codex alimentarius commission

FOOD AND AGRICULTURE **ORGANIZATION**

WORLD HEALTH **ORGANIZATION**

OF THE UNITED NATIONS

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME Tel.: 52251 Telex: 625852-625853 FAO I Cables: Foodagri Rome Facsimile: (6)522.54593

ALINORM 95/30A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME **CODEX ALIMENTARIUS COMMISSION Twenty-first Session** Rome, 3-8 July 1995

REPORT OF THE THIRD SESSION OF THE CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS Canberra, Australia, 27 February - 3 March 1995

Note: This report incorporates Codex Circular Letter CL 1995/8 - FICS

w/v6355

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CX 4/70.2

CL 1995/8-FICS March 1995

TO:

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

FROM:

Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla,

00100 Rome, Italy

SUBJECT: <u>Distribution of the Report of the Third Session of the Codex Committee on Food Import and Export Inspection and Certification Systems</u>

The report of the third Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) is attached. It will be considered by the Twenty-first Session of the Codex Alimentarius Commission in Rome from 3-8 July 1995.

PART A: MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION

The following matters will be brought to the attention of the 21st Session of the Codex Alimentarius Commission for adoption:

- 1. Draft Principles for Food Import and Export Inspection and Certification at Step 8; ALINORM 95/30A, paras. 18-30 and Appendix II.
- 2. Draft Guidelines for the Exchange of Information in Food Control Emergency Situations at Step 8; ALINORM 95/30A, paras. 31-41 and Appendix III.
- 3. General Statement on Provisions Concerning Inspection and Certification in Codex Standards; ALINORM 95/30A, paras. 90-97.

Governments wishing to propose amendments or to comment on the above matters should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 of the Procedure for the Elaboration of Codex Standards Including Consideration of Any Statements Relating to Economic Impact (*Codex Alimentarius Procedural Manual*, Eighth Edition, pp. 33-35) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, not later than 30 April 1995.

4. Proposed Draft Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food at Step 5; ALINORM 95/30A, paras. 68-76 and Appendix IV.

Governments wishing to submit comments regarding the implication which the proposed draft Guidelines or any provisions thereof may have for their economic interest should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (at

Step 5) (Codex Alimentarius Procedural Manual, Eighth Edition, pp. 27-29) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, not later than 30 April 1995.

PART B: REQUEST FOR COMMENTS

1. Proposed Draft Guidelines on the Principal Elements in an Electronic Documentation System; ALINORM 95/30A, paras. 81-83 and Appendix V.

The Committee agreed that it would be appropriate to obtain further detailed comments on the proposed draft Guidelines at Step 3, especially from countries which had little current experience in the use of the technology.

2. Application of the ISO 9000 Series to Food Inspection and Certification Systems; ALINORM 95/30A, paras. 84-89.

The Committee agreed that information on the practical application of the ISO 9000 Series to the food sector would be sought from countries for consideration at the next session, when the possible establishment of Codex Guidelines on the Application of the ISO 9000 Series to Food Inspection and Certification Systems could be considered.

Governments and interested International Organizations wishing to submit comments on the above subject matter are invited to do so not later than 30 September 1995 to the Chairman of the Committee at the following address:

Mr. Digby Gascoine
Director
Development and Evaluation Division
Australian Quarantine and Inspection Service
Department of Primary Industries and Energy
GPO Box 858
Canberra ACT 2601
Australia

In addition, please forward a copy of the comments to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy.

SUMMARY AND CONCLUSIONS

The third Session of the Codex Committee on Food Import and Export Inspection and Certification Systems reached the following conclusions during its deliberations:

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

- Agreed to advance the draft Principles for Food Import and Export Inspection and Certification to the Commission for adoption at Step 8 (para. 29);
- Agreed to advance the draft Guidelines for the Exchange of Information in Food Control Emergency Situations to the Commission for adoption at Step 8 (para. 41);
- Decided to discontinue the development of the proposed draft Glossary of Terms Based on Internationally Accepted Definitions (para. 46);
- Agreed to advance the proposed draft Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food to the Commission for adoption at Step 5 (para. 76);
- Agreed that France would revise the document on the Application of the ISO 9000 Series to Food Inspection and Certification Systems with a view towards the possible establishment of Codex Guidelines at its next session (para. 89);
- Agreed that a general statement on Provisions Concerning Inspection and Certification in Codex Standards be forwarded to the Commission for adoption and possible inclusion in the Codex Alimentarius Procedural Manual (para. 96); and,
- Agreed on its Current Status of Work (para. 101).

OTHER MATTERS OF INTEREST TO THE COMMISSION:

- Agreed that the proposed draft Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems be redrafted by Canada and the EC for circulation and government comment prior to its 4th session (para. 67);
- Agreed that the List of Contacts for Food Import Control and Information Exchange in Food Control Emergency Situations be revised by Australia on a regular basis by request (para. 80);
- Agreed to circulate the proposed draft Guidelines on the Principle Elements in an Electronic Documentation System for further comment at Step 3 (para. 83);
- Noted that the Codex Committee on Fish and Fishery Products would provide the technical details of a proposed Model Certificate for Fish Inspection Purposes for possible consideration at the 4th CCFICS session (para. 98); and,
- Requested the United States to elaborate proposed draft Guidelines for the Development of Agreements between Exporting and Importing Countries for consideration at the Committee's 4th session (para. 100).

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

Canberra, ACT, Australia; 27 February - 3 March 1995

INTRODUCTION

1. The Third Session of Codex Committee on Food Import and Export Inspection and Certification Systems was held in Canberra, ACT, from 27 February to 3 March 1995 at the kind invitation of the Government of Australia. The Session was chaired by Mr. Digby Gascoine of the Australian Quarantine and Inspection Service, Department of Primary Industries and Energy. It was attended by 197 delegates and advisers from 47 Member countries and 19 observers from 10 international organizations. The list of Participants is attached to this report as Appendix I.

OPENING OF THE SESSION (Agenda Item 1)

- The meeting was officially opened by Senator Bob Collins, Minister for Primary Industries and Energy. The Minister extended a warm welcome to participants at the third session of the Committee and especially welcomed those delegates from countries attending for the first time. In his opening address the Minister noted the importance of the World Trade Organisation (WTO) and, in particular, the obligation of members of the WTO to attune their food standards with Codex standards, except where there is a technical or risk management justification for adopting a different approach. He noted the WTO agreements were vital and important to the deliberations of this committee. The Minister also endorsed the priority of Dr Diouf, Director-General of the FAO, in regard to food security. Australia believed that food security should not be only global or national, but also household security. He said that there was a distinct relationship between assisting countries to make full use of their comparative economic advantage to achieve household food security and the work of Codex and this Committee. Food inspection and certification systems, the Minister said, make a major contribution to ensuring the safety of foods moving in international trade and domestic food supplies. In many countries, he noted that, rightly, food safety is near the top of the list of issues of common public concern. The Minister referred to both the professional and personal interest of members of delegations at the meeting have in protecting consumers. and facilitating trade. He expressed concern about the vulnerability of children through food borne diseases in all countries of the world and noted that the work of Codex has more recently been sharpened to focus on safety issues to cover the whole spectrum of food handlers, from producers to consumers. In closing he noted the work of Codex in terms of developing guidance on HACCP systems and the recognition of the use of quality systems as an alternative to traditional forms of inspection. This meeting provided each country represented with the opportunity to discuss what is being done individually and collectively towards ensuring the safety of foods moving in international trade and in ensuring market access for food products.
- 3. Mr. R.J. Dawson, Secretary of the Codex Alimentarius Commission and Chief, Joint FAO/WHO Food Standards Programme thanked Senator Collins for his remarks and for taking the time from his busy agenda to address the session. Mr. Dawson also expressed the

appreciation of FAO and WHO to the Government of Australia and in particular to the Australian Quarantine and Inspection Service, AQIS, for hosting and holding the session. He noted that the Committee's draft recommendations were very timely in view of the entry into force of the Agreements on the Application of Sanitary and Phytosanitary Measures and on Technical Barriers to Trade. Mr. Dawson noted that trade in good quality, safe food products was an essential part of FAO's approach to food security, and that food which was unsafe or of poor quality could not contribute to food security. Mr. Dawson also welcomed delegates to the session on behalf of the Directors-General of FAO and WHO.

