the country of despatch, country of processing and country of production.

67. It was suggested that for products that needed to be held or transported under specific temperature conditions, that these conditions should also be specified on the certificate.

STATUS OF THE PROPOSED DRAFT GUIDELINES AND CRITERIA FOR OFFICIAL CERTIFICATE FORMATS AND RULES RELATING TO THE PRODUCTION AND ISSUANCE OF CERTIFICATES

68. The Committee noted the interest in this work, but agreed that further work and additional contributions were required in order to agree upon an appropriate text. The Committee agreed to request the Delegations of the United Kingdom and Australia to re-draft the Guidelines in light of the views expressed in the present discussion and in the Conference Room Documents with a view towards circulating the text formally for comments at Step 3 of the Codex Procedure and consideration at its next Session.

DISCUSSION PAPER ON ISSUES RELATING TO THE JUDGEMENT OF EQUIVALENCE (AGENDA ITEM 6)¹¹

69. The Committee recalled its discussions on this matter at its previous session and the consideration given to the subject by the 45th Session of the Executive Committee.¹² In particular, it was noted that the Executive Committee had requested the Committee to develop concepts, identify issues for consideration of the Commission and other Codex Committees, and suggest how a systematic approach might be applied. The Executive Committee had suggested that as soon as work had proceeded beyond the initial stages, other relevant Codex Committees should initiate their own work as appropriate. It was noted that Commission had identified the matter as one of priority.

¹¹ CX/FICS 99/6 (Prepared by New Zealand, with assistance from Australia, Canada and USA); CRD 4 (Comments of Japan); CRD 6 (Comments of the European Community); CRD 8 (Comments of India).

¹² ALINORM 99/30, paras. 41-52 and ALINORM 99/3, paras. 35-36.

70. The Committee discussed the document in general terms and then considered in detail some elements of the proposed guidelines attached to the discussion paper before considering how work in this area might be developed further.

GENERAL ISSUES

71. Delegations stressed the importance of the issue in relation to the work of the Commission and the Committee. They noted the relationship between the proposals contained in the paper and the work already undertaken on Guidelines such as the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* and the *Draft Guidelines for the Development of Equivalence Agreements regarding Food Import and Export Inspection and Certification Systems* (see paras. 10 – 30, above). The importance of the guidelines as a means of applying the provisions of Article 4 of the SPS Agreement uniformly and consistently to food safety matters was also stressed. Several delegations and observers also referred to Article 2.7 of the TBT Agreement in relation to the recognition of equivalence for technical food control regulations other than food safety.

72. The Committee discussed the speed with which the work should be undertaken and at what point other Codex Committees should be invited to take up related areas of work within their own areas of responsibility. Several delegations were of the opinion that the paper should be developed carefully and slowly through a step-by-step approach, involving other Codex Committees along the way in order to achieve a Codex-wide consensus in this area. Some delegations expressed the view that it would be premature to initiate the Step Procedure for the future development of the text.

73. Many delegations referred to the new concepts in the paper, especially that of Food Safety Objectives, which had broad implications for the work of the Commission and other Committees, and that had yet to be fully discussed. Other delegations noted that several definitions and other issues had yet to be satisfactorily resolved. Attention was also drawn to the implications for some developing countries in their ability to judge equivalence and the need to improve the infrastructure capabilities of these developing countries.

74. The Delegation of New Zealand, on behalf of the author countries, noted that the 22nd Session of the Commission had given the Committee the mandate to develop guidelines for the determination of equivalence between food import and export inspection and certification systems. However, as the SPS Agreement made no distinction between systems and measures, the framework of the guideline had to be broadly based. The work of other Codex Committees, particularly the Committee on Food Hygiene, had already provided a basis for continued work in certain specific areas. The Delegation confirmed that more refinement was needed on the concept of Food Safety Objectives with guidance on how they should be developed and expressed, and on how they could be used in food import and export inspection and certification systems. The Delegation suggested that work on TBT-related issues could be developed in parallel to the present document.

