

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION OF THE
UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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ALINORM 01/30

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-fourth Session

Geneva, Switzerland, 2-7 July 2001

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

Adelaide, Australia, 21-25 February 2000

NOTE: *This report includes Codex Circular Letter CL 2000/6-FICS*

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CX 4/70.2

CL 2000/6-FICS
April 2000

TO: - Codex Contact Points
- Interested International Organizations

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

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

The report of the Eighth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems will be considered by the 47th Session of the Executive Committee of the Codex Alimentarius Commission (Geneva, Switzerland, 28–30 June 2000) and the 24th Session of the Codex Alimentarius Commission (Geneva, Switzerland, 2–7 July 2001).

PART A: MATTERS FOR ADOPTION BY THE 47TH SESSION OF THE EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION AT STEP 5

Proposed Draft Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates (ALINORM 01/30, paras. 33–49 and Appendix II).

Governments wishing to propose amendments or to submit comments regarding the implications which the proposed draft Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates or any provisions thereof may have for their economic interests should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (at Step 5) (*Codex Alimentarius Procedural Manual*, Tenth Edition, pages 20-21) to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (telefax: +39.06.5705.4593; E-mail: codex@fao.org) **not later than 15 May 2000.**

PART B: MATTERS FOR CONSIDERATION BY THE 47TH SESSION OF THE EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION

Proposed Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (ALINORM 01/30, paras. 62–65)

The Committee decided to proceed with the development of proposed draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems subject to subsequent approval as new work by the 47th Session of the Executive Committee of the Codex Alimentarius Commission.

SUMMARY AND CONCLUSIONS

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

MATTERS FOR ADOPTION BY THE 47TH SESSION OF THE EXECUTIVE COMMITTEE:

- The Committee agreed to forward the proposed draft Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates to the 47th Session of the Executive Committee for adoption at Step 5. In taking this decision, the Committee agreed to inform the Executive Committee that certain issues in particular remain under consideration (paras. 48-49).

MATTERS FOR CONSIDERATION BY THE 47TH SESSION OF THE EXECUTIVE COMMITTEE:

- The Committee decided to proceed with the development of proposed draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems with the understanding that development of the Guidelines would be subject to subsequent approval as new work by the 47th Session of the Executive Committee (para. 65).

MATTERS OF INTEREST TO THE 24TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

- The Committee decided that a revised first draft of the proposed draft Guidelines for Food Import Control Systems would initially be prepared by the Secretariat with a view towards its consideration by a drafting group that would take account of discussions at the current meeting, written comments submitted and proposed revisions to the document. The Committee further agreed that the revised proposed draft Guidelines would be circulated for comment at Step 3 and further consideration at its next meeting (paras. 30-32).
- The Committee agreed that a drafting group would prepare a revised version of the proposed draft Guidelines for the Utilization and Promotion of Quality Assurance Systems to Meet Requirements in Relation to Food for circulation and comment at Step 3 prior to its next meeting (para. 60).
- The Committee agreed that proposed draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems be developed by a drafting group for circulation and comment at Step 3 and further consideration at its next meeting (para. 69).
- The Committee agreed that the Codex Guidelines for the Exchange of Information in Food Control Emergency Situations as well as related Codex texts should be examined to determine whether or not the development of Risk Management Guidelines for Food Control Emergency Situations Involving International Trade would be necessary (para. 70).
- The Committee took note of the request of the Codex Committee on General Principles for relevant Codex Committees to identify and clarify the relevant factors taken into account in their work, in the framework of risk analysis, in order to facilitate its general debate on “other legitimate factors” relevant for the health protection of consumers and for the promotion of fair practices in trade (para. 73).
- The Committee agreed that at its next meeting it would consider the need for guidance on food export control systems (para. 75).

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INTRODUCTION

1. The Eighth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) was held in Adelaide, Australia from 21-25 February 2000 at the kind invitation of the Government of the Commonwealth of Australia. Mr. Digby Gascoine, Director, Policy and International Division, Australian Quarantine and Inspection Service, chaired the Session. It was attended by 160 participants representing 43 Members of the Commission and 15 international organizations.¹ The complete List of Participants is attached at Appendix I.

ADOPTION OF THE AGENDA (Agenda Item 1)²

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

MATTERS REFERRED FROM THE CODEX ALIMENTARIUS COMMISSION AND CODEX COMMITTEES (Agenda Item 2)³

3. The Committee noted matters of interest arising from the 23rd Session of the Codex Alimentarius Commission and the Codex Committee on Food Hygiene. The Codex Secretariat suggested that the Committee take account of the request of the 14th Session of the Codex Committee on General Principles (CCGP) to identify and clarify other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in the food trade when discussing items under its consideration (see paras. 73-74).⁴ It was noted that the 15th Session of the CCGP (Paris, France, 10-14 April 2000) would consider the subject of food safety objectives in the context of risk analysis and a Review of the Statements of Principle on the Role of Science and the Extent to which Other Factors are Taken into Account: Role of Science and Other Factors in Relation to Risk Analysis.

