

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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**ALINORM 99/30**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX ALIMENTARIUS COMMISSION**

**Twenty-third Session**

**Rome, 28 June - 3 July 1999**

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

*Melbourne, Australia, 23-27 February 1998*

**NOTE:** This report includes Codex Circular Letter CL 1998/6-FICS.

List of Abbreviations Used in this Report:

ALINORM	Reports of Codex Committee meetings 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
IHR	International Health Regulations of the World Health Organization
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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**CX 4/70.2**

**CL 1998/6-FICS  
March 1998**

**TO:** - Codex Contact Points  
- Interested International Organizations

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

**SUBJECT:** **Distribution of the Report of the Sixth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (ALINORM 99/30)**

The report of the sixth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems is attached. It will be considered by the twenty-third Session of the Codex Alimentarius Commission in Rome from 28 June - 3 July 1999.

## **MATTERS FOR ADOPTION BY THE 45TH SESSION OF THE EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION**

- 1. Proposed Draft Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems at Step 5; (ALINORM 99/30, paras. 10 - 33 and Appendix II).**

Governments wishing to submit comments regarding the implications which the proposed draft Guidelines or any provisions thereof may have for their economic interests should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (at Step 5) (*Codex Alimentarius Procedural Manual*, Tenth Edition, pages 20-21) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy **not later than 1 May 1998.**

## SUMMARY AND CONCLUSIONS

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

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

- Advanced the proposed draft **Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems** to the Executive Committee for adoption at Step 5 (paras. 10-33 and Appendix II);
- Proposed to the Executive Committee the elaboration of proposed draft **Guidelines/Recommendations for Food Import Control Systems** (paras. 34-36);
- Proposed to the Executive Committee the elaboration of proposed draft **Guidelines and Criteria for Official Certificate Formats**, and incorporating **Rules Relating to the Production and Issuance of Certificates** (paras. 37-40), and;
- Requested the Executive Committee to provide its opinion as to the extent to which issues relating to the **judgment of equivalence** were within the mandate of CCFICS and/or other Codex committees and how the subject should be considered further (paras. 41-52).

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

- Noted that the Codex Committee on Fresh Fruits and Vegetables was reviewing its draft **Code of Practice for the Quality Inspection and Certification of Fresh Fruits and Vegetables** in the context of CCFICS and other international documentation in order to evaluate the need for a Code specific to such produce (para. 5);
- Agreed not to pursue the development of a **database on rejections of foods** at this time (paras. 53-58);
- Agreed that a further discussion paper on the **Utilization and Promotion of Quality Assurance Systems** would be prepared for consideration at its next meeting (paras. 59-61), and;
- Agreed that a discussion paper be prepared on **Guidelines for the Establishment of a Database on Importing Country Legislation** for consideration at its next meeting (paras. 62-65).

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## **INTRODUCTION AND OPENING OF THE SESSION (AGENDA ITEM 1)**

1. The Sixth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems was held in Melbourne, Australia, from 23 to 27 February 1998, at the kind invitation of the Government of Australia. Mr. Digby Gascoine, Australia Quarantine and Inspection Service, chaired the Session. The meeting was attended by 252 participants from 55 Member countries and 15 international organizations. A List of Participants is attached to this report as Appendix I.

2. The Session was opened by Senator the Hon. Judith Troeth, Parliamentary Secretary to the Minister for Primary Industries and Energy in the Australian government. Referring to Australia's continuous efforts to supply safe and quality foods to consumers, she emphasized the importance of Codex in the facilitation of trade through the harmonization of food import and export inspection and certification. Senator Troeth noted the changing role of governments in food standards setting. Highly prescriptive standards were being replaced with horizontal standards that take account of the broad issues involved in achieving food safety, and, in so doing, provide recognition of alternative approaches capable of delivering equivalent outcomes. Senator Troeth also noted the complexities of issues before the Committee which needed a high level of cooperation between countries to meet mutual obligations, a willingness to be transparent, and a spirit to achieve harmonization.

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

3. The Committee adopted the Provisional Agenda as proposed. It agreed to consider a proposal made by India to prepare a discussion paper on "Guidelines for the Development of a Database with Regard to the Legislative Requirements of Importing Countries as Related to the SPS Agreement" under Other Business and Future Work (see paras. 62-65).

## **MATTERS REFERRED FROM CODEX COMMITTEES (AGENDA ITEM 3)<sup>2</sup>**

4. The delegation of India reiterated its opinion that developing countries needed time to initiate procedures for the application of various final Codex texts elaborated by the Committee, including the Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems.<sup>3</sup> The Committee noted that the Codex Committee on General Principles would be considering special or differential treatment for developing countries in the application of Codex standards, guidelines and related texts at its next session.

5. The Committee noted the offer made by the delegation of Canada at the 7th Session of the Codex Committee on Fresh Fruits and Vegetables<sup>4</sup> to review the draft Code of Practice for the Quality Inspection and Certification of Fresh Fruits and Vegetables<sup>5</sup> in the context of CCFICS and other international documentation in order to evaluate the need for a Code specific to such produce. The delegation of Canada informed the Committee that the review of such documentation (i.e., CCFICS, European Community, International Organization for Standardization) had commenced, and that their initial reaction was that a Code specific to fresh fruits and vegetables appeared to be justified. This view was supported by France, especially as related to quality, in addition to safety, provisions for fresh produce. The Code is currently being maintained at Step 7.