CONSIDERATION OF THE PROPOSED DRAFT GUIDELINES

Preamble and Scope

75. A number of delegations supported the development of guidelines for determining the equivalence of non-safety (TBT) measures, taking into account the provisions of Article 6 of the TBT Agreement. It was noted however, that the SPS and TBT Agreements treated the matter of equivalence differently. Opinions were therefore divided as to whether the present paper should be expanded to cover TBT matters; whether a separate paper covering TBT matters should be developed in parallel with the present paper; or whether a paper covering TBT matters should be developed only after guidelines on determining the equivalence of food safety matters had been completed, thereby allowing the Committee to concentrate on the latter.

76. Several delegations were of the opinion that the concept of Food Safety Objectives required further development, possibly in a parallel paper or Annex, especially in relation to the application of the “appropriate level of protection” concept. Some delegations also pointed out that emphasis in this

Committee should be on the determination of equivalence of systems and not of measures since the technical expertise in regard to specific measures was within the competence of other Codex Committees.

Definitions

77. Several delegations pointed to the differences between the definitions used in the text and the corresponding definitions adopted by the Commission or used in other texts developed by the Committee. It was agreed to use previously adopted definitions where these existed. It was noted that the definitions used in the text would need to be referred to the Committee on General Principles and other Codex Committees at an appropriate time.

78. It was agreed that more work was needed on the definition of *Food Safety Objective*, and that careful consideration should be given to the legal and political interpretations of this term. It was also suggested that the term “objectively demonstrated” required definition. Some delegations expressed concern over the proposed definition of *Appropriate Level of Protection*.

General Principles for the Judgement of Equivalence

79. One delegation was of the opinion that the rights of the importing country were insufficiently explained in this section.

Guidelines for the Judgement of Equivalence

80. Several editorial comments were made and one delegation expressed concern that the procedure outlined was excessively rigid and did not take into account the possibility of using approaches other than those based on Food Safety Objectives.

CONSIDERATION OF FUTURE DEVELOPMENTS

81. It was decided that the Commission should be requested to initiate formal work on the elaboration of *Guidelines for the Judgement of Equivalence of Sanitary Measures associated with Food Inspection and Certification Systems*. Should the Commission approve such work at Step 1, a revised draft of the text would be prepared in the light of the present discussion (Step 2) and circulated to Governments and interested international organizations for comments at Step 3. As noted above, some delegations expressed the view that the time was not yet right for the initiation of the formal Codex Step Procedure and stated that it would be better for the present paper to be redrafted and re-issued as a discussion paper. The Committee recalled, however, that the Step Procedure was used for the elaboration of Codex texts in order to ensure transparency and the full participation of Codex Member countries, and for effective communication at the appropriate time with other Codex Committees. It was noted that entry into the Step Procedure did not imply automatic advancement of any Codex text as the Committee or the Commission could at any time return a text to a previous Step in the Procedure.

82. During the discussion several delegations expressed their willingness to assist in further work on this subject. The Committee requested the Delegation of New Zealand, with the assistance of the other author countries to undertake a revision of the present text, taking into account the present discussion. This text would either be circulated at Step 3 of the Procedure or as a discussion paper, depending on the decision of the Commission.

83. It was agreed that all relevant Codex Committees would be informed of the present discussion and of the current status of work on the Guidelines, bearing in mind that the Guidelines could have implications for their present and future work programmes.

84. In regard to the proposal to develop guidelines on the judgement of equivalence of technical regulations other than sanitary measures, some delegations were of the view that it would be appropriate not to commence work on this aspect until the work on food safety related aspects of the judgement of equivalence had been well advanced. Others were of the view that such a sequential approach would mean the postponement into the indefinite future of important and relevant work. The Committee requested the advice of the Executive Committee and the Commission on how to proceed in this matter.