4. The Committee noted that the forthcoming 15th Session of the CCGP would also be undertaking a review of the Codex Code of Ethics for International Trade in Food (CAC/RCP 20-1979, Rev. 1 (1985)) and that comments had been requested under document CX/GP 00/8. In this regard, the Codex Secretariat informed the Committee that the relevant CCFICS guidelines elaborated to date had been included as references in the Proposed Draft Revised Code of Ethics for International Trade in Food.

5. The Committee noted that an FAO Conference on International Food Trade Beyond 2000: Science-Based Decisions, Harmonization, Equivalence and Mutual Recognition was held in Melbourne, Australia from 11-15 October 1999. A series of general recommendations of the Conference (the Melbourne Recommendations), as well as other recommendations addressed to the Commission or its subsidiary bodies, were scheduled to be presented to the 47th Session of the Executive Committee (Geneva, Switzerland, 28-30 June 2000).⁵ The recommendations addressed to the Commission or its subsidiary bodies included the recognition of the importance and urgency of developing Codex guidance on the judgement of equivalence of inspection and certification systems.

6. The Committee was informed that a proposed Joint FAO/WHO Expert Consultation on the Application of Equivalence Measures and Agreements was to provide advice to developing countries on technical requirements for the establishment of equivalence measures and agreements pertaining to food quality and safety. The Consultation was tentatively scheduled to be held before 2001.

¹ In connection with the current CCFICS Session, the World Trade Organization held a "Workshop on the Implementation of the SPS Agreement" on Thursday, 24 February 2000.

² CX/FICS 00/1.

³ CX/FICS 00/2.

⁴ ALINORM 99/33A, paras. 64-76.

⁵ CX/EXEC 00/47/4.

7. The Representative of WHO informed the Committee of recent discussions at the 105th Session of the WHO Executive Board in January 2000. The Director-General of WHO identified food safety as one of the seven priority areas of WHO and proposed a future plan of work in this regard. The Executive Board, composed of 32 Member States, had noted the importance of the work of the Codex Alimentarius Commission and requested WHO to strengthen its involvement in Codex work. The forthcoming 53rd Session of the World Health Assembly (May 2000) would discuss this matter further.

PROPOSED DRAFT GUIDELINES/RECOMMENDATIONS FOR FOOD IMPORT CONTROL SYSTEMS (Agenda Item 3)⁶

8. The 7th Session of the CCFICS agreed that Mexico, with the assistance of Australia, Canada, France, Germany, Japan, the Netherlands, South Africa and the United States, would redraft and restructure the proposed draft Guidelines/Recommendations for circulation and comment at Step 3 and consideration at its current meeting.⁷

9. Mexico indicated that the proposed draft Guidelines were intended to specify the elements, administration and management of food import control systems and to provide guidance on their implementation. Noting the importance of effective food import control systems to help ensure the quality and safety of food and facilitation of international trade, the Committee thanked Mexico and other countries participating in the drafting of the document and reviewed the revised text in detail. Among the changes to the text to which the Committee agreed were the following:

TITLE

10. The Committee decided to amend the title of the paper to read as *Codex Guidelines for Food Import Control Systems* in accordance with its terms of reference.

SECTION 1 – INTRODUCTION

11. The Committee revised the text to indicate that the Guidelines applied to both food safety and other standards while ensuring fair practices in food trade.

SECTION 2 – SCOPE

12. It was agreed to include the phrase “without introducing unjustified technical barriers to trade” at the end of paragraph 2 to better address both concepts of consumer protection and trade facilitation.

13. The Committee agreed to delete paragraph 3 as the concept of “appropriate level of protection” was already covered by other sections of the Guidelines.

SECTION 3 – DEFINITIONS

14. The Committee agreed to delete the terms *Appropriate level of protection*, *Memorandum of Understanding (MOU)* and *Mutual Recognition Agreement (MRA)*. The Committee deleted the second sentence of the definition for *Certification* as it constituted a description rather than a definition of the process.

15. The Committee aligned the definitions for *Risk management* and *Risk communication* as per recent revisions to these terms adopted by the 23rd Session of the Codex Alimentarius Commission.

16. The Committee agreed that the need for definitions for *Licensing*, *Laboratory Accreditation* and *Quality systems* would be referred to the drafting group (see para. 31).

⁶ CX/FICS 00/3 and comments submitted by Brazil, India and Korea (CX/FICS 00/3-Add. 1); Malaysia, Switzerland, United States (CRD 2); Brazil (CRD 7); Argentina (CRD 9); European Community (CRD 11).

⁷ ALINORM 99/30A, paras. 33-53.