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<sup>1</sup> CX/FICS 98/1.

<sup>2</sup> CX/FICS 98/2 and comments from India (CRD 1).

<sup>3</sup> CAC/GL 26-1997.

<sup>4</sup> ALINORM 99/35, paras. 71-75.

<sup>5</sup> ALINORM 97/35, Appendix XI and CX/FFV 97/14 - Add. 1.

6. The representative of the World Trade Organization (WTO) informed the Committee that the request of the 22nd Session of the Codex Alimentarius Commission<sup>6</sup> to clarify how the WTO would differentiate standards, guidelines and other recommendations was ongoing, and would be further discussed at the next session of the WTO Committee on Sanitary and Phytosanitary Measures in March 1998.

### **Other Matters**

7. The representative of World Health Organization (WHO) informed the Committee that WHO, in consultation with its Member States and other international organizations, was revising the International Health Regulations (IHR) to adapt them to the present volume of international traffic and trade and to take account of current trends in the epidemiology of communicable diseases, with a view to submitting proposals to the World Health Assembly in 1999. While IHR would remain based on the principle of maximum protection from the spread of disease of international public health importance with minimum interference with international trade and travel, the concept of syndrome notification was to replace the present disease notification scheme, which currently covered cholera, plague and yellow fever only.

8. Under the revised IHR, syndrome notification received by WHO would be assessed prior to being listed and would not be automatically listed in the Weekly Epidemiological Record, as was presently occurring with the disease-specific notifications under the present IHR. The revised IHR would allow WHO and the Member State concerned to jointly determine what control measures would be appropriate and identify which measures applied by other Member States would be deemed excessive or inappropriate. The revision of IHR was hoped to bring solutions to the issues of the reluctance of countries to report diseases for fear of sanctions and a lack of resources and health system capacity to deal with disease outbreaks.

9. In regard to the relationship between IHR and Codex texts, it was clarified that IHR formed an integral part of the global communicable disease monitoring and control system implemented by WHO, with a focus on the management of disease outbreaks of international public health importance, while existing Codex texts dealing with the microbiological hazards in foods mainly aimed at preventing foodborne diseases through the systematic implementation of hygienic control measures appropriate to the food operation in question. With regard to WHO's authority and competence of judging the appropriateness of specific sanitary measures, the Committee was informed that the current IHR already included procedures for dispute settlement through the exercise of good offices by the Director-General of WHO. The Director-General of WHO had in fact provided guidance about the irrelevance of specific trade restriction measures in certain cases of large-scale outbreaks of foodborne diseases, namely cholera.

### **PROPOSED DRAFT GUIDELINES FOR THE DEVELOPMENT OF EQUIVALENCE AGREEMENTS REGARDING FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (AGENDA ITEM 4)<sup>7</sup>**

10. The Proposed Draft Guidelines had been discussed at the Committee's Fourth and Fifth Sessions<sup>8</sup> based on proposals prepared by the United States of America. The Delegation of the United States stated that the present text had been prepared in the light of these prior discussions and comments received. It was noted that the Guidelines stressed the practical requirements which needed to be taken into account in the establishment of equivalence agreements and that agreements based on recognition

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<sup>6</sup> ALINORM 97/37, para. 172.

<sup>7</sup> CX/FICS 98/3 and comments from Argentina, Australia, Egypt, France, Paraguay, Peru, Republic of Korea, Uruguay (CX/FICS 98/3-Add.1), India, United States (CRD 3) and Colombia (CRD 4).

<sup>8</sup> ALINORM 97/30, paras 19-20 and ALINORM 97/30A, paras. 22-29.

of mutual compliance with requirements had been excluded from the text as previously agreed by the Committee. The revised text covered several types of agreements, including those devoted to either single or multiple issues (food quality and safety issues) or single or multiple products. It also provided flexibility by recognizing that in some situations equivalent systems were already in place whereas in other situations the equivalence of systems had yet to be determined or systems were still being established. The use of several terms which were considered either unclear or open to misinterpretation had been discontinued.

## **General**

11. The representative of FAO noted the work of that Organization with both developing and developed countries to establish effective control systems for food quality and safety based on Codex standards and related texts. Noting that Codex standards and other texts were used as benchmarks for international trade under both the WTO SPS and TBT Agreements, the representative pointed out that the text under discussion also needed to make clear and regular reference to Codex work. Moreover, in view of the real problems encountered in international trade in foods, as was evident from the available statistics on rejection of foods at the point of import, the scope of the agreements to be covered by the proposed draft Guidelines should explicitly refer to both food quality as well as safety issues and should emphasize integrated cost-effective food quality and safety systems. The representative also proposed a definition of “*Objectives*” linking the use of the term to food quality and safety systems which assure that food products meet Codex standards and related texts and any additional national requirements which were in conformity with the SPS and TBT Agreements. The Committee supported the principle that there should be significant reference to Codex standards and other texts in the Guidelines.