DISCUSSION PAPER ON THE DEVELOPMENT OF GUIDELINES FOR THE UTILIZATION AND PROMOTION OF QUALITY ASSURANCE SYSTEMS (AGENDA ITEM 7)¹³

85. The Committee noted the decision of its last Session that a discussion paper would be prepared by Australia for consideration at its current meeting.¹⁴ The Committee was informed that the paper was designed to explain the history, role of industry and the relationship between the Hazard Analysis and Critical Control Point (HACCP) System and other quality management systems including ISO 9000, as had been discussed at its previous session. The representative emphasized the intention of avoiding recommendations to use any particular systems and especially proprietary methods.

86. The Committee welcomed the work of Australia. Several delegations were of the opinion that further elaboration of the paper was necessary due to the adoption of quality assurance systems and the HACCP system on a voluntary basis by industry. Several delegations were of the opinion that the guidelines should concentrate on food safety (sanitary) issues rather than on quality factors. It was noted that quality systems were used between commercial partners while the HACCP system was often used on a regulatory basis. Concern was also expressed that the promotion of quality assurance systems was beyond the mandate of the Codex Alimentarius Commission.

87. The Delegation of Germany emphasized the importance of limiting the scope of the text to food inspection and certification systems only and not to quality assurance, audit, surveillance systems and the HACCP system. It was stated that HACCP may be integrated into the system on a voluntary basis and it was recognized that the voluntary use of quality assurance system might provide additional value.

88. Some delegations¹⁵ were of the opinion that the paper should be developed in a way to explain the relationship between quality assurance and HACCP systems and the mechanisms of these systems. It was stated that the application of HACCP should be additional to the use of good manufacturing practices taking into account the fact that HACCP was not necessarily the only applicable system. The text should be limited to develop guidelines on how to use the quality assurance systems applied by industry in the context of Food Import and Export Inspection and Certification Systems applied by regulators. Some delegations suggested that the text should be treated as an Information Paper only.

89. It was suggested that guidelines to harmonize inspection systems based on quality management systems were timely and could include issues such the frequency of surveillance and the use of third-party systems.

90. In response to concern expressed that the adoption of the guideline could result in unnecessary technical barriers to trade, it was pointed out that the purpose of the document was to assist both industry and regulators. Further elaboration of the text would not imply that the use of quality assurance systems was being made mandatory. It was for individual businesses to decide whether to implement a quality assurance system or not. However, once a quality assurance system was in place, the approach taken by regulators to inspection procedures could be modified to take the quality assurance system into account. This should result in a saving of resources while at the same time strengthening confidence in the outcome of the regulatory inspection.

91. The Delegation of Uruguay expressed concern at the content of the text and the possibility that it might lead to a situation where governments were compelled to apply it as a result of the WTO Agreements. The representative of WTO reaffirmed that Codex texts served as reference points under the SPS Agreement and reiterated the response of the Chair of the SPS Committee that how a text would be considered depended on its substantive content rather than on the category of the text.

92. The Delegation of Germany reminded the Committee that the 30th Session of the Codex Committee on Food Hygiene had discussed a paper on HACCP-like systems in small businesses with special reference to developing countries and such guideline should also be taken into account.

¹³ CX/FICS 99/7; CRD 10 (Comments of the European Commission); CRD 11 (Comments of Chile).

¹⁴ ALINORM 99/30, paras. 59-61

¹⁵ CRD 10 (Comments of EC); CRD 11 (Comments of Chile)

93. The Committee agreed to request the Commission to approve the elaboration of the Guidelines as new work. It agreed that the paper should be redrafted in the light of the comments expressed and in the Conference Room Documents and then circulated to governments for comments prior to discussion at the next session. The Committee appointed a drafting group consisting of United States, Canada, Denmark, France, India, New Zealand and South Africa to undertake the revision and requested Australia to coordinate this work.