SECTION 4 - ELEMENTS OF AN IMPORT FOOD CONTROL SYSTEM

4.3 - Regulations and standards

17. The Committee agreed to retain the first sentence of this section so as to emphasize that imported food standards should not be more rigorous than domestic standards that provide the appropriate level of protection. The second and third sentences of this section were deleted to eliminate redundancies.

4.5 - Administrative requirements

18. The Committee agreed that “*other resources*” should be added to those requirements (facilities and equipment) necessary to operate the programme. The Committee also agreed to add *storage capacity* and *access to updated documentation of regulatory requirements* to the list of facilities, equipment and other resources.

SECTION 5 – MANAGEMENT OF THE FOOD CONTROL SYSTEM ELEMENTS

5.1 – Risk analysis

19. The Committee agreed to delete this section in its entirety as the concept of risk analysis was adequately covered in other Codex texts and because the issue of minimizing undue delay at the port of entry would be addressed in other relevant sections.

5.2 – Application of performance history in inspection

20. The Committee agreed to change the title of this sub-section to “Frequency and type of inspection” to better reflect its contents. It agreed to merge paragraphs 21 and 22 into one paragraph and to amend the following bullet points:

- the second point to read “the affected consumer group”;
- the fourth point to read “the food inspection and certification system in the exporting country and existence of any equivalence, mutual recognition agreements or other trade agreements”;

and to introduce the following text in new points:

- “relevant information concerning foodborne illnesses and emergency situations where a food safety problem is suspected to be associated with the product”;
- “conformity history of the importer, transporter, exporter, manufacturer or supplier”;
- “mechanisms to monitor products after distribution”.

21. The Committee agreed to delete paragraph 23 with the understanding that the content of the paragraph would be duly covered by paragraph 33.

5.3 – Point of control

22. The Committee agreed to clarify this section to indicate that control of imported food could be conducted at one or more points in the food chain. The Committee noted the need to clarify the question of the application of controls prior to export.

5.4 – Recognition of foreign food export controls

23. The Committee revised the title of this section to read as “Recognition of exporting country food controls” and made consequential minor amendments to the text.

5.5 – Data exchange

24. The Committee noted that the Codex Guidelines for the Exchange of Information between Countries on Rejections of Imported Foods provided adequate information on the nature of data to be exchanged. However, the Committee refined and added to the list of data that may be exchanged between the competent authorities of trading countries.

SECTION 6 – OPERATION AND ADMINISTRATION OF FOOD IMPORT CONTROL SYSTEMS

6.1 – Details of the food import programme operation

25. The Committee agreed to delete the two bullet points of paragraph 33 as their content was already covered by the Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems. It further agreed to add the phrase “so as to avoid undue delay in clearance of products at the point of importation” at the end of paragraph 34.

26. The Committee modified the bullet points presented and agreed to add an additional point concerning “destination” to paragraph 36.

27. The Committee modified paragraph 38 to clarify that the inspection of products from sources with no compliance history or with a poor compliance history should be set at a higher intensity than products from other sources. It was also clarified that inspection procedures could be developed to automatically detain products from suppliers with a known poor compliance history.

28. The Committee agreed to:

- include a new paragraph 41 to ensure that duplicate inspections by importing control agencies should be avoided to the extent possible;
- modify paragraph 49 to ensure that a mechanism was in place for appeals of decisions resulting in rejections or unfair discretionary inspection procedures; and
- delete paragraphs 41, 42, 43, 46, 47 and 50.

OTHER ISSUES

4.1 – Aims and priorities

4.2 – Legal framework

29. Following extensive discussions, the Committee referred Sections 4.1 and 4.2 to an informal drafting group for consideration. The Committee continued its discussions on the revised draft of these sections on the basis of a paper prepared by the informal working group. As the Committee could not reach agreement on the revised Sections 4.1 and 4.2, it was decided to consider these sections in greater detail at its next Session.

Status of the proposed draft Codex Guidelines for Food Import Control Systems

30. Although the Committee had extensive discussions on the proposed draft Guidelines, it could not reach the necessary level of agreement to forward the text to the Executive Committee for adoption at Step 5.

31. The Committee therefore decided that a revised first draft of the proposed draft Guidelines would initially be prepared by the Secretariat with a view towards its consideration by a drafting group consisting of Australia, Canada, France, India, Japan, Mexico, Morocco, the United Kingdom and the United States. The Committee decided that the drafting group would take into account the discussions at the present meeting, written comments submitted and the proposed revisions to Sections 4.1 and 4.2 presented by the informal drafting group.

32. The Committee further agreed that the revised proposed draft Guidelines for Food Import Control Systems would be circulated for comment at Step 3 and further consideration at its 9th meeting.