12. The Committee confirmed that the Guidelines should be limited to “*Equivalence Agreements*” and that “*Conformity or Certification Agreements*” should be excluded, forming perhaps the subject of a separate text.

13. In response to a question concerning the potential status of Codex Guidelines on equivalence, it was noted by the representative of the WTO that the measures referred to in the SPS Agreement included testing, inspection and certification. The representative of the WTO was of the opinion that the Guidelines would be applicable under the SPS Agreement.

## **Section 1 - Scope**

14. The Committee extended this Section to provide an explanation of the nature of the agreements covered by the Guidelines, using text previously found in the Section on Definitions. Some Delegations expressed concern at the specific reference to Memoranda of Understanding as being among the instruments covered; other Delegations suggested the inclusion of a reference to “exchanges of letters” or “exchanges of diplomatic notes”.

## **Section 2 - Definitions**

15. The previous definition of “*Agreement*” was removed on the basis of the decision recorded above. The Committee noted that most of the Definitions included in the Proposed Draft Guidelines were identical to definitions previously adopted by the Codex Alimentarius Commission in the *Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995)* and the *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**

16. The Committee confirmed that Equivalence Agreements should cover food safety together with other legitimate requirements for consumer protection and assurance of fair practices in the food trade as specified in the Statutes of the Codex Alimentarius Commission and as recognized in the WTO SPS and TBT Agreements. The Committee recalled its decision, confirmed by the Codex Alimentarius Commission when it adopted the *Principles for Food Import and Export Inspection and Certification*, that the term “*food quality*” was understood to include food safety. However, it was generally understood that the aspects of quality which would be the subject of equivalency agreements would be those which were the subject of government regulations and would not extend to commercial quality considerations. In this regard, the Committee agreed to use the term “*Requirements*” as defined, wherever possible, as this term incorporated all standards and other measures relating to trade in foodstuffs covering the protection of public health, the protection of consumers and conditions of fair trading.

17. Several of the paragraphs in this section were re-arranged for the purposes of clarity.

### **Section 4 - Types of Agreements**

18. The Committee agreed to simplify this section partly by transferring certain elements to Section 7 (Consultative Process) and partly by eliminating redundant text.

19. The Committee agreed that the decisions by the importing country as to whether the exporting country’s measures met the requirements of equivalence must be made on the basis of objective criteria. It also agreed to state explicitly that agreements may be limited to specific areas of trade or specific products. Bearing in mind that equivalence agreements would cover both food safety and other requirements for consumer protection and assurance of fair practices in the food trade, it was agreed to reflect this in the present Section.

20. The Committee noted that equivalence agreements should cover control and certification systems designed to ensure conformity with requirements rather than design agreements which would attempt to determine equivalence with requirements directly. This was considered particularly important so that Codex standards, codes of practice, guidelines and other recommendations would not be undermined.

21. The Committee also agreed to retain the notion that agreements could be concluded when equivalence had not been established in respect of all requirements.

### **Section 5 - Considerations Before Entering into Bilateral or Multilateral Discussions**

22. The Committee agreed to remove an explicit reference to the use of the Hazard Analysis and Critical Control Point System (HACCP) as an example of a building block towards the development of agreements, because this system had been identified by the Codex Alimentarius Commission as one risk management option with the possibility of using other food safety management systems.

23. The consideration of the provision of technical assistance to developing exporting countries, to facilitate development of an equivalence agreement, was included.

### **Section 6 - Initiating Discussions Toward an Equivalence Agreement**

24. The Committee agreed that in the case of a refusal of a request to prepare an agreement, the statement of reasons why such a request was refused should be accompanied by any relevant recommendations which could facilitate the development of future agreements.

## **Section 7 - Consultative Process for Equivalence Agreements**

25. The Committee noted that the paragraph in this Section concerning assessment and verification of control systems was based on parts of the adopted *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997)*. It agreed that it would be inappropriate to attempt to reword or to condense this carefully constructed text, and decided instead to make clear reference to the appropriate Sections of CAC/GL 26-1997.

26. The Committee agreed to expand the details of some of the examples of types of information to be exchanged between parties to facilitate the consultation process. It also agreed that an exchange of information on the structure and operation of rapid alert systems would be useful to this process.

27. The Committee redrafted the paragraph dealing with provisions for lists of establishments (“firms” in the previous draft) so as to clearly define the rights and obligations of the parties to the agreement in the establishment and maintenance of such lists. The delegation of Brazil stated its view that the right of the importing country to refuse imports should be qualified by an obligation to adequately demonstrate to the exporting country the basis for refusal. The delegation of Malaysia called for the deletion of the words “in addition to or in lieu of certificates” as they were not consistent with the wording of Paragraph 16 of the text. The delegation of Malaysia was informed that the statement recognized that equivalence agreements may result in dispensing with certificates.