ADOPTION OF THE AGENDA (Agenda Item 2)2

4. The Committee adopted the Provisional Agenda as the Agenda for the Session.

MATTERS OF INTEREST ARISING FROM CODEX COMMITTEES (Agenda Item 3)³

- 5. The Committee noted that the 41st Session of the Executive Committee (June 1994) had confirmed (at Step 1) the CCFICS proposal for new work concerning the "Application of the ISO 9000 Series to Food Inspection and Certification Systems" (see paras. 84 to 89) and the Codex Committee on Food Hygiene proposal (in collaboration with CCFICS) concerning "Implications for the Broader Application of the Hazard Analysis Critical Control Point System⁴. The Executive Committee had also adopted (at Step 5) the "Proposed Draft Principles for Food Import and Export Inspection and Certification" (see paras. 18 to 30) and the "Proposed Draft Guidelines for Information Exchange in Food Control Emergency Situations" (see paras. 31 to 41)⁵.
- 6. The Codex Secretariat encouraged governments and interested international organisations to submit comments on the document concerning the "Development of Objective Criteria for Assessing the Competence of Testing Laboratories Involved in the Official Import and Export Control of Foods" and the proposed draft "Code of Practice for the Control and Inspection of Tropical Fresh Fruits and Vegetables". The Committee decided to discuss the Codex Committee on Fish and Fishery Products proposal for CCFICS consideration of the

¹ Throughout this report, the Agreements on the Application of Sanitary and Phytosanitary Measures and on Technical Barriers to Trade will be referred to as the SPS and the TBT Agreements, respectively.

² CX/FICS 95/1

³ CX/FICS 95/2

⁴ ALINORM 95/13, para. 102.

⁵ ALINORM 95/3, para. 47 and Appendix II.

⁶ CL 1994/10-MAS, ALINORM 95/23

⁷ CL 1994/27-TFFV, ALINORM 95/35

identification of requirements to be included in a model certificate for fish inspection purposes⁸ and the previous CCFICS request⁹ for the Codex Secretariat to provide information on FAO publications on Legislation Related to the Certification of Agricultural Products under "Other Business" (see paras. 98-99).

7. The Committee agreed to discuss its Medium-Term Objectives and Future Programme of Work¹⁰ as scheduled under agenda item 14 (see paras. 100 to 101).

MATTERS OF INTEREST ARISING FROM OTHER INTERNATIONAL AND REGIONAL ORGANIZATIONS WORKING IN RELATED FIELDS (Agenda Item 4)

Office International des Epizooties (OIE) (World Organization for Animal Health)

Since the successful completion of the Uruguay Round, the Office International des 8. Epizooties (OIE) (World Organization for Animal Health), continued to play a key role in The Organization's technical guidelines for zoning and facilitating global trade. regionalization of animal diseases and the use of risk assessment was a key factor in the application of the SPS Agreement. Membership of OIE now stood at 140 Member countries. OIE achieved its goals by technical cooperation and training and the worldwide exchange of animal disease information currently published on a weekly, monthly or annual basis. It paid particular attention to emergency disease outbreaks. As part of advancing free trade objectives there was recognition by OIE of the need to continue to develop new risk management strategies and technologies to reduce animal health related risks to an acceptable level. OIE stressed the need for the development of uniform and acceptable approaches to risk acceptance requiring a more quantitative approach based on transparent, defensible, biological standards. The establishment of an improved integrated worldwide animal health information system is a priority for the 1990's to underpin import risk analysis.

International Organization for Standardization (ISO)

9. The Representative of ISO advised the Committee that ISO developed consensus standards in many areas. It was the sister organization to the International Electro-technical Organization (IEC) and the International Telecommunications Union (ITU) which operated similarly in their defined areas. ISO through its technical Committee TC/176 had developed quality systems and quality management standards including the ISO 9000 series. First published in 1987 and refined by revision in 1994 these standards were now in near universal use. The ISO Committee on Conformity Assessment (CASCO) provided guides on all steps in conformity assessment from testing, through inspection to product and quality system certification and the accreditation of bodies carrying out these tasks. ISO IEC Guide 25 on conformity assessment was being revised to align it better with ISO 9000 and a guidance document on suppliers' declaration of conformity of standards or specification was in preparation.

⁸ ALINORM 95/18, para. 7.

⁹ ALINORM 95/30, paras. 67 - 70.

¹⁰ CX/FICS 95/2, Appendix III.

AOAC International

10. AOAC International is an international association of analytical chemists and microbiologists involved in a variety of analytical work; including, primarily, food and agricultural product analysis. AOAC's primary mission is to promote the use of validated methods and appropriate techniques to ensure high quality analytical measurement in the analytical services. AOAC accomplishes its mission by providing a mechanism for the scientific validation and publication of analytical methodology, convening conferences for the exchange of information, and providing training on subjects related to improving laboratory quality assurance and analytical measurements. AOAC is currently working with FAO and WHO to donate and distribute over 450 sets of the 15th edition of Official Methods of Analysis of the AOAC to laboratories in developing countries to assist them in improving their analytical abilities.

Consumers International

- 11. In January 1995, the International Organization of Consumers Unions changed its name to Consumers International. Under its new name, Consumers International will carry on the work it began in 1960, to support and strengthen the consumer movement world-wide and represent the interests of consumers at the United Nations and international bodies such as the Codex Alimentarius Commission. Consumers International's membership has increased by 20 percent in the last three years, which is the greatest growth in its 35-year history. The organization now included 203 members in more than 80 countries; (half of its membership is in the developing world) with 5 Regional Offices in Latin America and the Caribbean; Central and Eastern Europe; and for the developed economies.
- 12. In 1994, Consumers International published a briefing paper on Codex and a book on the Uruguay Round of trade negotiations, outlining, amongst other things, the implications of the SPS and TBT Agreements for consumers. At its September 1994 World Congress in Montpellier, France, Consumers International decided to give its Codex work the highest priority. To establish the level of current consumer involvement in the food standard setting process, a questionnaire has been sent out to all member organizations. The results of this were to be used as the basis for a paper on consumer involvement in Codex that the organization intends to submit to the Twenty-first Session of the Commission. The establishment of strong import and export inspection and certification systems, which are both transparent and accountable was seen by Consumer International as a matter of vital importance by consumers world-wide to protect them from unfit foodstuffs, fraud and deception.

Food and Agriculture Organization of the United Nations (FAO)

13. The Committee was informed of the efforts of WTO/CODEX/OIE/IPPC to advise member countries on the requirements of the new SPS Agreement through the holding of Regional workshops. The first such WTO/CODEX/OIE/IPPC Regional Workshop was held at the FAO Regional Office in Bangkok for ASEAN countries in late 1994. Both government and industry representatives participated. A similar workshop was being planned to be held for the countries of the Pan American Region in Mexico City in May, 1995. Also, two similar workshops were to be held in late 1995 in Africa.

- 14. FAO continued its efforts to strengthen national food control infrastructures of several member countries. Activities were being carried out in over 50 projects of technical assistance, including establishing and strengthening national export inspection and certification programmes, strengthening national food control programmes, and assisting in conducting national food contamination programmes.
- 15. In response to a request made by the Executive Committee of the CAC, FAO and WHO were to hold a Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues. The Consultation was to be held at WHO Headquarters, Geneva from 13 to 17 March 1995. The report of the Consultation was to be made available to the CAC and its Committees, to Member Governments and to the FAO and WHO for use in food control matters, including the preparation of Codes of Practice and standards.
- 16. FAO held a Technical Expert Consultation on Integrating HACCP into Food Control Programmes in Vancouver, Canada in late 1994. The report of the Consultation, including the recommendations was to become available in March 1995 and would be widely distributed. As a result of this Consultation a Working Group was held in February, 1995 which designed a *Training of Trainers Programme on the Use of HACCP*. A pilot programme on this subject is scheduled to be carried out in Thailand in mid-1995 with the objective of training both government and industry representatives who will then be used to train others in the Thai language.
- 17. An FAO/AQIS Workshop on Food Import Control Systems had been held immediately prior to the Session, attended by ten countries of the Asia-Pacific Region and a Representative of the EC. Participants at the Workshop exchanged information on their respective food import control systems, including registration and pre-certification systems, and concluded that systems focussed on high risk foods were likely to give better results.

DRAFT PRINCIPLES FOR FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION AT STEP 7 (Agenda Item 5)¹¹

18. The Committee noted that the proposed Draft Principles for Food Import and Export Inspection Certification had been adopted at Step 5 by the 41st Session of the Executive Committee. The Committee considered the proposed Draft Principles in the light of government comments submitted at Step 6, and reviewed the text paragraph by paragraph.

Section 1 - Introduction

19. In reply to concern expressed by several delegations the Committee confirmed that the word quality, when used in relation to food, comprised the totality of attributes including food safety. This was not to be taken as meaning that food safety was in any way subsidiary to other quality factors but to indicate that quality food must, in and of itself, be safe. Such an

ALINORM 95/30, Appendix 2. Government comments in response to CL 1994/21-FICS from Canada, Denmark, Egypt, Malaysia, Thailand, United Kingdom, USA and IFGMA in CX/FICS 95/3 and comments from European Community in Conference Room Document No. 3.

¹² ALINORM 95/3, para. 47 and Appendix II.

approach was consistent with ISO terminology defining Quality. The Committee therefore amended paragraph 1 of the Introduction to indicate that quality included safety. Paragraph 3 of the Introduction was amended to delete reference to the word quality because in general it was not possible to limit inspection for safety to the distribution process or prior to final sale.