PROPOSED DRAFT GUIDELINES AND CRITERIA FOR OFFICIAL CERTIFICATE FORMATS AND RULES RELATING TO THE PRODUCTION AND ISSUANCE OF CERTIFICATES (Agenda Item 4)⁸

33. The 7th Session of the CCFICS requested Australia and the United Kingdom to redraft the proposed draft *Guidelines and Criteria for Official Certificate Formats and Rules Relating to the Production and Issuance of Certificates* for circulation and comments at Step 3.⁹ The Committee also noted that the forthcoming 4th Session of the Codex Committee on Milk and Milk Products (Wellington, New Zealand, 28 February – 3 March 2000) would be considering a *Model Export Certificate for Milk and Milk Products* (CX/MMP 00/17) and that a progress report on the CCMMP deliberations would be reported to the 9th Session of the CCFICS.

34. The Committee thanked Australia and the United Kingdom for their work and agreed to the Guidelines with minor changes. Among changes to the text agreed to by the Committee were the following:

TITLE OF THE GUIDELINES

35. The Committee retitled the text as proposed draft *Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates* as suggested by the author countries.

PREAMBLE

36. The Committee added a Preamble section to indicate that the Guidelines were predicated on the presumption that commercial parties were responsible for product safety and conformity with requirements at all stages of food production.

OBJECTIVES

37. The Committee agreed that issues of quarantine related to animal and plant health were not within its terms of reference and therefore, clarified this section to indicate that certificates contained information to meet importing country requirements for both safety and fair trade in food. It was also agreed that the definition for *requirements* would be cross-referenced to the Codex Principles for Inspection and Certification (CAC/GL 20-1995).

PRINCIPLES

38. The Committee clarified the leading paragraph to this section to indicate that certificates should only be required in cases where it was necessary to ensure product safety or to ensure fair trade practices. The Committee revised the bullet points regarding the design or use of certificates by deleting irrelevant text and by adding a new point concerning certificate use to minimize the risk of fraud. The bullet points were also rearranged for clarity.

SCOPE

39. After extensive debate, the Committee decided to extend the Guidelines to the use of officially recognized certificates in addition to official certificates with the understanding that the term officially recognized certificates would be placed in square brackets pending the development of a definition in the future. It further agreed to delete the second sentence of paragraph 3 as issues of transparency and non-discrimination were adequately covered elsewhere. The Committee decided to move the Scope section to immediately after the section concerning Objectives.

CRITERIA

Standard Format

40. The Committee agreed that the terms *original copy* and *duplicate copy* should be clearly defined and that separate conditions concerning the use of electronic certification should be developed in the future. The Committee also agreed to add a section in square brackets indicating that certificates issued by officially

⁸ CX/FICS 00/4 and comments submitted by Canada, India (CX/FICS 00/4-Add. 1); United States (CRD 3); Brazil (CRD 7); Argentina (CRD 9); Thailand (CRD 10).

⁹ ALINORM 99/30A, paras. 54-68.

recognized bodies may, or may not, be required to have a unique identification number as appropriate to the circumstances, with the understanding that this issue would be further discussed in the future.

41. The Committee supported the opinion of Canada and other delegations that the alternate provisions proposed in paragraph 12 of CX/FICS 00/4 were subject to further debate and therefore the paragraph remained in square brackets. The Committee agreed that definitions of the terms *officially printed copies*, *officially recognized certificates*, *officially recognized bodies* and *official certificates* would be elaborated. It also modified paragraph 11 to indicate that certificates should be designed so as to minimize the risk of fraud.

Details of the consignment

42. The Committee agreed in principle that this sub-section should contain a minimum list of categories of information to be included in certificates rather than developing an exhaustive list and modified the introductory paragraph accordingly. The Committee revised and re-ordered the existing bullet points in this section, deleted irrelevant points and added additional points concerning the nature of the food, identity of the production establishment, country of dispatch and any other information required by the importing country.

Health attestation

43. The Committee changed the title of the section to *Attestation* to more accurately reflect the content of the corresponding text. The Committee further modified this section to indicate that the Guidelines did not address matters related to animal and plant health, notwithstanding the fact that animal and plant health attestations may be contained in certificates. The Committee also decided to include attestations to product conformity with particular grade or other requirements.

Responsibility of the certifying authority

44. The Committee clarified this section to indicate that the certifying authority should be designated and adequately empowered by national legislation or regulation to provide the particular attestations required within a certificate.

Responsibility of certifying officers

45. The Committee revised and re-ordered the existing bullet points in this section, deleted irrelevant points and added an additional point indicating that the certifying officer should be appropriately designated by the certifying authority.

Instructions for commercial parties

46. After extensive debate, the Committee decided that the responsibilities of commercial parties should be addressed in the Preamble to the Guidelines. This Section was therefore retitled as Presentation of Original Certificate and the remaining paragraph indicated that the importer was responsible for ensuring that the product was presented to the importing country authorities in accordance with the importing country's regulations.

Replacement certificate

47. The Committee clarified this Section to indicate that a replacement certificate should reference the number of the original certificate.