28. The Committee noted that the text provided for exchange of information on the evaluation and accreditation of analytical (test) laboratories, where this was appropriate and that the word “*accreditation*” had not as yet been defined by Codex. It was noted that the Commission had adopted several texts in this area as Codex recommendations and that the Codex Committee on Methods of Analysis and Sampling (CCMAS) was continuing its work in this area. It was agreed that appropriate references, including in relation to the meaning of “*accreditation*”, arising from the work of the CCMAS would be made in the Guidelines.

## **Section 8 - Pilot Studies**

29. Following a question posed by one Delegation, the Committee agreed that the text of these paragraphs should be worded to indicate that the elements to be covered by pilot studies were optional, for example, any provisions to establish pilot procedures for inspection and certification. It agreed that only those private organizations which had been officially recognized by the competent authorities should be involved in pilot studies.

30. The Committee did not accept a proposal to include provisions concerning confidentiality in view of its commitment to transparency as expressed in other sections of the text under discussion.

## **Section 10 - Implementing the Agreement**

31. The Committee agreed to include provisions relating to the maintenance and further operation of equivalence agreements, and their period and termination.

## **Appendix - Contents of Agreements**

32. The Committee accepted a number of proposals for clarification of the proposed draft text.

## **Status of the Proposed Draft Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems**

33. Several Delegations expressed their opinion that the text should be returned to Step 3 for further comments and further discussion at the Committee’s next Session. Noting that the Codex Step Procedure provided for a further round of comments and further discussion and Steps 6 and 7, the

Committee decided to advance the Proposed Draft Guidelines to Step 5 for consideration by the 45th Session of the Executive Committee. The text of the Proposed Draft Guidelines may be found in Appendix II to this report.

#### **DISCUSSION PAPER ON THE DEVELOPMENT OF CODEX GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS (AGENDA ITEM 5)<sup>9</sup>**

34. The Delegation of Mexico noted that this matter had first been raised at the Committee's Fourth Session and that a preliminary paper had been discussed at the Committee's Fifth Session. The 22nd Session of the Commission had requested Mexico, in collaboration with the Secretariat, to revise its preliminary discussion paper for consideration at the present meeting.<sup>10</sup> Based on a survey conducted by Mexico with the assistance of the Secretariat and several other delegations, the discussion paper outlined the principles which should be inherent in a food import control system and approaches to designing an effective system.

35. The Committee thanked the delegation of Mexico for the paper which received wide support from the delegations and observers present. It endorsed in principle the proposal to elaborate Guidelines in this area. Some Delegations expressed the opinion that the Guideline might be better developed as recommendations or a *vademecum*. Attention was drawn to the problem of references to sub-national authorities and the potential risk on interference in domestic or internal food inspection arrangements. A question was raised concerning the possible status of a guideline or recommendations on food import control systems under the WTO Agreements, but the Committee noted that advice on this matter had been requested by the Commission from the WTO SPS Committee. Some delegations proposed that because Codex work on risk assessment was still under development, work in this area should proceed gradually and that the paper should be developed only as an information paper.

36. The Committee agreed to propose to the Executive Committee that work on the elaboration of proposed draft Codex Guidelines/Recommendations for Food Import Control Systems be initiated and requested the Delegation of Mexico to prepare an appropriate draft for discussion at the Committee's next session at which time the matter of the nature of the document would be addressed.

#### **DISCUSSION PAPER ON THE DEVELOPMENT OF GUIDELINES AND CRITERIA FOR A GENERIC OFFICIAL CERTIFICATE FORMAT (AGENDA ITEM 6)<sup>11</sup>**

#### **DISCUSSION PAPER ON RULES RELATING TO THE PRODUCTION AND ISSUANCE OF CERTIFICATES (AGENDA ITEM 7)<sup>12</sup>**

37. At its 22nd Session, the Codex Alimentarius Commission agreed that the Committee should not undertake the elaboration of a generic official certificate *per se*, but requested it to consider a discussion paper addressing general guidelines and criteria for official certificates.<sup>13</sup> The paper for discussion under Agenda Item 6 had been prepared by Australia on this basis. At the suggestion of the Delegation of the United Kingdom (author country for Agenda Item 7), the Committee decided to consider these two items together.

38. The Committee welcomed the proposals put forward in the two papers. It stressed that Guidelines should define carefully the responsibilities of the commercial parties and competent

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<sup>9</sup> CX/FICS 98/4 and comments from India (CRD 1).

<sup>10</sup> See ALINORM 97/30, paras. 30-31; ALINORM 97/30A, paras. 40-44; ALINORM 97/37, para. 142.

<sup>11</sup> CX/FICS 98/5 and comments from India (CRD 1).

<sup>12</sup> CX/FICS 98/6 and comments from Argentina, Australia, Egypt, Republic of Korea, South Africa, Uruguay, United States (CX/FICS 98/6 - Add.1) and Colombia (CRD 4).

<sup>13</sup> ALINORM 97/37, paras. 140-141

authorities involved in the preparation and issuance of certificates. Moreover, it agreed that certification was not always necessary and that there was a continued danger of a proliferation of certificates, adding to the costs to the food trade and to the competent authorities. It was proposed that model certificates could be drafted on the basis of related commodity groupings. The possibility of transmission of certificates or the information contained therein by electronic means or via the Internet was also stressed. One Delegation proposed that the English language, together with other languages as appropriate, should be used for all certificates.