Section 2 - Definitions

- 20. The Committee retained the definition of *Audit* as being consistent with the relevant ISO definition, however it was noted that the Spanish text of this definition was not appropriately worded.
- 21. The definition of *Certification* was amended to replace the expression "competent authorities" which could lead to confusion as to the nature of the authority having final responsibility for government-to-government certification. The Committee agreed to use the expressions "official certification bodies or officially recognized certification bodies". It was acknowledged that the use of the term "official" in this context pertained to a government agency and that the words "official" and "government" were co-equal terms.
- 22. The definition of *Inspection* was amended slightly to improve its clarity. The Committee did not accept a proposal to restrict inspection or certification to the verification of conformity to Codex standards, as the principles were intended to be general in their application.
- 23. The definitions of Official Inspection Systems and Official Certification Systems and Officially Recognized Inspection Systems and Officially Recognized Certification Systems were amended to indicate that the agency having jurisdiction was a government agency (see para. 21 above). The Committee confirmed decisions taken at its previous session that inspection and certification by non-government systems was an acceptable arrangement provided that authority had been delegated or officially recognized by a legislative, government or government agency for the operation of such systems. An amendment was made to the definition of Official Inspection Systems and Official Certification Systems to emphasise this. The Delegation of Brazil noted that national legislation in that country did not provide for the use of an official national inspection system, inspection being carried out by federal, state and municipal authorities.
- 24. The Committee decided to maintain the definition for Requirements and revised the definition for Risk Assessment so that it referred to both the likelihood and severity of adverse effects. In the latter case it was noted that the 21st Session of the Commission in July 1995 would discuss the report of the FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues (see para. 15). Among the issues to be discussed would be the establishment of Codex-wide definitions in this field. The Committee noted that it may be necessary to amend this definition at a later date. The Committee also noted that food standards sometimes addressed the potential for adverse effects due to allergenicity and requested advice on how to deal with risk analysis in this context.

Section 3 - Principles

- 25. The Committee noted that the food inspection and certification systems to which the present text referred did not extend to the protection of animal or plant life or health. These matters were appropriate mandates of the OIE and IPPC respectively.
- 26. The Committee recognized that contamination of the primary production environment could be localized and amended the Principles accordingly.
- 27. In regard to *transparency* the Committee recalled that significant changes had been introduced into the text to open the principles and operations of food inspection and certification systems to public scrutiny. It did not therefore deem it necessary to adopt a separate definition for transparency.
- 28. The Committee confirmed that the special and differential treatment accorded to developing countries in designing and applying food inspection and certification systems provided flexibility in the design and the application of the systems but not in the standards to which they applied.

Status of the draft principles for food import and export inspection and certification

- 29. The Committee advanced the draft principles for food import and export inspection and certification to Step 8 of the procedure for submission to the 21st Session of the Codex Alimentarius Commission for adoption. The revised draft principles are contained in Appendix II of this report.
- 30. The Committee noted that similar principles were being developed by the MERCOSUR group of countries (Argentina, Brazil, Paraguay, Uruguay) to facilitate trade in foods, and that comments by countries on these principles were invited.

DRAFT GUIDELINES FOR INFORMATION EXCHANGE IN FOOD CONTROL EMERGENCY SITUATIONS AT STEP 7 (Agenda Item 6)¹³

31. The proposed draft Guidelines for Information Exchange in Food Control Emergency Situations, developed by the government of Sweden, were adopted by the 41st Session of the Executive Committee (June 1994) at Step 5.¹⁴ Government comments at Step 6 were requested under CL 1994/21-FICS.¹⁵ The Committee agreed to the following changes:

¹³ ALINORM 95/30, Appendix III

¹⁴ ALINORM 95/3, para. 47 and Appendix II.

Canada, Denmark, Egypt, Malaysia, the United Kingdom, the United States (CX/FICS 95/4); the International Federation of Grocery Manufacturer Associations (CX/FICS 95/4 and CX/FICS 95/4-Add. 1); and, the European Community (Conference Room Document 3).

Paragraph 2

32. The Committee clarified this paragraph by indicating that exporting country food control authorities should promptly notify "by telecommunication the appropriate authorities" in countries which have imported or are the destination of foods. The Committee also added a sentence indicating that countries should inform the public where appropriate. The reference to "telecommunication" was also inserted into paragraph 3.

Paragraph 5

33. The Committee clarified this section by indicating that each country should identify a "primary" contact point for food control emergency situations. In view of the elaboration of the List of Contacts for Food Import Control Agencies (see paras. 77-80), the Committee also agreed that comments should be requested on those contact points responsible for food control emergency situations with a view towards creating one comprehensive list (i.e., List of Contacts for Food Import Control and Information Exchange in Food Control Emergency Situations).

Paragraph 7

- 34. In response to the concerns of several delegations that providing information to international organizations should not be a matter of routine, the Committee was informed that WHO published a weekly epidemiological report on specific notifiable diseases. The Committee was also informed of efforts by FAO to provide information to governments on food related disease outbreaks (e.g., cholera, plague).
- 35. In view of this discussion, the Committee decided to amend this paragraph by indicating that information "should" be provided to FAO, WHO and other international organizations only when specifically requested to do so.

Paragraph 9

36. The Committee clarified this section by indicating that information provided on specific food-borne health hazards should be in accordance with the format included in the Annex to the Guidelines. It was also agreed that all such foods, as opposed to the "most important" foods, should be identified. This decision was made with the understanding that only those foods specifically linked to the incident required identification.

Paragraph 10

37. The Committee decided to combine paragraphs 10 and 11 and created a new paragraph 10 which stressed that implicated food shipments should be clearly identified and that information be provided on measures taken to prevent further contamination, to recall and detain product, to indicate final disposition and any action taken.

Annex to the Guidelines

- 38. The Committee added a preamble at the beginning of the Annex for clarity of use of the standard format.
- 39. In the section entitled "Nature of the Health Hazard", the Committee added categories concerning veterinary drugs, environmental contaminants and other identified hazards. It was also indicated that in all cases, the specific hazard and the levels or prevalence of hazards of concern should be identified.
- 40. In the section entitled "Identification of Foods Concerned", the Committee agreed to add description and quantity of product, type and size of package, lot identification and seller/importer information. The indent concerning "information on trade in food" was deleted as this was considered superfluous to the exchange of information.

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

41. The Committee expressed its appreciation to Sweden for its work and agreed to forward the revised Guidelines to the 21st Session of the Codex Alimentarius Commission for adoption at Step 8. The Guidelines are attached to this report as Appendix III.

PROPOSED DRAFT GLOSSARY OF TERMS BASED ON INTERNATIONALLY ACCEPTED DEFINITIONS (Agenda Item 7)¹⁶

- 42. The Committee recalled that it had decided to circulate the proposed draft Glossary of Terms Based on Internationally Accepted Definitions for comment and review at its current session. The Glossary had been prepared in order to include additional terms to those included in the proposed draft Principles and to assist the Committee in its future work. It had been decided that the Glossary would be an internal reference paper for exclusive use of the Committee, which would not be developed as a document for adoption by the Commission.¹⁷
- 43. Several delegations noted that in the interest of international harmonization and transparency, definitions established by other Codex Committees or international organizations (e.g., ISO) should not be modified when included in the Glossary. The validity of establishing a Glossary purely for the Committee's internal use was also questioned, as was the inclusion of less relevant or unnecessary terms. In this regard, the Committee reaffirmed its previous decision that the Glossary should only contain those terms which were indispensable to the Committee's future work. Considerable support was given to the Criteria for the inclusion of terms in the proposed draft glossary of terms proposed by the USA in written comments (CRD 1).

¹⁶ CX/FICS 95/5 and comments from the United States (CX/FICS 95/5-Add. 1 and Conference Room Document 1), Australia (CRD 5), Thailand (CRD 6), Malaysia (CRD 9) and the European Community (CRD 3).

¹⁷ ALINORM 95/30, paras. 37-40

- 44. Several delegations expressed concern that the Glossary had the potential to be utilised by the WTO under the TBT and SPS Agreements. The Codex Secretariat informed the Committee that unless the Glossary were to be formally adopted by the Commission, it would have no formal status in Codex and could not be published as part of the Codex Alimentarius. It was also indicated that if the document was truly restricted to the Committee's internal use, the glossary would not have official status and could be not be used as an official source of definitions.
- 45. In view of this, several delegations felt that the Committee would be setting an unnecessary precedence for unofficial glossaries to be used as a reference source in the context of the Uruguay Round WTO Agreements. Other delegations felt that the Glossary should receive official status through adoption by the Commission, particularly in the interest of establishing uniform and consistent terms between various international bodies.

Status of the Proposed Draft Glossary of Terms Based on Internationally Accepted Definitions

46. The Committee decided to discontinue the development of the Glossary at the present time, with the understanding that the Australian Secretariat would revise and maintain the Glossary for use by the Committee as a future reference source if and when required. It was also noted that this recommendation would be forwarded to the Executive Committee for approval.