Status of the Proposed Draft Codex Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates

48. The Committee agreed to forward the *Proposed Draft Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates* to the 47th Session of the Executive Committee for adoption at Step 5 (see Appendix II). The Committee further agreed that a drafting group under the direction of Australia and the United Kingdom, with the participation of Canada, France, India, the Netherlands, New Zealand, South Africa, the United States and the European Commission, would review comments submitted during the current discussions of the Committee as well as comments submitted at Step 6 subsequent to CCEXEC adoption with a view towards the consideration of an amended text at the Committee's 9th Session. In the interests of transparency, all comments submitted at Step 6 by the due date would be reproduced in their entirety in the working paper to be prepared for the next meeting.

49. In taking this decision, the Committee agreed to inform the 47th Session of the Executive Committee that the following issues in particular remain under consideration:

- provisions concerning electronic certification;
- the two proposals contained in the new paragraph 14;
- the boundaries between official/officially recognized certification bodies and other agencies in light of the wide range of certification presently used to facilitate trade; and,
- definitions for additional terms (e.g., paras. 40 and 41, above).

PROPOSED DRAFT GUIDELINES FOR THE UTILIZATION AND PROMOTION OF QUALITY ASSURANCE SYSTEMS (Agenda Item 5)¹⁰

50. The 7th Session the CCFICS requested the 23rd Session of the Codex Alimentarius Commission to approve the elaboration of *Proposed Draft Codex Guidelines for the Utilization and Promotion of Quality Assurance Systems* as new work¹¹. The 23rd Session of the Commission noted¹² the general support for the elaboration of the Guidelines and agreed that a substantive working paper be prepared for presentation at the 8th CCFICS Session. The proposed draft Guidelines were prepared by Australia with the participation of Canada, Denmark, France, India, New Zealand, South Africa, and the United States. The proposed draft Guidelines were presented by Australia.

51. The Committee thanked Australia and the other countries for their work and generally supported the continued development of the Guidelines in view of the importance of quality assurance systems in providing consumer protection and in facilitating trade in food.

52. Some delegations were of the opinion that the Guidelines should be limited to matters of food safety because other provisions relating to quality were subjective and therefore the elaboration of Codex guidelines covering both aspects could potentially lead to a situation in which unjustified non-tariff barriers to trade could be applied. It was also suggested that quality assurance systems related to non-safety measures should be voluntary and that resources and infrastructures for the promotion of quality assurance systems were limited.

53. Other delegations believed that the guidelines should relate to the use of quality assurance systems which include both safety and other quality factors. However, it was noted that the current document should clarify the relationship between HACCP principles and quality assurance systems including the ISO 9000 series and the relationship between quality objectives and food safety objectives. It was noted that good manufacturing practice and the Codex General Principles of Food Hygiene should be used in the first instance to ensure the quality and safety of foods.

54. Some delegations suggested that the Guidelines should focus more directly on how voluntary quality assurance systems could be used to assist those responsible for official controls.

55. The Committee agreed to modify the title to read as *Proposed Draft Guidelines for the Utilization and Promotion of Quality Assurance Systems to meet Requirements in Relation to Food* in order to confirm that the scope of the text referred to all aspects of food quality, including safety.

56. In view of divergent opinions concerning the successful integration of HACCP principles into a broader quality assurance system, the Committee deleted the second sentence of paragraph 2 in the Scope section. In response to concerns, the Committee noted that the text of the Guidelines did not mandate the use of quality assurance systems.

57. The Committee agreed that the definitions needed to be revised to take account of recent decisions of the Commission and definitions established by the ISO.

¹⁰ CX/FICS 00/5 and comments from Canada, India, ISO (CX/FICS 00/5-Add. 1); United States (CRD 4); Brazil (CRD 7); European Community (CRD 8); Argentina (CRD 9); and, Thailand (CRD 10).

¹¹ ALINORM 99/30A, paras. 85-93.

¹² ALINORM 99/37, paragraph 205 and Appendix VIII.

58. The Committee agreed that elements of a quality assurance system (paragraph 5, Section 3) should also include: corrective actions, internal audit, supplier assessment, traceability, measurement, reliability and system review. The Committee noted that the linkage between HACCP principles and quality assurance systems in paragraph 7 and in Appendix I needed to be addressed in a much clearer and discursive manner.

59. The Committee noted that ISO Standards did not require a recall procedure (paragraph 19) as such but provided for the identity of products at any stage. Some countries considered that public communication of the recall process was essential and should be reflected in the text.

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

60. The Committee agreed that Australia, with assistance from Canada, Denmark, France, India, the Netherlands, New Zealand, South Africa, Switzerland, the United States and the European Commission, would prepare a revised version of the document for circulation and comment at Step 3 prior to the next session of CCFICS.

61. It was further agreed that the drafting group would primarily address the use as well as promotion of generic quality assurance systems; the relationship between quality assurance and HACCP principles; written comments; and, discussions at the current meeting.