39. In regard to the Discussion Paper on Rules Relating to the Production and Issuance of Certificates, it was agreed that the contents of the papers needed rearrangement in order to combine it with the other document.

40. The Committee agreed to recommend to the Executive Committee that work be started on the Guidelines and Criteria for Official Certificate Formats, based on commodity-specific certificates and incorporating Rules Relating to the Production and Issuance of Certificates. Subject to the Executive Committee's approval, the Committee requested the Delegations of Australia and the United Kingdom to jointly prepare a draft for consideration at the Committee's next session.

#### **DISCUSSION PAPER ON ISSUES RELATING TO THE JUDGMENT OF EQUIVALENCE (AGENDA ITEM 8)<sup>14</sup>**

41. The discussion paper was prepared by New Zealand, with assistance from Australia, Canada and the United States, at the request of the Committee at its 5th Session.<sup>15</sup> The delegation of New Zealand introduced the discussion paper, and specific examples of equivalence determinations were presented by Australia, Canada, New Zealand and the United States.

42. The discussion paper described the basis for the judgment of equivalence of sanitary measures associated with different food inspection and certification systems in regard to the relevant principles of the SPS Agreement and the *Codex Principles for Food Import and Export Inspection and Certification*.<sup>16</sup> The Committee noted that the SPS Agreement obliged countries to accept the sanitary and phytosanitary measures of other Members as equivalent, even if these measures differed from their own, if the exporting country objectively demonstrates to the importing country that its measures achieve the importing country's appropriate level of protection. The Codex Principles also recognized that different inspection/certification systems may be capable of meeting the same objectives and are therefore equivalent, and that the obligation to demonstrate equivalence rests with the exporting country.

43. The discussion paper promoted the elaboration of guidelines for the systematic application of equivalence and incorporated a risk-based approach for sanitary (i.e. health related) measures only. The paper included definitions related to equivalence previously established by Codex and the WTO and indicated the prerequisite considerations and principles necessary in judging equivalence.

44. The application of risk analysis, the categorization of sanitary measures, the appropriate level of protection, the consideration of food safety objectives and the steps required in the judgment of equivalence were also highlighted.

45. The representative of FAO emphasized the assistance provided by that Organization to developed and developing countries alike in food control. He also noted that the judgment of equivalence should include many other factors not directly related to sanitary measures. The representative noted that the proposed guidelines should cover health-related SPS measures as well as other measures which were clearly under the Codex mandate of consumer protection and the facilitation

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<sup>14</sup> CX/FICS 98/7 and comments from Egypt and India (CRD 1).

<sup>15</sup> ALINORM 97/30A, para. 53.

<sup>16</sup> CAC/GL 20-1995.

of international trade and which were subject to the TBT Agreement. This statement was supported by several delegations.

46. Several delegations supported the development of guidelines, especially in view of the importance of elaborating a systems based approach to address WTO and Codex elements related to equivalence, and in consideration of the Committee's broad mandate related to inspection and certification. It was noted that the equivalence procedures lessened the burden of costly and resource intensive traditional inspection methods, facilitated international trade, and provided a scientifically based risk approach for consumer protection. It was suggested that the other important non health related elements related to equivalence could be addressed more effectively in a separate set of guidelines, or in a more generic document related to both health and quality.

47. Other delegations noted that the elaboration of guidelines for the determination of equivalence did not relate to the mandate of the Committee and that in any case, the Committee should restrict its work to the equivalency of food control systems without dealing with matters such as food safety *per se*, which could be more effectively addressed by other Codex committees specifically concerned with food safety measures, such as the Codex Committee on Food Hygiene. It was also suggested that the judgment of equivalence should be incorporated into or annexed to the Committee's guidelines regarding the development of equivalence agreements. Brazil and other delegations stated that inspection and certification should best be left to individual governments, especially in consideration of the difficulty in the application of overly subjective equivalence measures or ill defined food safety objectives which could result in serious financial and resource burdens and the potential creation of barriers to international trade.

48. The WTO representative emphasized that the SPS Agreement obliged Members to accept sanitary or phytosanitary measures as equivalent, and that Members shall enter into consultations with the aim of achieving bilateral and multilateral agreements of recognition of the equivalence of specified sanitary or phytosanitary measures. He noted the resource and financial burdens of developing countries in this regard, but emphasized that the negotiating history of the SPS Agreement, examples of trade practices between developing countries and industrialized countries and WTO technical assistance missions indicated that establishing equivalence of SPS measures was a long term cost saving exercise and was already or would eventually provide a multitude of benefits to these countries.