DISCUSSION PAPER ON GUIDELINES FOR THE ESTABLISHMENT OF A DATABASE ON IMPORTING COUNTRY LEGISLATION (AGENDA ITEM 8)¹⁶

94. The Committee recalled that this matter had first been raised at its Sixth Session (1998) at which time the Committee had requested the Delegation of India, assisted by other interested delegations, to prepare a discussion paper for consideration at the present Session.¹⁷ In introducing the paper, the Delegation of India stated that there was a need for clear information of importing countries' requirements in order to facilitate trade, avoid misunderstanding, and reduce the number of rejections at the point of import. The Delegation stated that the paper envisaged a two-step process; the identification of the information required followed by the identification of the format in which the information was to be presented. It was noted that the question of languages to be used could create problems and would need to be decided at a later date. As discussed at the Committee's Sixth Session, the preferred means of disseminating the information was by a series of linked web sites on the Internet, with a central web site established by the Codex Alimentarius Commission.

95. Many delegations supported the continued development of the proposed guidelines in order to provide up-to-date information on regulatory requirements. Several delegations felt that the matter was urgent because a number of countries were currently establishing their web sites. The principle that such information should be freely exchanged and made widely available was also strongly supported. It was also suggested that such information could be used as the basis for an international alert system. The representative of Consumers International reiterated its call for an international database on food import rejections.

96. Some delegations drew attention to major difficulties in the technical implementation of the proposal and in assuring the availability of staff and budgetary resources that were implied. Questions were also raised as to the quality of the information that would be made available and its currency in light of rapidly changing regulatory requirements. The legal responsibility of how such information might be used was also questioned.

97. Several delegations drew attention to the transparency provisions of both the SPS and TBT Agreements, including the requirement to maintain enquiry points and to inform other WTO Members of changes in their regulations and other measures. It was also pointed out that guidelines for such a database should be limited to the competence of the Codex Alimentarius Commission and not include matters that were the competence of other bodies, such as phytosanitary requirements under the responsibility of the IPPC.

98. The Codex Secretariat pointed out that the proposal as written may extend beyond the competence of the Codex Alimentarius Commission, in particular the Commission's mandate as expressed in Article 1 of its Statutes. Work underway in the Codex Committee on General Principles in relation to revision of the Acceptance Procedure and its replacement with a notification process would also have to be taken into account. In view of the resource implications, careful consideration would have to be given to the identification of sources of funding additional to the current Codex budget. The Secretariat also pointed out that the paper as written implied operational responsibilities and went beyond the idea of guidelines for governments on how to establish a database. Some delegations

¹⁶ CX/FICS 99/8 (Prepared by India); CRD 4 (Comments of Japan); CRD 3 (Comments of USA); CRD 4 (Comments of Japan); CRD 5 (Comments of EC); CRD 8 (Comments of India).

¹⁷ ALINORM 99/30, paras. 62-65.

observed that if the proposed work proved to be outside the mandate of the Commission, India should not have been assigned the work in the first place.

99. It was pointed out by the Delegation of India that the document could be modified initially to cover guidelines on the type of information and format. Several delegations stated that the guidelines should concentrate on how information should be formulated in a way that it could be made available on the Internet. However, before undertaking any further development of the guidelines, the Committee agreed to request the advice of Legal Counsel as to whether the proposed activity was included in the mandate of the Commission as expressed in its Statutes, and whether it was within the Terms of Reference of the Committee. It was agreed that matters not in the Commission's competence should be excluded. The Committee also requested the opinion of the Committee on General Principles on the status of the proposed activity in relation to the ongoing work of revising the Codex Acceptance/Notification Procedure.

OTHER BUSINESS AND FUTURE WORK (AGENDA ITEM 9)

CRITERIA FOR EVALUATING ACCEPTABLE METHODS OF ANALYSIS FOR CODEX PURPOSES: DISPUTE SETTLEMENT PROCEDURE¹⁸

100. In relation to its work in the above area, the Codex Committee on Methods of Analysis and Sampling had referred to this Committee for consideration, a technical annex¹⁹ on a proposed dispute settlement procedure to be used in cases where the results of laboratory analyses were not in agreement.