DISCUSSION PAPER ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEM (Agenda Item 6)¹³

62. The 7th Session of the CCFICS¹⁴ requested the Commission to approve the elaboration of proposed draft *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* as new work. The 46th Session of the Executive Committee was of the opinion that priority should be given to the development of judgement of equivalence regarding matters of food safety, and proposed that a paper be prepared for the next Session of the CCFICS on the matter of judgement of equivalence systems for controlling the safety and quality of foods and outlining the issues involved.¹⁵ Noting this opinion, the 23rd Session of the Commission decided that the CCFICS should continue to consider this item as a discussion paper, and as concepts in this area fell within the mandates of other Codex committees, the discussion paper would need to be circulated to these committees for their comments.¹⁶ New Zealand prepared, in cooperation with Australia, Canada and the United States, a discussion paper which included a suggested framework for determining the equivalence of sanitary measures associated with food inspection and certification systems. The Committee thanked New Zealand and the other countries involved in the preparation of the Guidelines.

63. The Committee supported the development of Guidelines within the Codex step procedure. Most delegations supported the priority consideration of the judgement of equivalence of sanitary measures on a separate and if possible parallel track to the judgement of equivalence of technical regulations. Other delegations noted the difficulty in separating sanitary aspects from those related to technical matters, and suggested that the Committee might consider merging the two concepts at a later stage. It was also noted that the paper should take account of the work and definitions developed in other Codex committees, and should stress the primacy and importance of adhering to Codex texts and the mandate of the Commission when elaborating the Guidelines.

64. It was suggested that the flow chart for the determination of equivalence (figure 1), which referred to “objective basis for comparison” instead of “food safety objective”, would need to be updated to reflect the current text.

¹³ CX/FICS 00/6 and comments submitted by the European Community (CRD 5); Peru (CRD 6); Brazil (CRD 7); Thailand (CRD 10).

¹⁴ ALINORM 99/30A, paras 69-84

¹⁵ ALINORM 99/4, paras. 24-26

¹⁶ ALINORM 99/37, para. 203

Status of the Discussion Paper on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems

65. The Committee requested New Zealand, with assistance from Argentina, Australia, Canada, France, Japan, Morocco, the United States and the European Commission, to proceed with the development of Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems for circulation and comment at Step 3 prior to the 9th Session of the CCFICS. This decision was taken with the understanding that the development of the Guidelines would be subject to subsequent approval as new work by the 47th Session of the Executive Committee. The Committee also noted that its work in this area would be drawn to the attention of other Codex committees, including CCGP and CCFH.

DISCUSSION PAPER ON THE JUDGEMENT OF EQUIVALENCE OF TECHNICAL REGULATIONS ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS (Agenda Item 7)¹⁷

66. The 7th Session of the CCFICS requested the advice of the Executive Committee and the Commission on the possible development of guidelines on the judgement of equivalence of technical regulations other than sanitary measures.¹⁸ The 23rd Session of the Codex Alimentarius Commission agreed¹⁹ with the views of the 46th Session of the Executive Committee²⁰ that CCFICS should proceed to develop guidance on the equivalence of systems for inspection and certification in relation to technical regulations other than sanitary measures in parallel with food safety issues.

67. The Committee thanked Australia for the development of the discussion paper, which included a suggested framework for determining the equivalence of technical regulations associated with food inspection and certification systems. The Committee supported the development of guidelines on the judgement of equivalence of technical regulations on a parallel, but separate, track to the judgement of equivalence of sanitary measures with the understanding that at a later stage the two papers could possibly be merged into one document. It was also suggested that the focus of work should be on the equivalence of systems rather than on the equivalence of technical measures expressed in terms of specific values.

68. In considering this issue, the Committee observed that the majority of imported foods were rejected or retained for reasons other than food safety and that the notion of equivalence used in the WTO SPS and TBT Agreements was applied differently. In this regard, several delegations were of the opinion that it would be inappropriate at this stage to combine this document with the document on the determination of equivalence of sanitary measures. The Committee noted further that “quality” should be defined as should the role of “risk” relative to non-safety quality factors; further, “equivalence” should be clarified when dealing with technical as opposed to sanitary or inspection measures. The paper should take account of the work and definitions developed in other Codex committees and should stress the primacy and importance of adhering to Codex texts and the mandate of the Commission when elaborating the Guidelines.

Status of the Discussion Paper on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems

69. The Committee agreed that proposed draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems would be developed by Australia, with the assistance of France, South Africa and the United States, for circulation and comment at Step 3 and further consideration at its next meeting.

¹⁷ CX/FICS 00/7 – Revised and comments submitted by Brazil (CRD 7); Thailand (CRD 10).