49. The Committee noted that the TBT Agreement as well as the Codex Principles for Food Import and Export Inspection and Certification stated that countries shall give positive consideration to accepting as equivalent the technical regulations of other countries, even if these regulations differ from their own. It was noted that if countries used Codex standards they could easily achieve equivalence. It was also noted that although the Committee's terms of reference did not mention equivalency *per se*, the consideration of the subject appeared to be encompassed by the Committee's mandate related to the consideration of all matters related to the inspection and certification of foods, and to the Commission's mandate in the protection of consumers and the facilitation of international trade in foodstuffs.

50. Several delegations noted that as new concepts had been introduced in regard to the present document, it would be desirable if the delegations were given an opportunity to examine the document in their own countries, in all its aspects, including the availability of technical resources, especially in developing countries.

51. The Committee agreed with the basic principle that Codex standards should be applied in international trade, as stipulated in the SPS and TBT Agreements. The importance of establishing equivalent means of meeting food safety objectives based on Codex texts was also emphasized. The Committee reaffirmed that its work should be confined to the consideration of the equivalency of food control systems and not to the equivalency of specific requirements or standards.

52. The Committee thanked New Zealand and the other author countries for their excellent efforts. Noting the division of opinion on whether or not to proceed with the elaboration of Codex guidance in this area, the Committee agreed to the following:

- The Executive Committee would be requested to provide its opinion as to the extent to which issues relating to the judgment of equivalence, as presented in discussion paper CX/FICS 98/7, were within the mandate of CCFICS and/or other Codex Committees and how the subject should be considered further.
- There should be an examination of the relationship between the Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997), the proposed draft Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems and issues raised in the discussion paper regarding the judgment of equivalence.
- The proposed draft Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems and the discussion paper on the subject of the judgment of equivalence should be maintained on separate but parallel paths for the time being.
- Comments will be requested on the above and forthcoming discussions related to this subject after the 45th Session of the Executive Committee meeting in June 1998.
- Subject to the guidance of the Executive Committee, a revised discussion paper would be prepared by New Zealand for Committee's 7th Session, taking into account comments by governments and addressing the issues which had emerged during the meeting.

#### **DISCUSSION PAPER ON THE DEVELOPMENT OF A DATABASE ON REJECTIONS OF FOODS (AGENDA ITEM 9)<sup>17</sup>**

53. The Committee recalled that this matter had been discussed briefly at the Committee's 5th Session (1997) at which time the Committee suggested that a paper might be prepared by Consumers International.<sup>18</sup> The representative of Consumers International highlighted the potential benefits of instituting such a database; in particular, that it could provide a means of identifying problems in international trade; allow the monitoring of the quality and safety of foods moving in trade and ensure transparency in the operation of import/export control systems. Such a database could also have potential as the basis of an early warning system for problems related to foods in trade.

54. The representative of WHO, noting that the paper made specific reference to the potential role of that Organization on maintaining such a database, stated that because a large number of detentions of food were not related exclusively to food safety matters, the maintenance of data on these other matters might fall outside the Organization's mandate. He suggested that rather than a central database, a distributed network of national databases accessible via the Internet might be a suitable alternative. In this regard, it was proposed that the establishment of a directory or inventory of national databases could be developed. It was also proposed that the establishment of guidelines or a uniform format for the presentation of data might usefully form part of the future work of the Committee.

55. Several delegations and observers made reference to the databases available nationally or regionally. The representative of the European Union stated that information on food safety within the EU was available publicly through the Internet.

56. The Committee noted a number of problems in establishing a global database of rejections, including:

- the lack of uniform criteria for causes of rejection;

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<sup>17</sup> CX/FICS 98/8 and comments from Egypt and India (CRD 1).

<sup>18</sup> ALINORM 97/30A, paras. 51-52.

- rejections by an importing country might be disputed or may not be made on scientific grounds, and that the inclusion of such data in a database would be prejudicial;
- that the true causes of rejection might not be the fault of the exporter or the exporting country, but the conditions of transport or conditions of storage on arrival at the destination;
- the possibility that such data, without corresponding data on the domestic food situation, could give a false impression as the quality and safety of foods in trade;
- that the reasons for formal rejection were often minor and correctable;
- possible misuse of the data;
- the cost of establishing and maintaining such a database and ensuring that it would be kept up-to-date;
- that the establishment of such a database lay outside the mandate of the Codex Alimentarius Commission.

57. The representative of FAO noted that a survey had been carried out some years ago, with the assistance of Finland, into trade problems, especially rejections, in relation to contaminants in foods. He suggested that it might prove useful to repeat this survey under the new conditions of trading brought about by the WTO Agreements should resources become available.

58. The Committee expressed its continuing support, in principle, for the open provision of food control data as an essential component of ensuring consumer confidence in the food supply. It also noted that improvements in the development and availability of national databases would certainly occur in the future. The Committee agreed that the issue would be a matter of continuing interest. However, in view of the problems inherent in this exercise, practical difficulties and resource implications, the Committee agreed not to pursue this matter further at this time.