PROPOSED DRAFT GUIDELINES FOR THE DESIGN, OPERATION, ASSESSMENT AND ACCREDITATION OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS AT STEP 4 (Agenda Item 8)¹⁸

- 47. The Committee recalled that the programme of work outlined at its first session included the development of guidance documents relating to harmonized import and export inspection and certification systems, including guidelines on the design and operation of food inspection and certification systems, application of equivalence principles, decision criteria and action, criteria of competence for food inspection and certification bodies, procedures for accreditation and assessment and verification. Documents covering these topics were prepared and discussed by the Committee at its second session in 1993. Following an extensive debate on the documents submitted, the Committee at its second session requested the delegation of Canada and the representative of the EC, working in cooperation with the individual author countries and the Secretariat, to prepare a concise revised document with the maximum amount of integration possible between the various subjects. 19
- 48. The document was introduced by the delegation of Canada and the representative of the EC. In preparing the document attention had been paid to guidance on how to apply the

¹⁸ CX/FICS 95/6 and Comments of United Kingdom (CX/FICS 95/6 Add. 1), New Zealand, United States of America (CX/FICS 95/6 Add. 2) International Dairy Federation (CRD 2), European Community (CRD 3), Malaysia and Thailand (CRD 8) and the European Accreditation Certification/European Cooperation for Accreditation of Laboratories - EAC/EAL (CRD 12).

¹⁹ See ALINORM 95/30, paras. 41 - 62, especially paragraph 62.

general principles of food import and export inspection and certification in a manner which would not be too bureaucratic or restrict trade. It was further noted that some elements of the document; for example, definitions would need to be revised as a consequence of changes made to the principles themselves (see paras. 18 to 30 above).

General

49. The Committee expressed its overall general satisfaction with the document. However, concern was expressed that aspects of transparency were not well incorporated and that the rights of consumers, their representatives and other interested parties to have scrutiny over food import and export inspection and certification systems were not well incorporated within the draft Guidelines.

Section 1 - Scope

50. It was suggested that the scope should specify that the guidelines should set out the development of equivalent import and export inspection and certification systems rather than the development of harmonized systems.

Section 2 - Definitions

- 51. In relation to the definition of *Risk Assessment* and the possibility of other definitions used in association with risk analysis, the Committee agreed to maintain the text established in its discussion on the principles of import and export inspection and certification and to await advice which may be forthcoming from the Joint FAO/WHO Expert Consultation in this area (see para. 15). Some delegations noted that the terms related to risk were not used consistently throughout the document.
- 52. Several delegations drew attention to the need to define equivalence in a manner which was more closely in line with the article on equivalence in the SPS Agreement.

Section 3 - Principles and General Considerations

- 53. It was noted that the Section entitled Principles described in fact the purpose of the document rather than setting down principles.
- 54. Several delegations were of the opinion that the objectives and purpose of inspection and certifications systems should be limited exclusively to human health and safety matters. However, in light of the Committee's previous discussions on this issue, there was general agreement that such systems should address consumer and commercial fraud and similar issues.
- 55. Although the Committee recognized that responsibility for quality and safety of food rested with the producer, and that control systems such as HACCP were strongly encouraged for use at the producer and industry level, it was agreed that the document should clearly state that the official inspection and certification of foods was the responsibility of governments even if the application of the certification and inspection systems had been delegated to non-government institutions or carried out by officially recognized non-government institutions. In

this regard, some delegations stated that it was not possible for importers to apply HACCP systems or ISO 9000 systems directly to imported foods.

Section 4 - Equivalence

56. The Committee agreed that this Section required extensive redrafting in order to simplify some of the requirements and to indicate, in a positive way, that countries wishing to establish equivalence of their systems with their trading partners should take into account the systems in operation in the exporting country. Some delegations, however, stated that the nature of inspection, or other controls which would be instituted as a result of recognizing systems in operation in the exporting country, could be discriminatory to domestic production.

Section 5 - Infrastructure

- 57. Considerable attention was paid to the provisions relating to food legislation in this Section. Some delegations were of the opinion that the Section should be restricted to the application of Codex standards and related texts. Other delegations stated that the coverage of these paragraphs should be as complete as possible, excluding contractual relationships between commercial buyer and seller. It was also pointed out that provisions regarding ethical rules and professional secrecy were not clear. However, as such provisions were not normally part of food legislation the question may need to be addressed in terms of legitimate confidentiality. Special attention needed to be paid to controls over rejected products.
- 58. In relation to control programmes and administrative procedures outlined in the document several delegations requested that reference to HACCP based systems used to ensure adequate food hygiene should be strengthened, as the Guidelines for the Application of the HACCP System had already been adopted by the Commission.²⁰
- 59. In regard to certification systems, several delegations stated that bilateral or other government-to-government agreements were more appropriate means of meeting food control objectives than was certification. It was recognized, however, that such agreements may not cover all international trade, and that some developing countries in particular relied on appropriate certification.
- 60. The Committee paid considerable attention to the control of laboratory performance. It was indicated that laboratory results had to be scientifically acceptable regardless of the status of accreditation of individual laboratories. Quality assurance systems were essential to providing such acceptability.
- 61. In relation to the internal audit of national systems questions were raised as to the degree to which such audits should be undertaken by external auditors.

Section 6 - Decision Criteria and Action

62. Several delegations expressed concern at the provisions relating to the frequency and intensity of controls. One concern was that a number of different principles had been included in this section without adequate explanation. It was suggested that the frequency and

²⁰ ALINORM 93/40, para. 242.

intensity of controls could be linked to the use of electronic data systems in order to select consignments for inspection on the basis of risk assessment.

63. It was agreed that clear and explicit decision-making criteria were required in the application of inspection systems in order to protect operators from arbitrary decision making and that these criteria should be objectively based.

Section 7 - Competence of National Inspection and Certification Bodies

Section 8 - Assessment and Verification

Section 9 - Accreditation

64. It was suggested that exporting countries may not be aware of all requirements of the importing countries and that this should be taken into account. In regard to criteria which should be included in the assessment and verification of food inspection and certification systems, it was indicated that such criteria should include, among other criteria, the results of random testing.

International Documentation

65. The Committee noted the list of international documentation relating to objective criteria and the development of these criteria for the assessment of the competence of inspection and certification bodies. This information was contained in Appendix 1 to the proposed draft guidelines which also included the texts of documents presented at the Committee's Second Session in CX/FICS 93/5 Add.3, Appendices 1 and 2. An extensive debate took place which included proposals to extend the references. In this regard, it was noted that ISO/IEC Guide 40 was to be revised by ISO/CASCO. The Committee agreed that it would be inappropriate to publish the information contained in the Appendix in detail primarily because such information was being regularly revised by the author organizations and that it would be an onerous task for Codex Alimentarius to make consequential amendments based on revisions by these organizations. It agreed however that it would be very helpful to provide governments with a reference list of documents. It was agreed therefore that a separate reference list would be maintained and updated on a regular basis by the Australian Secretariat and that reference to the availability of this list would be included in the document.

Guidelines on Procedures for Auditing the Inspection and Certification Systems of an Exporting Country by an Importing Country²¹

- 66. The Committee supported the inclusion of this document to the draft guidelines. In discussing this Appendix delegations made the following points:
 - the document should be focussed on the system rather than on food products;
 - the definition of "audit" could be deleted as this was now covered by the Principles on Food Import and Export Inspection and Certification;

Originally "Guidelines on Procedures for Conducting an Assessment and Verification of an Importing Country" (CX/FICS 95/6, Appendix 2).

- countries exporting a product for the first time could be disadvantaged by the absence of a history of exporting activity;
- the principles of the ISO 10 000 series on auditing should be incorporated to the greatest extent possible.

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

67. The Committee requested that the document be redrafted in the light of the extensive comments and suggestions and be recirculated for further comments at Step 3 prior to its next Session. The delegation of Canada and the representative of the European Community offered their continued assistance in the redrafting of the document.

PROPOSED DRAFT GUIDELINES FOR THE EXCHANGE OF INFORMATION ON REJECTIONS AT STEP 4 (Agenda Item 9a)²²

- 68. The Committee recalled that at its last session it was agreed that the proposed draft Guidelines for the Exchange of Information on Rejections would be prepared by Sweden for circulation and government comment.²³ The Committee decided that the Guidelines should emphasize the bilateral nature of information exchange and address the questions of rejected or re-exported cargoes and of protecting the confidentiality of information.²⁴
- 69. The Committee amended the title to "Proposed Draft Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food". A footnote was also added to indicate the availability of the List of Contacts for Food Import Control and Information Exchange in Food Control Emergency Situations through the Australian Codex Contact Point (see also paras. 77 to 80).
- 70. In the section concerning Scope, a cross reference was added to the "Codex Guidelines for the Exchange of Information in Food Control Emergency Situations". The Committee also clarified that the Guidelines only applied to rejections caused by failure to comply with importing country requirements.
- 71. In the General Considerations section, the Committee added "evidence of misrepresentation or consumer fraud" as an additional reason for notification of rejection to the exporting country.
- 72. The Committee also indicated (in General Considerations) that the provision of information to the public on rejected food was subject to constraints imposed by confidentiality. It was also suggested that if information was provided to the public only on the rejection of imported foods it could lead to new trade barriers. As several delegations felt that providing information to FAO on rejections of imported food should not be mandatory,

²² CX/FICS 95/7

²³ Conference Room Document 10 (United States)

²⁴ ALINORM 95/30, paras. 63-66

the Committee clarified that such information should only be provided on request. The Representative of FAO indicated that resource constraints needed to be considered in relation to the application of this provision. The paragraph was placed in square brackets so that governments commenting on the document would pay particular attention to the questions raised.