¹⁸ ALINORM 99/30A, paras 69-84

¹⁹ ALINORM 99/37, para. 217

²⁰ ALINORM 99/4, paras. 24-26

OTHER BUSINESS AND FUTURE WORK (Agenda Item 8)

DISCUSSION PAPER ON RISK MANAGEMENT GUIDELINES FOR FOOD CONTROL EMERGENCY SITUATIONS INVOLVING INTERNATIONAL TRADE²¹

70. A discussion paper on this topic was presented by Australia as a result of discussions and the request of the 23rd Session of the Codex Alimentarius Commission.²² Although the Committee agreed that the topic was of general interest, it suggested that the Codex Guidelines for the Exchange of Information in Food Control Emergency Situations (CAC/GL 19-1995), as well as related Codex texts, should be examined to determine whether or not the development of guidelines would be necessary. The difficulty in obtaining information to facilitate the decision-making process in food control emergency situations was also noted, as was the difficulty in developing generic guidance for each type of unique situation.

71. The representative of WHO informed the Committee of the proposed revision of the International Health Regulations (IHR) of WHO, which addresses risk management of urgent international public health events, and offered to provide the Committee with relevant information at its next meeting.

72. The Committee accepted the offer of Australia to prepare a discussion paper for consideration at its next meeting which would address the adequacy of relevant Codex texts and would outline the issues involved in regard to food control emergency situations.

ROLE OF SCIENCE AND OTHER FACTORS IN RELATION TO RISK ANALYSIS

73. The Committee noted that the 14th Session of the Codex Committee on General Principles had requested the relevant Codex committees to identify and clarify the relevant factors taken into account in their work, in the framework of risk analysis, in order to facilitate its general debate on “other legitimate factors” relevant for the health protection of consumers and for the promotion of fair practices in trade.²³ The forthcoming 15th Session of the CCGP (Paris, France, 10-14 April 2000) would be conducting a *Review of the Statements of Principle on the Role of Science and the Extent to which Other Factors are Taken into Account: Role of Science and other Factors in Relation to Risk Analysis*.²⁴

74. The Committee took note of the request of the CCGP, but did not have time to discuss or debate the issue in detail. It noted that the representative of the European Commission was of the opinion that the following “other legitimate factors” had been considered by the CCFICS:

- economic aspects of controls;
- practical aspects of measures;
- ability to introduce measures/capacity of measures;
- availability of expertise;
- feasibility of sampling;
- consumer information and confidence;
- availability of resources;
- preservation of confidentiality;
- good manufacturing practice/good agricultural practice; and,
- religious considerations.

Switzerland also added the following points:

- social/cultural factors; and,
- consumer information.

²¹ Conference Room Document 1

²² ALINORM 99/37, paras. 235-238

²³ ALINORM 99/33A, paras. 64-76

²⁴ CX/GP 00/7

OTHER ISSUES

75. The Committee agreed that, at its next meeting, Morocco would submit for consideration by the Committee a document on the need for guidance on food export control systems.

DATE AND PLACE OF NEXT SESSION (Agenda Item 9)

76. The Committee was informed that the 9th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems was tentatively scheduled to be held in Australia from 27 November to 1 December 2000, subject to discussions between the host government and FAO.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Document Reference (ALINORM 01/30)
Proposed Draft Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates	5	47 th CCEXEC Governments Drafting Group 9 th CCFICS	Paras. 33-49 and Appendix II
Proposed Draft Guidelines for Food Import Control Systems	2/3	Secretariat Drafting Group Governments 9 th CCFICS	Paras. 8-32
Proposed Draft Guidelines for the Utilization and Promotion of Quality Assurance Systems to Meet Requirements in Relation to Food	2/3	Drafting Group Governments 9 th CCFICS	Paras. 50-61
Proposed Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems	1/2/3	47 th CCEXEC Drafting Group Governments 9 th CCFICS	Paras. 62-65
Proposed Draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems	2/3	Drafting Group Governments 9 th CCFICS	Paras. 66-69
Discussion Paper on Risk Management Guidelines for Food Control Emergency Situations Involving International Trade	-----	Australia 9 th CCFICS	Paras. 70-72
Discussion Paper on Food Export Control Systems	-----	Morocco 9 th CCFICS	Para. 75

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**PROPOSED DRAFT GUIDELINES FOR GENERIC OFFICIAL CERTIFICATE FORMATS
AND THE PRODUCTION AND ISSUANCE OF CERTIFICATES****At Step 5****PREAMBLE**

1. These guidelines are based on the presumption that commercial parties are responsible for product safety and conformity with requirements at all stages of food production.

OBJECTIVES

2. Certificates should contain essential information that meets the objectives of the importing country's requirements in respect of food safety and facilitation of fair trade in food. The level of information required should be adequate for the importing country's purpose and not impose unnecessary burdens on the exporting country or exporter, nor should there be a requirement for the disclosure of information that is commercial-in-confidence unless it is of relevance to public health. Certificates should only be required in cases where it is necessary to ensure product safety or to ensure fair trade practices.

SCOPE

3. These guidelines concern the design and use of official and [officially recognized certificates] that attest to attributes of food presented for international trade. Certificates should be required only where necessary to ensure product safety and wholesomeness, or otherwise facilitate trade.