101. Delegations were of the opinion that the Annex as presented was overly technical for consideration by CCFICS and that the model presented was only one of several possible solutions to the problem. By being overly prescriptive, it was considered that the model could restrict the rights that WTO Members had acquired under the SPS and TBT Agreements. It was also suggested that under the circumstances described in the document consideration might be given to developing advice based on relevant principles that took into account problems relating to sampling (including consideration of the inherent heterogeneity of samples and which party bore the cost of re-sampling) and the time period for the settlement of the dispute.

102. Although the Committee noted the number of issues raised, it questioned whether it was competent to consider such technical issues. The Committee recommended the use of laboratory accreditation systems based on objective quality assurance criteria as a means of minimizing situations where disputes might arise.

DATE AND PLACE OF NEXT SESSION (AGENDA ITEM 10)

103. The Committee was informed that the Eighth Session of the Committee would be held from 21 to 25 February 2000. Members of the Commission would be informed in due course of the venue of the Session; consideration was being given to the city of Adelaide.

¹⁸ CX/FICS 99/2, paras. 21 *et seq* and Annex; CRD 4 (Comments of Japan).

¹⁹ CX/MAS 98/5, Annex IV.

SUMMARY STATUS OF WORK

Subject	Step	Action by:	Document Reference (ALINORM 99/30A)
Draft Guidelines for the Development of Equivalence Agreements regarding Food Import and Export Inspection and Certification Systems	8	23 rd CAC	Paragraphs 10-32 Appendix II
Proposed Draft Guidelines/Recommendations for Food Import Control Systems	3	Mexico Australia, Canada, France, Germany, Japan, Netherlands, South Africa, USA: 8 th CCFICS	Paragraphs 33-53
➤ Proposed Draft Guidelines and Criteria for Official Certificate Formats and Rules relating to the Production and Issuance of Certificates	3	Australia, United Kingdom: 8 th CCFICS	Paragraphs 54-68
➤ Proposed Draft Guidelines for the Judgement of Equivalence of Sanitary Measures associated with Food Inspection and Certification Systems	1	23 rd CAC; New Zealand, Australia, Canada, USA: 8 th CCFICS	Paragraphs 69-84
Proposed Draft Guidelines for the Utilization of and Promotion of Quality Assurance Systems	1	23 rd CAC; Australia, USA, Canada, Denmark, France, India, New Zealand, South Africa	Paragraphs 85 - 93
Discussion Paper on Guidelines for the Establishment of a Database on Importing Country Legislation	-	Legal Counsel; CCGP	Paragraphs 94-99

ALINORM 99/30A
Appendix I

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Appendix II

**DRAFT GUIDELINES FOR THE DEVELOPMENT OF EQUIVALENCE AGREEMENTS
REGARDING FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION
SYSTEMS**

(Advanced to Step 8)

SECTION 1 - SCOPE

1. This document provides practical guidance for governments desiring to enter into bilateral or multilateral equivalence agreements concerning food import and export inspection and certification systems. Such agreements may be binding instruments taking the form of “international agreements” under the Vienna Convention on the Law of Treaties, or they may be other less formal arrangements such as memoranda of understanding.

SECTION 2 - DEFINITIONS

2. *Audit* is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.¹

3. *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.¹

4. *Certification system* means official and officially recognized certification systems.

5. *Equivalence* is the capability of different inspection and certification systems to meet the same objectives.²

6. *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.¹

7. *Inspection system* means official and officially recognized inspection systems.

8. *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.¹

9. *Officially recognized inspection systems and officially recognized certification systems* are systems which have been formally approved or recognized by a government agency having jurisdiction.¹

10. *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.¹

¹ Codex Alimentarius: Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995).

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

SECTION 3 - PURPOSE OF AGREEMENTS

11. Countries³ may wish to enter into agreements⁴ concerning food import and export inspection and certification systems to:

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

12. Equivalence agreements are not generally intended as a condition for trade but rather as a means for ensuring that importing country requirements are met with minimal trade impediments. For example, such agreements may result in reducing the importing country's rate of physical checks or sampling to test against standards or to avoid additional certification in the country of origin.