- 73. In the section concerning Importation Details, the Committee simplified the section by deleting specific elements related to the provision of information on rejections. The Committee also simplified the section concerning Rejection Decisions, and clarified the section regarding Reasons for Rejection.
- 74. In the section on Action Taken, the Committee clarified that if importing countries were aware that rejected foods were being transhipped to other destinations, such information should be provided to the other country concerned. Concern was however expressed that the text went wider than this and put an obligation on importing countries to circulate notifications about consignments over which they had no direct knowledge or control.
- 75. The title and introductory paragraph of the Appendix to the Guidelines was revised and simplified. Notwithstanding the opinion of some delegations that specific examples of Reasons for Rejection in the Appendix were unnecessary, the Committee agreed to maintain this section as proposed. However, a note was added indicating that information on sampling and analytical methods and test results should be provided upon request.

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

76. The Committee thanked Sweden for its efforts and agreed to forward the proposed draft Guidelines to the 21st Session of the Commission for adoption at Step 5. The proposed draft Guidelines are attached to this report as Appendix IV.

CONSIDERATION OF THE LIST OF CONTACTS FOR FOOD IMPORT CONTROL AGENCIES (Agenda Item 9b)²⁵

- 77. The Committee recalled that at its previous session governments were requested to specify which of the contacts for food import control agencies also handled information exchange in food control emergency situations²⁶ (also see paras. 31-41). The List of Contacts for Food Import Control Agencies was revised on the basis of government comments submitted in response to CL 1993/37-FICS. Several delegations at the current CCFICS meeting indicated that new or revised information would also be provided in the future.
- 78. The Committee agreed that in addition to information as to which agencies were responsible for specific foods, information should also be provided concerning the primary contact agency irrespective of the food type.

²⁵ CX/FICS 95/7-Add.2 (Revised)

²⁶ ALINORM 95/30, paras. 67-69

79. In response to inquiries concerning the status of the document within Codex, the Committee was informed that the list could be periodically revised on the basis of government comments provided to the Australian Secretariat. It was also suggested that footnotes could be added to the Guidelines for the Exchange of Information in Food Control Emergency Situations and for the Exchange of Information Between Countries on Rejections of Imported Food to indicate the availability of the List at the Australian Codex Contact Point.

Status of the List of Contacts for Food Import Control and Information Exchange in Food Control Emergency Situations

80. The Australian Secretariat agreed to maintain the list as proposed, with the understanding that revisions to the List of Contacts for Food Import Control and Information Exchange in Food Control Emergency Situations would be requested by Australia on a regular basis. It was also agreed that the Australian Codex Contact Point would serve as distributor of the list when requested.

PROPOSED DRAFT GUIDELINES ON THE PRINCIPLE ELEMENTS IN AN ELECTRONIC DOCUMENTATION SYSTEM AT STEP 4 (Agenda Item 10)²⁷

- 81. The Committee recalled that at its previous session it had been decided to circulate the proposed draft Guidelines for comment at Step 3²⁸, with the view towards their consideration at the Committee's current session. The document was introduced by the Delegation of Australia, which also provided information on common data elements within the context of the UN/EDIFACT Guidelines. The Delegation also pointed out that the document now included provisions concerning the security of data along the lines recommended by UN/EDIFACT. A EDIFACT document describing the details of the draft Electronic Sanitary/Phytosanitary Certificate (SANCRT) and giving an example was distributed to delegates.
- 82. A number of delegations expressed concern at the recommendation, at several points in the document, that a central facility be established for the reception of electronic certificates. In some cases, such a requirement would create constitutional or administrative problems. The Committee agreed that such facilities could be centralized or regionalized provided that, in the latter case, the facilities were linked. Similarly, references to export inspection agencies would have to be modified to provide for countries where such agencies did not exist under the law.

²⁷ CX/FICS 95/8 and Addendum.

United States (CX/FICS 95/8-Add.1); the European Community (CRD 3); OIE (CRD 11); and UN/EDIFACT (unnumbered information document containing a draft recommendation for the Electronic Sanitary/Phytosanitary Certificate).

²⁹ ALINORM 95/30, paras. 76-79

Status of the Proposed Draft Guidelines on the Principle Elements in an Electronic Documentation System

83. The Committee agreed that it would be appropriate to obtain further detailed comments on the Proposed Draft Guidelines, especially from countries which had little current experience in the use of the technology. It therefore agreed to circulate the Proposed Draft Guidelines to governments and interested international organizations at Step 3 of the Procedure. The Proposed Draft Guidelines are attached as Appendix V to the present report.

PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF THE ISO 9000 SERIES TO FOOD INSPECTION AND CERTIFICATION SYSTEMS AT STEP 2 (Agenda Item 11)³⁰

- 84. The Committee recalled that its terms of reference included responsibility for preparing guidance on the application of quality assurance systems to food import and export inspection and certification. At its Second Session the Committee addressed the issue of the use of the ISO 9000 series of standards for application to food import and export inspection and certification systems.³¹
- 85. The document was introduced by the delegation of France which explained that care had been taken to prepare a concise document of relevance to control authorities, certification authorities and the food industry. The document identified the regulatory requirements which needed to be addressed whether they be requirements contained in Codex or other requirements. It further recognized that the introduction or use of such a system was voluntary but could as required be taken into account by competent authorities. The document made a clear distinction between certification of the processor enterprise and product as well as official certification and commercial certification.
- 86. The Committee expressed its appreciation for the work undertaken by the delegation of France.
- 87. Several delegations stressed the appropriateness and importance of the ISO 9000 series of standards in general applications. However, a number of delegations questioned the usefulness, based on experience in their own countries, of the ISO 9000 series in the food sector. These countries were of the opinion that the main quality system required for protection of consumer health were the Guidelines for the Application of the HACCP System already adopted by Codex.³² These delegations expressed their reservation in regard to the establishment of the Guidelines based on the ISO 9000 Series.
- 88. Other delegations pointed out, on the other hand, that the HACCP system and the ISO 9000 standards were fully compatible and that HACCP could be incorporated into an ISO

³⁰ CX/FICS 95/9 and comments from European Community (CRD 3), USA (CRD 4) and ISO (CRD 7).

³¹ ALINORM 95/30, paras. 85-87.

³² ALINORM 93/40, para. 242.

9000 system designed to meet regulatory requirements.³³ These delegations were of the opinion that the use of the ISO 9000 system enhanced official control but did not in any way replace it. They noted that the decision to implement an ISO 9000 quality system was a voluntary one on the part of the enterprise concerned. They further indicated that conformity with ISO 9000 standards should not be used by importing countries as a prerequisite for import.

89. The Committee agreed that it was premature to consider the document within the context of the Codex procedure for the elaboration of standards and related texts. It requested the delegation of France to revise the document in the form of draft Guidelines in light of the comments made at the present session. It was agreed information on the practical application of the ISO 9000 series to the food sector would be sought from countries for consideration at the next session, when the possible establishment of Codex Guidelines on the Application of the ISO 9000 Series to Food Inspection and Certification Systems could be considered.

REVIEW OF EXISTING CODEX STANDARDS OR CODES WITH A VIEW TOWARDS THE HARMONIZATION OF INSPECTION AND CERTIFICATION SYSTEMS (Agenda Item 12)³⁴

- 90. The Committee recalled that at its previous session it was agreed not to come to a conclusion on the above matter and therefore, could not provide substantive advice to other Codex Committees.³⁵ It decided, however, to discuss the matter further at its Third session.
- 91. The Australian Secretariat informed the Committee that the working paper presented two options for its consideration, namely; 1) a general policy statement for adoption by the Commission as a Codex recommendation, and; 2) a specific text intended for inclusion in Codex Standards, Codes and Guidelines along lines developed by other Codex Committees.
- 92. The Codex Secretariat informed the Committee that although both of the proposed approaches were outside the Committee's terms of reference, the general text (i.e., Option 1) could be recommended to the Commission for adoption and inclusion in the Codex Alimentarius Procedural Manual under Section J, "Relations Between Codex Committees".
- 93. Several delegations were of the opinion that CCFICS did not have the authority to instruct other Codex Committees and therefore, suggested to recommend adoption of the general policy text (Option 1).
- 94. Other delegations were of the opinion that other Codex Committees could not be compelled to adopt a specific text for inclusion in Codex Standards (Option 2). It was also stated that regardless of a potential CCFICS recommendation for the inclusion of a specific text, Codex Standards generally did not contain provisions related to inspection and certification.

³³ Regulatory requirements are often known as "technical regulations". See Annex 1 of the TBT Agreement.

³⁴ CX/FICS 95/10 and comments from the European Community in CRD 3.