4. These guidelines do not deal with matters of animal and plant health since these are not under the mandate of Codex. However, it is recognized that, in commercial practice, certificates may contain information relevant to these matters.

5. These guidelines envisage the possible use of paper and electronic forms of certification.

DEFINITIONS

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

Official certificates [to be developed]

Officially printed copies [to be developed]

Officially recognized certificates [to be developed]

Officially recognized certification bodies

*Requirements*¹ 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.

PRINCIPLES

6. Certificates should be required only when necessary to ensure product safety or to otherwise facilitate trade. The rationale and requirements for export certification should be communicated in a transparent manner and consistently implemented in a non-discriminatory manner. Certificates should be designed and used in a manner that:

- meet requirements in respect of food safety and the facilitation of fair trade in food;
- simplifies and expedites the certification process;

¹ Codex *Principles for Inspection and Certification* (CAC/GL 20-1995)

- clarifies the responsibility of all parties;
- satisfies compulsory trade description requirements;
- provides for accurate identification of the consignment being certified;
- minimizes the risk of fraud.

CRITERIA

STANDARD FORMAT

7. Certificates should contain a declaration by the official, or officially recognized, certification body and be duly signed and sealed by an officer authorized by the competent authority for this purpose. The certificate should clearly identify the certifying body with letterhead and/ or logo.

8. Each official certificate should have a unique identification number and be printed in an unambiguous style in a language, or languages, fully understood by the certifying officers and by the receiving authority. A record of unique identification numbers assigned to batches of printed certificates should be maintained by the competent authority and be able to be related to the distribution of the certificates. [Certificates issued by officially recognized bodies may, or may not, be required to have a unique identification number as appropriate to the circumstances.]

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

10. Certificates, in any form, should be designed so as to minimize the risk of fraud (for example, use of watermark paper, use of paper that cannot be photocopied, or other security measures).

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

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

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

14. [Certificates may be issued after goods have been exported provided adequate measures are in place to ensure the consignment to which the certificate relates, is intact, identifiable and has not been modified or otherwise manipulated in any way. These measures may include the provision of documentation by another officially recognized body if the consignment has passed out of the control of the issuing authority.] / [No certificate may be issued after the consignment has left the control of the relevant authority except where, under exceptional circumstances, it may be possible to issue a certificate on the basis of assurances from an officially recognized body if the consignment has been under continuous official supervision during transport.]

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

DETAILS OF THE CONSIGNMENT

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

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

- nature of the food;
- name of product;
- quantity, in the appropriate units;
- lot identifier or date coding;
- identity of production establishment;
- name and contact details of the importer (consignee);
- name and contact details of the exporter (consignor);
- country of dispatch, and;
- any other information required by the importing country.

STATEMENT OF ORIGIN

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

ATTESTATIONS

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

- public health status;
- product conformity with particular grade or other requirements;
- the status (licensing details) of processing and/or packaging establishment in the exporting country; and,
- reference to any associated bilateral/multilateral agreement.

RESPONSIBILITIES OF THE CERTIFYING AUTHORITY

19. The certifying authority should be designated and adequately empowered by national legislation or regulation in a transparent manner to provide the particular attestations required in a certificate.

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

21. The authorities should have in place an effective system to prevent, to the extent practicable, the fraudulent use of official certificates.

RESPONSIBILITIES OF CERTIFYING OFFICERS

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

23. The certifying officers should:

- be appropriately designated by the certifying authority
- be fully conversant with the requirements to which they are attested on the certificate;

- have access to a copy of regulations or requirements that are referred to on the certificate or clear information and guidance notes issued by the competent authority explaining the criteria that the product must meet before being certified;
- have no conflict of interest in the commercial aspects of the consignment and be independent from the commercial parties;
- only certify matters which are within their own knowledge (or which have been separately attested to by another competent party); and
- only certify in respect of the circumstances known at the time of signing the document.

PRESENTATION OF ORIGINAL CERTIFICATES

24. The importer (consignee) is responsible for ensuring that the product is presented to the importing country's authorities with the original certificate in accordance with the importing country's requirements.

INSTRUCTIONS FOR COMPLETING THE FORM

25. Certificates should always be issued and presented, to the exporter or his/her agent, in the original.
26. A copy of the certificate (clearly marked "COPY" or "DUPLICATE") should be provided to the competent authorities in both the exporting and importing countries, on request.
27. When signing a certificate, the officer should ensure that:
- the certificate contains no deletions other than those required by the text of the certificate;
 - any alterations of the certified information are initialled and sealed by the certifying officer using the official stamp of the competent authority;
 - the certificate bears his/her signature, the name and official position of the certifying officer in clear lettering and, where appropriate, his/her qualifications;
 - the certificate bears the date on which the certificate was signed and issued and, where appropriate, the time for which the certificate will remain valid;
 - no portion of the certificate is left blank in a manner that would allow it to be amended after signature by the certifying officer.

REPLACEMENT CERTIFICATES

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