SECTION 4 – SCOPE AND TYPES OF AGREEMENTS

13. The guidelines herein are intended to cover both bilateral and multi-lateral agreements. Such agreements may cover trade in one or both directions between trading partners.

14. As agreed by the parties, an equivalence agreement covering control and certification systems may relate to any aspect of food safety or other relevant requirement for food. Such agreements may be limited to specific areas of trade or specific products. Such agreements may be entered into where equivalence has been established in respect of some or all requirements.

15. Equivalence agreements may include provisions for certificates or other forms of certification of particular traded products or may provide for dispensing with certificates and other forms of certification.⁵

SECTION 5 - CONSIDERATIONS BEFORE ENTERING INTO BILATERAL OR MULTILATERAL DISCUSSIONS

16. The importing country considers and determines whether the exporting country's measures meet the importing country's requirements. Any decision must, however, be made on the basis of objective criteria.

17. In general, significant resources are needed to develop agreements. Exporting and importing countries may therefore need to establish priorities for consultations leading to development of agreements in recognition of the limited resources available to conduct the necessary assessments. Such priorities should not conflict with World Trade Organization (WTO) rights and obligations.

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

- a) whether priority should be given to certain product categories because of the public health risks they pose;

³ For the purpose of these guidelines, "country" includes regional economic integration organizations to which a group of countries have transferred competencies as regards food import and export inspection and certification systems and/or the negotiation of equivalence agreements with other countries.

⁴ See Section 1 - Scope. Although this guideline refers to "countries" and "agreements," in many cases competent authorities will enter into agreements or other arrangements.

⁵ See paragraph 45 in CAC/GL 26-1997.

- b) whether there is significant trade between the exporting and importing countries for the product(s) that will be the subject of an agreement, and whether an agreement between the two countries would facilitate trade;
- c) whether the exporting country appears to have sufficient infrastructure and resources to maintain an appropriate control system;
- d) whether the exporting country's products have a low rate of non-compliance with importing country requirements;
- e) whether the exporting country recognizes and abides by the Codex Code of Ethics in International Trade in Food;
- f) whether significant resources would be conserved as a result of the agreement.

19. A country entering into discussions towards an equivalence agreement should be prepared to facilitate assessment and verification activities both before and after conclusion of the agreement.⁶

20. Countries that are not yet ready to enter into equivalence agreements may wish to work jointly toward the development of such agreements. Amongst other things, information exchange, joint training, technical cooperation, and the development of infrastructure and food control systems can serve as building blocks towards the later development of agreements. An importing developed country should consider providing technical assistance to exporting developing countries to establish systems that enable food exports to meet importing country requirements and facilitate the development of equivalence agreements.

SECTION 6 - INITIATING DISCUSSIONS TOWARD AN EQUIVALENCE AGREEMENT

21. The country initiating discussion towards an equivalence agreement should identify:

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

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

23. In the event that the recipient of such an approach has difficulty in responding positively to the approach it should provide a statement of reasons and any relevant recommendations to facilitate the future development of equivalence agreements.

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

SECTION 7 - CONSULTATIVE PROCESS FOR EQUIVALENCE AGREEMENTS

25. As a first step in the consultative process, the importing country should make readily available the texts of its relevant control measures and identify the objectives of these measures. For food safety control measures, the importing country should identify the health risk(s) addressed by each measure. Where certain health hazards, such as foodborne pathogens, are known to exist in the exporting country and not in the importing country, these hazards and the measures to address them should be identified.

26. The exporting country should provide information that demonstrates that its own safety control system achieves the importing country's objectives and/or level of protection, as appropriate:

⁶ See CAC/GL 26-1997 for guidelines on the conduct of such assessment and verification activities.