#### **DISCUSSION PAPER ON THE DEVELOPMENT OF GUIDELINES FOR THE UTILIZATION AND PROMOTION OF QUALITY ASSURANCE SYSTEMS (AGENDA ITEM 10)<sup>19</sup>**

59. The Committee noted that its Terms of Reference required it “to develop guidelines for the utilization, as and when appropriate, of quality assurance systems to ensure that foodstuffs conform with requirements and to promote the recognition of these systems in facilitating trade in food products under bilateral/multilateral arrangements by countries”.<sup>20</sup> This subject had therefore been discussed on several occasions by the Committee, most notably at its Fourth and Fifth Sessions, but little progress had been made.<sup>21</sup> In presenting the paper, Mr. Dean noted the previously expressed concern of countries that Codex guidance in this matter should avoid promoting any one quality assurance system. The manner in which proprietary and competing systems were being aggressively promoted and marketed was another concern for food control authorities. He also noted that clarification was needed of the relationship between quality assurance systems, the Hazard Analysis and Critical Control Point (HACCP) System, and other food safety management systems.

60. The Committee noted the views of several delegations that more information and guidance was needed on this subject, but that this should not be related to any specific proprietary or commercial system of quality assurance. On the other hand, it also noted the views of those delegations which felt that there was adequate, even considerable, information available and that there was no need for the Commission to undertake work in this area.

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<sup>19</sup> CX/FICS 98/9 (Prepared by an FAO Consultant, Mr. John Dean).

<sup>20</sup> Procedural Manual of the Codex Alimentarius Commission, 10th Ed., 1997, pages 94 - 95.

<sup>21</sup> ALINORM 97/30, paras. 14-18; ALINORM 97/30A, paras. 18-21.

61. Noting this division of opinion, the Committee agreed that it would not be appropriate to seek a mandate to undertake the elaboration of guidelines as proposed in the working document. Nevertheless, it agreed that it would be appropriate to keep the topic on the Committees agenda and accordingly that a further discussion paper would be prepared for consideration at the next Session. The government of Australia offered to coordinate the preparation of such a paper.

#### **OTHER BUSINESS AND FUTURE WORK (AGENDA ITEM 11)**

##### **Guidelines for the Development of a Database with Regard to the Legislative Requirements of Importing Countries as Related to the SPS Agreement**

62. The delegation of India noted that the lack of information on importing country requirements, especially in regard to health related SPS measures, often resulted in the rejection of exports at the entry point in the importing country. It was often difficult to obtain such information due to problems such as the involvement of more than one organization in establishing these requirements and the availability of requirements in different languages which necessitated translation. India therefore suggested that guidelines for the development of a database on legislation of various countries might be considered by the Committee, to be made available via electronic media.

63. Several delegations noted the existence of such databases in their own countries and it was suggested that an inventory might be made of such systems as a first step. The delegation of Argentina informed the Committee that they have a database on food legislation which contains the regulations of national bodies, the Argentina Food Code, local legislation and MERCOSUR standards. It was available through the Internet site under the Secretary of Agriculture, Livestock, Fish and Food and was developed with the technical support of INPPAZ from PAHO.

64. The WHO representative noted that the Pan American Health Organization (PAHO) maintained a database on Latin American food law, and also suggested that any inventory proposed by the Committee should also take account of initiatives already undertaken by private firms. The WTO representative indicated that addresses of inquiry points and central government authorities of WTO Members, as well as the WTO Members notifications of SPS Measures, were available under the WTO Internet Home Page. The FAO representative also noted that an inventory should take account of both health and quality legislation as it was often difficult to differentiate between the two. The difficulty in establishing and the expenses associated with maintaining these systems was also stressed.

65. The Committee accepted the offer of India, assisted by other interested delegations, including Argentina, Australia and Canada, to prepare a discussion paper on Guidelines for the Establishment of a Database on Importing Country Legislation for consideration at its next meeting.

#### **DATE AND PLACE OF NEXT SESSION (AGENDA ITEM 12)**

66. The Committee was informed that its 7th Session was tentatively scheduled to be held in Melbourne, Australia from 15-19 February 1999, with the final location and dates to be determined between the Codex and Australian Secretariats.



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

**CURRENT STATUS OF WORK**

<b>SUBJECT</b>	<b>STEP</b>	<b>FOR ACTION BY</b>	<b>REFERENCE*</b>
Proposed Draft Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems	5	45th CCEXEC Governments 7th CCFICS	paras. 10-33 and Appendix II
Proposed Draft Guidelines/Recommendations for Food Import Control Systems	1/2	45th CCEXEC Mexico 7th CCFICS	paras. 34-36
Guidelines and Criteria for Official Certificate Formats and Rules Relating to the Production and Issuance of Certificates	1/2	45th CCEXEC AUL/UK 7th CCFICS	paras. 37-40
Discussion Paper on Issues Relating to the Judgment of Equivalence	-----	45th CCEXEC Governments New Zealand 7th CCFICS	paras. 41-52
Discussion Paper on the Utilization and Promotion of Quality Assurance Systems	-----	Australia 7th CCFICS	paras. 59-61
Discussion Paper on Guidelines for the Establishment of a Database on Importing Country Legislation	-----	India 7th CCFICS	paras. 62-65

\* All references refer to the report of the sixth Session of the Codex Committee on Food Import Inspection and Certification Systems (ALINORM 99/30).