³⁵ ALINORM 95/30, paras. 80-82

- 95. It was also suggested that the CCFICS did not have the authority to take action in either case. The delegation of Malaysia supported this opinion, especially in view of the inconsistency in the interpretation of terms used by various Codex bodies and the difficulties associated with harmonizing a wide variety of Codex standards. Malaysia also stated that CCFICS should not unnecessarily impose conditions on other commodity committees without consideration of the already agreed to format laid out in Codex standards.
- 96. Taking into account the above discussions, the Committee concluded that the following general statement should be forwarded to the Commission for adoption and possible inclusion in the Codex Alimentarius Procedural Manual as a general Codex recommendation:

Subject and commodity Committees should refer to the principles and guidelines developed by the Codex Committee on Food Inspection and Certification Systems when developing provisions and/or recommendations on inspection and certification and make any appropriate amendments to the standards, guidelines and codes within the responsibility of the individual committees at the earliest convenient time.

97. The Delegation of Malaysia reserved its position on this decision.

OTHER BUSINESS (Agenda Item 13)

Model Certificate for Fish Inspection Purposes

98. The 21st Session of the Codex Committee on Fish and Fishery Products agreed that it would be useful to develop a model certificate specially for fish inspection purposes with the objective of facilitating international trade, and suggested that CCFICS consider this matter so as to identify the requirements to be included in such a certificate. This proposal was supported by the Committee. It was agreed however that it would be more appropriate for this Committee to provide general advice on the layout and formats of inspection certificates and for individual commodity committees to provide the technical details of such certificates. The Chairman of the Fish Committee indicated that work could begin immediately on this task and that an initial paper may be available for comment by the CCFICS at its next Session prior to further elaboration by the CCFFP. It was noted by the Committee that an IDF Model Certificate for Milk and Milk Products was available.

Legislation Related to the Inspection and Certification of Agricultural Products

99. At the Committee's 2nd Session the Secretariat agreed to provide information to the Committee on FAO's legislation service in collating information on food and agriculture legislation relevant to the work of the Committee.³⁷ The Secretariat reported that towards the end of 1994 FAO Legislative Study no.54 entitled Legislation Governing Food Quality Control and Certification: Authorities and Producers had been published in French and that the English and Spanish versions of this title would be published in the near future. FAO Legal Service continued to collect information on current legislation and on the role and

³⁶ ALINORM 95/18, para. 7.

³⁷ ALINORM 95/30 para. 70.

responsibilities of the public and the private sector involved regarding the control of foodstuff quality.

MEDIUM-TERM OBJECTIVES AND FUTURE PROGRAMME OF WORK (Agenda Item 14)

- 100. The delegation of the United States proposed the elaboration of draft guidelines for the development of agreements between exporting and importing countries. The objectives of such guidelines would be to establish mutual agreements in an effort to enhance consumer protection and to provide for the efficient and effective regulation and expeditious movement of acceptable products in international trade. The representative of the EC expressed the EC's full support for this initiative and restated their opposition to the excessive use of certification stating that mutual recognition agreements were the preferred method of trade facilitation. The Committee requested the United States to prepare a draft document for consideration at the Committee's next Session.
- 101. The Committee noted that with the advancement of two major items of work to Step 8 and with the suspension of work on the glossary of terms and definitions its programme of work had been substantially modified. However, the work of the Committee remained consistent with the medium-term objective of the Commission no.9 Harmonization of Testing Procedures and Inspection and Certification Systems. The Committee's Current Status of Work is annexed to this Report.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 15)

102. The Secretariat reported that the Commission at its 20th Session had agreed that the CCFICS should continue to meet in the future with the understanding that it should exercise caution in setting its programme of work.³⁸ The Chairman indicated that the Committee's 4th Session would be held in Canberra in approximately one year's time.

³⁸ ALINORM 93/40 paras. 278-280.

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT CERTIFICATION AND INSPECTION SYSTEMS

CURRENT STATUS OF WORK

Subject	STEP	FOR ACTION BY:	DOCUMENT REFERENCE
Draft Principles for Food Import and Export Inspection and Certification	8	21st CAC	ALINORM 95/30A Appendix II
Draft Guidelines for the Exchange of Information in Food Control Emergency Situations	8	21st CAC	ALINORM 95/30A Appendix III
Proposed Draft Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food	5	21st CAC Governments 4th CCFICS	ALINORM 95/30A Appendix IV
Proposed Draft Guidelines on the Principle Elements in an Electronic Documentation System	3	Governments 4th CCFICS	ALINORM 95/30A, Appendix V
Proposed Draft Guidelines for the Design, Operation, Assessment and Accreditation Food Inspection and Certification Systems	3	Canada/EC Governments 4th CCFICS	ALINORM 95/30 paras. 47-67
General Statement on Provisions concerning Inspection and Certification in Codex Standards		21st CAC	ALINORM 95/30A, paras. 90-97
Application of the ISO 9000 Series to Food Inspection and Certification Systems	2	France 4th CCFICS	ALINORM 95/30A paras. 84-89
Proposed Draft Guidelines for the Development of Agreements between Exporting and Importing Countries	1	21st CAC USA 4th CCFICS	ALINORM 95/30A, para. 100
List of Contacts for Food Import Control and Information Exchange in Food Control Emergency Situations		Governments Australia 4th CCFICS	ALINORM 95/30A, paras. 77-80

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DRAFT PRINCIPLES FOR FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION

(at Step 8)

SECTION I - Introduction

- 1. Official and officially recognized inspection and certification systems are fundamentally important and very widely used means of food control; the following principles apply to such systems. The confidence of consumers in the quality (including safety) of their food supply depends in part on their perception as to the effectiveness of food control measures. A substantial part of the worldwide trade in food, for example in meat and meat products, depends upon the use of inspection and certification systems. However, inspection and certification requirements may significantly impede international trade in foodstuffs. Consequently it is desirable that the design and application of these systems should reflect appropriate principles.
- 2. Inspection of food may occur at any stage in the production and distribution process. For some foods, inspection oversight of harvesting, processing, storage, transport, and other handling of product may be the most appropriate means of ensuring food safety. According to the methods of preservation used, it may be necessary to maintain inspection oversight on a continuous basis up to the time of retail sale. Inspection systems may be focused on the foodstuffs themselves, on the procedures and facilities employed in the production and distribution chain, on the substance and materials which can be incorporated into or contaminate foodstuffs.
- 3. Inspection should be carried out at the most appropriate stages (e.g. control of refrigeration at every stage of the cold chain). For some requirements, eg those pertaining to product description, it may be possible to limit inspection to the distribution process and prior to final sale.
- 4. In both design and use, food inspection and certification systems should be governed by a number of principles which will ensure an optimal outcome consistent with consumer protection and facilitation of trade.

SECTION 2 - Definitions

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

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

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

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

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

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

Risk assessment is the evaluation of the likelihood and severity of adverse effects on public health arising, for example, from the presence in foodstuffs of additives, contaminants, residues, toxins or disease-causing organisms.

SECTION 3 - Principles

6. Food inspection and certification systems should be used wherever appropriate to ensure that foods, and their production systems, meet requirements in order to protect consumers against food-borne hazards and deceptive marketing practices and to facilitate trade on the basis of accurate product description.

Fitness for purpose

7. Inspection and certification systems should be fully effective in achieving their designated objectives having regard to the determination of the acceptable level of protection which is required.

Risk assessment

- 8. Inspection systems to ensure food safety should be designed and operated on the basis of objective risk assessment appropriate to the circumstances. Preferably the risk assessment methodology employed should be consistent with internationally accepted approaches. Risk assessment should be based on current available scientific evidence.
- 9. Inspection systems should be applied to particular commodities and processing methods in proportion to the assessed risks. In undertaking a risk assessment or in applying the principles of equivalence, importing countries should give due consideration to statements by exporting countries on a national or area basis of freedom from food-related disease or risk of contamination.

Non-discrimination

10. Countries should ensure that they avoid arbitrary or unjustifiable distinctions in the level of risk deemed to be appropriate in different circumstances so as to avoid discrimination or a disguised restriction on trade.

Efficiency

11. Inspection and certification systems should have adequate means to perform their task. In the choice of inspection and certification systems, there should be regard to costs to consumers and to the costs in money and time to the affected food industry and government consulting with interested bodies as appropriate. Such systems should be no more restrictive of trade than is necessary in order to achieve the required level of protection.

Harmonization

12. Member countries should use Codex standards, recommendations and guidelines (or those of other international organizations whose membership is open to all countries) whenever appropriate as elements of their inspection and certification systems. Countries should participate actively in the work of the Codex Alimentarius Commission and other relevant international bodies to promote and facilitate the development, adoption and review of Codex norms.

Equivalence

13. Countries should recognise that different inspection/certification systems may be capable of meeting the same objective, and are therefore equivalent. The obligation to demonstrate equivalence rests with the exporting country.