- Equivalence agreements for food safety (sanitary) control measures are entered into after an importing country determines that an exporting country's control measures, even if different from those of the importing country, achieve the importing country's appropriate level of health protection.
 - Equivalence agreements for other relevant requirements for food are entered into after an importing country determines that the exporting country's control measures, even if different than those of the importing country, meet the importing country's objectives.
27. The development of equivalence agreements is facilitated by the use of Codex standards, recommendations and guidelines by both parties.
28. To facilitate the consultative process, information should be exchanged, as appropriate, on:
- a) legislative framework, including the texts of all relevant legislation, which provides the legal basis for the uniform and consistent application of the food control system that is the subject of the agreement;⁷
 - b) control programs and operations, including the texts of all the exporting country's pertinent measures that would be the subject of the agreement, as well as other materials that relate to control programs and operations;⁸
 - c) decision criteria and action;⁹
 - d) facilities, equipment, transportation and communications as well as basic sanitation and water quality;¹⁰
 - e) laboratories, including information on the evaluation and/or accreditation of laboratories, and evidence that they apply internationally accepted quality assurance techniques;¹¹
 - f) details of the exporting country's systems for assuring competent and qualified inspection¹² through appropriate training, certification, and authorization of inspection personnel; and the number and distribution of inspectors;
 - g) details of the exporting country's procedures for audit of national systems, including assurance of the integrity and lack of conflict-of-interest of inspection personnel;¹³
 - h) details of the structure and operation of any rapid alert systems in the exporting country.
29. Countries may wish to prepare side-by-side tables to organize the above-mentioned information and identify differences between the countries' control systems.
30. The importing and exporting countries should identify a process for jointly considering differences in measures/requirements.
31. Representatives of the importing country should have the opportunity to satisfy themselves that the exporting country's control systems operate as outlined. This can be accomplished by appropriate assessment and verification of processes as described in Section 9 and the related Annex of the

⁷ See paragraphs 20-23 in CAC/GL 26-1997.

⁸ See paragraphs 24-29 in CAC/GL 26-1997.

⁹ See paragraphs 30-37 in CAC/GL 26-1997.

¹⁰ See paragraphs 38-40 in CAC/GL 26-1997.

¹¹ See paragraphs 41-42 in CAC/GL 26-1997.

¹² See paragraph 43 in CAC/GL 26-1997.

¹³ See paragraphs 47 and 52-57 in CAC/GL 26-1997.

Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems.

32. Participants in the agreement should establish procedures to:
- a) periodically audit and verify that equivalence continues to exist after conclusion of an equivalence agreement; and
 - b) resolve any problems identified during audit and verification.

A problem resolution procedure should be developed including provision for the importing country to re-examine products to verify that the exporting country has corrected its deficiencies.

33. The participants in the agreement should discuss and decide whether the equivalence agreement should include provisions for the use, in addition to or in lieu of certificates, of a list of establishments which have been shown to be in compliance with the exporting country's equivalent control measures. The importing country can use this list of establishments to monitor imported shipments. The exporting country would be responsible for providing the list, and updates when appropriate, to the importing country. The importing country retains the right to refuse imports from an establishment and to arrange with the exporting country the removal of an establishment from the list, providing reasons for its action.

34. Participants in the agreement should agree to procedures for information exchange in the event of a food emergency control situation.¹⁴

35. Participants in the agreement should agree to procedures to follow in the case of food shipments that are found not to comply with the terms of the equivalence agreement.

36. Participants in the agreement should agree to procedures for terminating the agreement, in case either party is not satisfied that the terms of the agreement are being met.

37. To enhance public confidence in the agreement while respecting legitimate concerns to retain confidentiality, the relevant competent authorities of the particular countries should¹⁵ provide the public--including consumers, industry, and other interested parties--an opportunity to comment at an appropriate time on the proposed content of the agreement.¹⁶

SECTION 8 - PILOT STUDIES

38. Before entering into an agreement, the competent authorities in the importing and exporting countries may agree to the conduct of a trial or pilot study.