**ALINORM 99/30**

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

**(Advanced to Step 5)**

**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.<sup>22</sup>

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.<sup>22</sup>

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.<sup>23</sup>

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.<sup>22</sup>

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.<sup>22</sup>

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.<sup>22</sup>

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.<sup>22</sup>

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<sup>22</sup> Codex Alimentarius: Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995).

<sup>23</sup> 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. Countries<sup>24</sup> may wish to enter into agreements<sup>25</sup> 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 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 - 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. The importing country determines whether the exporting country's measures meet the importing country's requirements. Its decision must, however, be made on the basis of objective criteria.

15. As agreed by the parties, an equivalence agreement may cover control and certification systems relating to any aspect of food safety or other relevant requirement for food. Agreements may be limited to specific areas of trade or specific products. Agreements may be concluded when equivalence has not been established in respect of all requirements.

16. 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.<sup>26</sup>

### **SECTION 5 - CONSIDERATIONS BEFORE ENTERING INTO BILATERAL OR MULTILATERAL DISCUSSIONS**

17. In general, significant resources are needed to develop agreements. Exporting and importing countries may need to establish priorities with respect to consideration of requests for 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.
- 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.

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<sup>24</sup> 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.

<sup>25</sup> See Section 1 - Scope. Although this guideline refers to "countries" and "agreements," in many cases competent authorities will enter into agreements or other arrangements.

<sup>26</sup> See paragraph 45 in CAC/GL 26-1997.

- 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.<sup>27</sup>

20. Countries that are not yet ready to enter into equivalence agreements may wish to work toward the development of such agreements. Amongst other things, information exchange, joint training, technical cooperation, and the development of infrastructure and food safety control systems can serve as building blocks towards the later development of agreements. An importing country should consider providing technical assistance to developing exporting 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. An initial contact should be made to determine whether the other country is prepared to pursue an agreement. The initiating country should identify:

- a) the type of equivalence agreement;
- b) the product(s) to be covered;
- c) the competent authority 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. In the event that the recipient of a request for an agreement may not be prepared to cooperate with the request, it should provide a statement of reasons and any relevant recommendations to facilitate the future development of equivalence agreements.

23. Before consultations begin, both parties should verify that legal authority exists to discuss and enter into such an agreement.

24. Both countries should provide the relevant information (outlined in Section 7 below) needed for the consultative process.

## **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 measures, the importing country should identify the health risk(s) addressed by each measure. Where certain health risks, such as foodborne pathogens, are known to exist in the exporting country and not in the importing country, these risks and the measures to address them should be identified.

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

- Equivalence agreements for food safety (sanitary) measures are concluded after an importing country determines that an exporting country's control measures, even if different than those of the importing country, achieve the importing country's level of health protection.
- Equivalence agreements for all other measures are concluded 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.

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<sup>27</sup> See CAC/GL 26-1997 for guidelines on the conduct of such assessment and verification activities.

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.<sup>28</sup>
  - 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.<sup>29</sup>
  - c) Decision criteria and action.<sup>30</sup>
  - d) Facilities, equipment, transportation and communications as well as basic sanitation and water quality.<sup>31</sup>
  - e) Laboratories, including information on the evaluation and/or accreditation of laboratories, and evidence that they apply internationally accepted quality assurance techniques.<sup>32</sup>
  - f) Details of the exporting country's systems for assuring competent and qualified inspection<sup>33</sup> 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.<sup>34</sup>
  - 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 Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems.
32. The participating competent authorities 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.
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 "acceptable" establishments -- that is, 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.

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<sup>28</sup> See paragraphs 20-23 in CAC/GL 26-1997.

<sup>29</sup> See paragraphs 24-29 in CAC/GL 26-1997.

<sup>30</sup> See paragraphs 30-37 in CAC/GL 26-1997.

<sup>31</sup> See paragraphs 38-40 in CAC/GL 26-1997.

<sup>32</sup> See paragraphs 41-42 in CAC/GL 26-1997.

<sup>33</sup> See paragraph 43 in CAC/GL 26-1997.

<sup>34</sup> See paragraphs 47 and 52-57 in CAC/GL 26-1997.

34. The participating competent authorities should agree to procedures for information exchange in the event of an emergency food safety situation.<sup>35</sup>
35. The participating competent authorities 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. The participating competent authorities 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, participating competent authorities should provide the public--including consumers, industry, and other interested parties--an opportunity to comment on the basis for equivalence determinations.<sup>36</sup>

## **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.

## **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 new or revised measures that pertain to the agreement.

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<sup>35</sup> See Codex Guidelines for the Exchange of Information in Food Control Emergency Situations (CAC/GL 19-1995).

<sup>36</sup> See paragraph 58 in CAC/GL 26-1997.

***CONTENTS OF EQUIVALENCE AGREEMENTS***

The following information should 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 which 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 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.
- 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. *Period of Agreement:* The date on which the provisions of the agreement enter into force, and the means for modification and termination of the agreement should be described.
- t. *Signatures:* Signatures, titles, names and signature dates of an official representing each of the competent authorities that is a participant in the agreement.