Transparency

- 14. While respecting legitimate concerns to preserve confidentiality, the principles and operations of food inspection and certification systems should be open to scrutiny by consumers and their representative organizations, and other interested parties.
- 15. Importing countries should provide information on existing requirements and proposed changes to requirements should be published and, except in the case of serious and immediate danger, an adequate time period permitted for comment. The views of exporting countries, and particularly those received from developing countries, should be taken into account in taking a final decision. A reasonable period should be allowed before a new requirement takes effect in order to permit exporting countries, and in particular developing countries, to make necessary changes to methods of production and control measures.
- 16. Importing countries should make available to the exporting countries, upon request, timely advice as to the basis of the decision they have taken regarding the compliance of foods with their relevant requirements.

17. Upon request by the competent authorities of the importing countries, the exporting countries should provide access to view and assess the actual working of their relevant inspection and certification systems.

Special and differential treatment

18. In the design and application of food inspection and certification systems, importing countries should take into account of the capabilities of developing countries to provide the necessary safeguards.

Control and inspection procedures

19. Importing countries should complete without undue delay any procedures necessary to assess compliance with requirements. Information requirements and any fees imposed by importing countries should be limited to what is reasonable and necessary.

Certification validity

20. Countries that certify exports of food and those importing countries which rely on export certificates should take measures to assure the validity of certification. Validation measures by exporting countries may include achieving confidence that official or officially recognised inspections systems have verified that the product or process referred to in the certificate conforms with requirements. Measures by importing countries may include point of entry inspection systems, audit of exporting inspection systems, and ensuring that certificates themselves are authentic and accurate.

DRAFT GUIDELINES FOR THE EXCHANGE OF INFORMATION IN FOOD CONTROL EMERGENCY SITUATIONS¹ (at Step 8)

Preamble

- 1. For the purposes of these guidelines the term "food control emergency situations" is taken to mean situations where there is a clearly identified risk of serious untoward health effects associated with the consumption of certain foods. In most cases the nature of the agent causing such health effects will be known (e.g. an identified microbiological or chemical agent). However, emergency situations may arise where consumption of a certain foodstuff is associated with serious health effects but the agent causing these effects has not been identified. Such situations are also covered by these guidelines.
- 2. The <u>food control authorities</u> in exporting countries should <u>promptly notify</u> by telecommunication the appropriate authorities in countries which have imported or are the destination of foods with which an emergency situation has arisen. The initial information may often be incomplete and should therefore be supplemented by further notification(s) as and when the situation develops and more detailed information becomes available. Where appropriate countries should keep their public informed of food emergency situations.
- 3. The food control authorities in importing countries which detect problems during import control of foodstuffs which they consider to be so serious as to indicate a food control emergency situation should inform the exporting country promptly by telecommunication.
- 4. It is in the interests of both importing and exporting countries that information exchange in food control emergency situations is rapid. In this way risks to human health can be minimized and the foodstuffs concerned can be rapidly identified and removed from the market. This helps to prevent unwarranted action against other foods from the same country which are not involved in the emergency situation.
- 5. Each country should identify a primary Contact Point for food control emergency situations which can act as the national focal point for information exchange in such situations.

Standard format for information exchange in food control emergency situations

- 6. The most important information elements to be considered are discussed below and a standard format for information exchange in food control emergency situations is attached as an Annex.
- 7. Although these guidelines are primarily intended for information exchange between importing and exporting countries, copies or summaries of selected information should be provided to FAO,

Governments and organizations interested in receiving a List of Contacts for Food Import Control and Information Exchange in Food Control Emergency Situations should contact the Codex Contact Point for Australia, Australian Quarantine and Inspection Service, GPO Box 858, Canberra 2601, ACT Australia: telefax no. +61.6.2723103.

WHO or other international organizations on request, to assist in international food control emergency situations.

Nature of the health hazard

8. The nature of the health hazard should be described clearly and briefly. If possible, the agent (microorganism, chemical, etc.) causing the health hazard should be identified. However, if there is a clear association between consumption of a food and the appearance of serious untoward health effects this should be reported even though the agent causing the effects has not been unequivocally identified.

Foods concerned

9. In cases where the health hazard is associated with a specific food or foods these should be identified in detail in accordance with the standard format annexed to these guidelines. In other cases, where contamination is spread over a wide area and affects many different categories of foods, all such affected foods should be identified.

Action taken

- 10. The action taken to reduce and eliminate the hazard should be reported briefly. This may include, for affected food, at least the following:
 - measures taken to identify and prevent the sale of the food;
 - measures taken, at source, to prevent further problems;
 - identification of agencies responsible for supervising recall from the market detaining the product and supervising its final disposition.

Contact point for further information

11. Agencies responsible for coordinating the response should keep countries receiving the affected food informed of action taken, and provide the name, address, telephone/telefax number of persons or organizations who can provide further details about the hazard, the foods concerned, action taken and other relevant information.

DRAFT STANDARD FORMAT FOR INFORMATION EXCHANGE IN FOOD CONTROL EMERGENCY SITUATIONS

The following should constitute the advice provided by countries in food control emergency situations.

Nature of the health hazard

- Biological/microbiological contamination (specify organism or toxin of concern).
- Chemical contamination, e.g. toxic levels of residues of pesticides, drugs, industrial chemicals, environmental contaminants.
 - Radionuclide contamination (specify radionuclide(s) of concern).
- Other identified hazards (e.g. foreign bodies).
- Unknown agent specify serious adverse health effects of associated with consumption of specified foods.

In each of the above cases, the specific hazard and its level or prevalance based on available information should be notified.

Identification of foods concerned

Description and quantity of product(s)

Type and size of package

Lot identification

Other identification marks/stamps

including container and shipping details

Name and address of producer, manufacturer, seller or importer as appropriate.

Action taken

Information on action taken (e.g. recall and/or destruction of food concern, prohibition on sale of food from certain area or establishment)

- measures taken to identify and prevent the sale of the food;
- measures taken, at source, to prevent further problems;
- measures taken to recall food from markets and to detain products and recall products from the market;

measure taken regarding final disposition.

Contact point for further information

Name, address, telephone/telefax no. of persons or organizations who can supply further information.

PROPOSED DRAFT GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD¹ (at Step 5)

Scope

- 1. The following guidelines provide the basis for structured information exchange on import rejections. The most important information elements to be considered in such guidelines are shown in Appendix 1 and each category is discussed in more detail below. The guidelines are intended to cover all types of food.
- 2. These guidelines deal only with import rejections caused by failure to comply with importing country requirements. Information exchange in food control emergency situations is dealt with in the Draft Guidelines on for the Exchange of Information in Food Control Emergency Situations.

General Considerations

- 3. When the food control authorities in an importing country reject a consignment of food presented for importation they should always provide information to the importer of the consignment giving the reasons for the rejection. This information should also be provided to the exporter if the control authorities receive such a request.
- 4. When the rejection of the consignment arises from
 - evidence of a serious food safety or public health problem in the exporting country; or
 - evidence of misrepresentation or consumer fraud; or
 - evidence of a failure in the inspection or control system in the exporting country; or
 - repeated failures of a correctable nature (eg labelling errors, mislaying of documents); or
 - bad handling, storage or transport subsequent to inspection/certification by the authorities in the exporting countries,

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

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

- 5. Upon receipt of such a communication, the food control authorities in the exporting country should undertake the necessary investigation to determine the cause of the problem that has led to the rejection of the consignment. They should acknowledge receipt of the communication from the importing country and should provide that country with the results of the investigation as soon as they are available. Bilateral discussions should take place as necessary.
- 6. It is also open to an importing country to supply information on rejections to an exporting country even when this is not specified in these guidelines.
- 7. In some countries information about the results obtained in public food control is freely available, whereas in others legal constraints may prevent or restrict the dissemination to third parties of information on, for example, import rejections. In some cases information cannot be exchanged before a certain time has elapsed. So far as possible countries should minimise restrictions on the disclosure to other countries of information on rejected foods.
- [8. From the consumer point of view, it is desirable that important information from food import control activities relating to health risks and unfair trading is freely available. Subject to any constraints imposed by confidentiality, countries should upon request make information on rejections of imported food as well as domestic food available to the public. To enable FAO to assist exporting countries in their efforts to meet the requirements of importing countries, information on rejections of imported food should be made available to FAO on request.]

Identification of the food concerned

9. A certain amount of basic information is required in order to be able to identify the consignment or lot of food that has been refused entry when presented for importation. The most important information in this respect is a description of the nature and quantity of the food, any lot identification or other identification stamps, marks or numbers and the name and address of the food producer or manufacturer. Information about the exporter (if the exporter is not the manufacturer or producer) and information about importers or sellers could also be useful. Where a lot has been certified, the certificate serial number provides an important method of identification.

Importation details

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

Rejection decision

11. It is important to obtain information about the decision to refuse importation, especially who made the decision, when it was made and whether the whole or only part of the consignment was refused entry.