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

- a) description and time frame of the trial program.
- b) roles and capabilities of involved government and officially recognized private organizations.
- c) procedures for inspection and certification.
- d) audit procedures and frequency.
- e) description of training or information needs.

¹⁴ See Codex Guidelines for the Exchange of Information in Food Control Emergency Situations (CAC/GL 19-1995).

¹⁵ The delegations of Singapore, Uruguay, Vietnam, Malaysia and Egypt reserved their position on use of the word "should".

¹⁶ See paragraph 58 in CAC/GL 26-1997.

SECTION 9 - DRAFTING THE AGREEMENT

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

SECTION 10 - IMPLEMENTING THE AGREEMENT

41. A notice announcing the agreement, or the text of the agreement itself, should be published by all the signatory governments. The text of the agreement should be made available to the public of each country in that country's official language(s).

42. After the agreement comes into effect, each party should promptly notify the other party or parties of any proposed new or revised measures that pertain to the agreement.

APPENDIX A

CONTENTS OF EQUIVALENCE AGREEMENTS

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

- a) *Title*: The name given to the agreement may vary, depending on the preferences and legal requirements of the parties to the agreement.
- b) *Parties*: The names of the parties to the bilateral or multilateral agreement.
- c) *Purpose*: A brief statement of the specific purpose of the agreement.
- d) *Scope*: Identification of the products and measures that are the subject of the agreement. Note exceptions where necessary.
- e) *Definitions*: Definitions of terms used in the agreement, as needed. Where possible, definitions in WTO and Codex documents should be used.
- f) *Substantive Obligations*: A comprehensive description of each participant's obligations and specific responsibilities.
- g) *Competent Authorities*: The title of each competent authority that will be responsible for the implementation of the agreement.
- h) *Equivalence Finding*: A statement of the control systems or parts of systems that have been found to be equivalent by the importing party(ies) to the agreement.
- i) *Assessment and Verification Provisions*: A description of the methods to verify compliance with the provisions of the agreement, including audit procedures and/or provisions for participants to utilize officially recognized third parties (including competent authorities in countries that are not signatories to the officially recognized agreement). The plans for continuing verification should be clearly described.
- j) *Criteria for Certification*: When certificates are part of agreements to meet requirements, a list of the criteria, by attribute, that should be used by the competent authorities of the exporting and importing countries to determine if the product meets the importing country's standards.
- k) *Sample Collection*: A listing of references and sample procedures that the importing and/or exporting country will use for testing and/or certification.
- l) *Analytical and Other Methodology*: A listing of the methods and equivalent procedures that the participating competent authorities will use to determine the compliance of product(s) covered by the agreement.
- m) *Administrative Procedures*: Procedures and guidance for the practical implementation and application of the agreement.
- n) *Information Exchange and Cooperation*: A listing of the types of sharing of expertise, providing assistance, and exchanging information that will help assure the quality and safety of the product(s) covered by the agreement.
- o) *Transparency*: Description of the types of information that should be exchanged on a routine basis, including but not limited to revised laws and standards, analytical findings, and inspection results.

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- p) *Notifications:* A description of the situations and procedures that should be followed when reporting significant changes in factors affecting the safety of traded products; situations where there is an identified risk of serious public health effects related to traded products; and steps being taken to resolve such situations.
 - q) *Dispute Settlement:* A description of the consultative procedures, joint committee, and/or other mechanisms that should be employed by the participants to resolve disputes under the agreement. Such procedures and mechanisms should not limit the rights or obligations of the parties under the World Trade Organization (WTO) Agreements.
 - r) *Liaison Officials:* For each participating competent authority, at least one liaison official should be identified by title/position, address, telephone number, fax number, and e-mail address. (It is not necessary to include the name of a specific individual.)
 - s) *Entry into Force:* The date on which the provisions of the agreement enter into force.
 - t) *Review, modification and termination:* The methods for the review, modification and termination of the agreement.
 - u) *Signatures:* Signatures, titles, and names of officials representing the competent authority that are participants in the agreement and the date(s) of signature.