Reasons for rejection

- 12. The reason(s) why a consignment of food has been refused entry should be briefly stated and reference should preferably be made to the regulations which have been contravened.
- 13. In the case of biological contamination, or contamination by biological toxins, the identity of the organism or toxin concerned should be given as specifically as possible. When the level of a chemical contaminant in a food has been found to be above the maximum permitted level, the contaminant (eg pesticide or veterinary drug residue, heavy metal, mycotoxin) should be specified, together with the level found and the maximum permitted level. Similarly, contraventions of regulations on food additive or compositional standards should be specified. Some countries only accept certain foods (eg fresh and frozen meat) only from specifically approved establishments in the exporting country. If such foods are refused entry because evidence that they come from such an establishment is lacking or incomplete, this should be stated.
- 14. Foods may be rejected because they are found to be unacceptable when subjected to an organoleptic examination or because they have technical/physical defects, eg leaking cans, broken seals and damaged boxes. In such cases information on the reason for rejection should be stated clearly.
- 15. Where consignments of imported food are rejected on the basis of analysis performed in the importing country, the importing country authority should make available upon request details of the sampling and analytical methods employed and the results obtained.

Action taken

- 16. Information should be supplied about the action taken following the rejection or retention of a consignment of food. This should include information about the fate of the consignment, such as whether it was destroyed or detained for reconditioning.
- 17. If the rejected food is re-exported, the conditions attached to such re-export should be stated. For example, some countries permit re-export only to the country of origin or to countries which have stated in advance that they are prepared to accept the consignment knowing that it has been refused entry elsewhere. Authorities which have rejected a particular consignment of imported food may be aware that food or food product which presents a similar risk is destined for or has been received in other countries. If such shipments could pose a significant health risk, the other destination countries should also be informed of the rejection.
- 18. In some cases it is also valuable to inform the embassy or other representative body of the exporting country of the situation so that the country concerned can take action to rectify the deficiencies found and thus avoid rejection of future shipments.

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

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

Identification of the food concerned

Description and quantity of product

Type and size of package

Lot identification

Other identification stamps, marks or numbers

Certificate number

Name and address of manufacturer, producer, seller and/or importer as appropriate

Importation details

Port or other point of entry

Name and address of importer (if available)

Date presented for entry

Details of Rejection decision

Whole/part of (specify) consignment rejected

Name and address of agency making decision to reject

Date of decision

Name and address of agency which can provide more information on reason for rejection

Reason(s) for rejection

Biological/microbiological contamination

Chemical contamination

Radionucleide contamination

Incorrect or misleading labelling

Compositional defect

Non-conformity with food additive requirements

Organoleptic quality unacceptable

Technical or physical defects eg packaging damage

Incomplete or incorrect certification

Does not come from an approved country, region or establishment

Other reasons

Note:

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

Action taken

Food destroyed

Food held pending reconditioning/rectification of deficiencies in documentation

Import granted for non-food use

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

Importer notified

Embassy/food control authorities of exporting country notified

Authorities in other likely destination countries notified

Other

PROPOSED DRAFT GUIDELINES ON THE PRINCIPAL ELEMENTS IN AN ELECTRONIC DOCUMENTATION SYSTEM (at Step 3)

Scope

- 1. This document identifies the principal elements and provides guidance on the application of electronic documentation systems applied to food export certification and systems for use by importing countries for the receipt of food certification in electronic form.
- 2. The elements that apply to export and import control systems differ somewhat and are dealt with separately in these guidelines. However, a basic tenet of electronic date information systems is achieving single data entry. This single data entry concept can be extended to cover all those agencies involved in the export chain, such as: insurance, banking, land and sea transport, port authorities, etc. Experience in some countries suggests that such entities may number in excess of 20 and share a data requirement commonality of between 70% and 85%. Likewise, there is a commonality in the data supplied by the importer to the customs service and to the import and export inspection agency/s.

Export documentation systems

- 3. The principal elements of an electronic based export documentation system are:
 - a processing system capable of producing certification in an electronic format;
 - an electronic interface between the exporter client and the certification/inspection agency, in the form of a communication link with computer terminals compatible with a central processing unit;
 - a communications link between the individual field officer (on-site inspector) of the inspection agency and the agency itself which, inter alia, allows confirmation by the field officer of data input from the exporter client;
 - a link between the inspection agency and the competent authority of the importing country and any other relevant agency; and
 - customs agencies in the exporting and importing countries may serve as intermediaries in the communication and control process.
- 4. An electronic export documentation system must interact between commercial and government controlled export processes and is required to support a number of functions such as:
 - processing of the individual exporter's notification to export; the issue of export approval; and
 - the generation of the actual product certification.

- 5. In most instances, interaction will be with three basic user categories:
 - (i) members of the exporting community.

Exporters, or their agents, will need to communicate electronically with the inspection agency for both the issue of their notice to export and to update, query, forward or transfer such notices;

- connection to the central processing system could be either direct or via a commercial carrier (value added network) using EDI techniques.
 - (ii) field inspection staff.

Inspection staff stationed permanently on processing/packing establishments will need to communicate (via personal computers) with the central processing facility to monitor progress of the exporter's application to export, and to report on inspection outcomes;

- consideration should be given to establishing appropriate lines of communication, such as direct access to the central processor, or via a value added network;
- issues that will determine such linkage will include costs and required security levels.
 - (iii) the government inspection agency, and other agencies which have legislative involvement in the export process.

Communication by inspection staff who are not permanently located at an establishment but who are required to supervise loading out of product may be via a portable personal computer (laptop) or from their base office. Dial-up facilities will be required.

- 6. The inspection agency should establish regional documentation outlets as necessary to meet geographical and commercial considerations;
 - there will be a need for such outlets to have direct connection to the central processing system to amend data input by the exporters and agency field staff.
- 7. Customs services interact closely with export inspection agencies, both in maintaining barriers to illegally exported goods and for the collection of data similar to that supplied by the exporter to the inspection agency. These two agencies should work together to ensure that the software interface package available to the exporter combines the data entry requirements of both agencies.
- 8. In order to ensure that the customs and export inspection agencies are operating in harmony in both the gathering of data and the execution of barrier controls, it would be necessary to link their respective data systems.

Import control systems

- 9. The principal elements for an import control system would include:
 - a centralised processing facility that will allow receipt, verification and translation of an incoming EDIFACT-based certification document. Such a facility may be centralized or regionalized and could be run by the customs service which would download the data to the import inspection agency;

- an electronic link between the inspection agency and the importer client/broker to enable the incoming certification data to be electronically transmitted to the importer's office in a manner that will allow the importer to input additional data required for product clearance; and
- the establishment of a data base or bases that can interact with the import clearance system. This facility would carry data relating to the performance of the individual overseas exporters/manufacturers and so enable the import inspection agency to vary the level of physical inspection in accordance with the level of assessed risk.
- 10. The importer should supply both the customs service and the import inspection agency with common data. Both agencies should work together to rationalise the data input requirements of the importer as data carried on an incoming electronic certification document which is captured by a government agency should not be required to be re-entered by anyone concerned with the import clearance process.

Security issues

11. Security in relation to electronic documentation systems is often thought of on two fronts. On one hand it is about **confidence** by senders and receivers in message integrity and confidentiality, and on the other about the **legal status** of electronically exchanged documents.

Confidence

- 12. The matter of confidence relates to:
 - establishing and maintaining an acceptable degree of confidence that messages have originated from an identifiable and authorised individual, entity or process at an identifiable and authorised location; and
 - that the data/information reaches its destination unaltered and has remained confidential in transit.
- 13. The longer term treatment of confidential information by third party networks after successful delivery, and the reliability of software used by trading partners are also important aspects of a system effecting confidence in security of the electronic data environment.

Legal Status

- 14. Electronic documents have the same legal status as paper documents. The electronic process can perform the following functions:
 - Documentation Function electronic documents can be accepted as documents in a similar sense to paper documents;
 - Evidentiary Function electronic documents can be produced/reproduced in a form that is acceptable in a court (this relates to rules for admissibility of business records); and
 - Authorisation Function electronic documents received from a particular sender can be accepted as primae facie evidence that the document has been created and sent by that sender.

Risk factors

- 15. The major risk factors to consider in establishing an electronic documentation system are also the most obvious. These include:
 - electronic documents may be sent without authority by an authorised user or by a spurious system;
 - electronic documents may not be received by the intended recipient and the sender is unaware of this non-receipt;
 - either a legitimate sender or legitimate recipient of an electronic document may later deny having sent or received the document;
 - the integrity of an electronic document is violated between sender and recipient without either party being aware of the change;
 - confidentiality of an electronic document is violated between sender and recipient without one or both parties being aware.
- 16. There are other manifestations of these basic risk factors and other detailed issues of confirmation, acknowledgement, timing, retention etc which need to be considered when developing an electronic documentation system.

Defences

- 17. There are a number of ways to limit or minimise risks, including various security related procedures such as site security and insider risk awareness, and security facilities such as access restrictions and encryption methodologies.
- 18. Risk analysis and other conventional risk management tools and techniques including risk shedding and sharing through network provider and trading partner agreement are important defence mechanisms.
- 19. Intending developers should critically examine the risk factors as they apply to their EDI strategies and in particular to take a well considered position in negotiation of agreements with electronic message carriers and trading partners.