

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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**ALINORM 08/31/30**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX ALIMENTARIUS COMMISSION**

**Thirty-First Session**

**Geneva, Switzerland, 30 June – 5 July 2008**

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

*Surfers Paradise, Queensland, Australia, 26 -30 November 2007*

**Note:** This report includes Codex Circular Letter CL 2007/44-FICS

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**CL 2007/44-FICS**  
**December 2007**

**To:** Codex Contact Points  
Interested International Organizations

**From:** Secretary,  
Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme  
Viale delle Terme di Caracalla  
00153 Rome, Italy

**Subject:** **Distribution of the Report of the Sixteenth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (ALINORM 08/31/30)**

The report of the Sixteenth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems will be considered by the 31<sup>th</sup> Session of the Codex Alimentarius Commission (Rome, Italy, 30 June -5 July 2008).

## **MATTERS FOR ADOPTION BY THE 31<sup>TH</sup> SESSION OF THE CODEX ALIMENTARIUS COMMISSION**

**Proposed Draft Appendix to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems*, advanced to Steps 5/8 of the Codex Procedure, with the omission of Steps 6 and 7 (ALINORM 08/31/30, Appendix II). See also para. 44 of this report.**

Governments and international organizations wishing to submit comments on the above document should do so in writing, *preferably by e-mail*, to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (e-mail: [codex@fao.org](mailto:codex@fao.org), telefax : +39 06 57054593), **not later than 31 March 2008.**

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## SUMMARY AND CONCLUSIONS

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

### **Matters for Adoption / Approval by the 31<sup>st</sup> Session of the Commission and for Critical Review by the 61<sup>st</sup> Session of the Executive Committee**

#### Proposed draft Standards and Related Texts at Step 8 and 5/8 of the Uniform Procedure

The Committee agreed to forward to the Commission for final adoption:

- the proposed draft Appendix to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (see para. 44 and Appendix II).

#### New Work

The Committee agreed to forward to the Commission, through the Executive Committee, for approval as new work:

- a project document on the development of Guidelines for the Conduct of Foreign Audit Team Inspections (see para. 64 and Appendix III).
- a project document on the development of a Generic Model Health Certificate, as an Annex to the *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* (CAC/GL 38-2001) (see para. 85 and Appendix V).

### **Matters of Interest to the 31<sup>st</sup> Session of the Commission**

The Committee decided to maintain annual meetings for the time being (see para. 93).

### **Matters of Interest to other Committees**

#### Codex Committee on Fresh Fruit and Vegetables (CCFFV)

The Committee commented on the *Draft Guidelines for the Inspection and Certification of Fresh Fruits and Vegetables for Conformity to Quality Standards* at Step 5 and agreed to refer the discussion and written comments to CCFFV and invited all delegations wishing to provide any further comments to the draft Guidelines to do so in reply to Circular Letter CL 2007/20-FFV (see paras 9-13).

#### Codex Committee on Milk and Milk Products (CCMMP)

The Committee agreed to forward its recommendations on the consistency of the Model Export Certificate for Milk and Milk Products to the 8<sup>th</sup> Session of CCMMP for its consideration and to refer individual comments, including written comments submitted at its current and previous sessions, to CCMMP for its consideration (see paras 73-79 and Appendix IV).

### **Other Matters**

The Committee agreed:

- to defer consideration on the revision of the *Codex Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995) and the *Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997) until further notice (see para. 47);
- to establish an electronic Working Group to revise the discussion paper on the Need for Guidance for National Food Inspection Systems for consideration at its next session (see para. 58);
- to establish an electronic Working Group to prepare a revised discussion paper on the Need for further Guidance on Traceability/ Product Tracing for consideration at its next session (see para. 72);
- the Delegation of the United States to prepare a discussion paper on issues related to the intentional contamination of foods (see para. 92).

**LIST OF ABBREVIATIONS USED IN THIS REPORT**

|           |  |
|-----------|--|
| CAC/GL    | Codex Alimentarius Commission / Guidelines                                     |
| CAC/RCP   | Codex Alimentarius Commission / Recommended Code of Practice                   |
| CCFICS    | Codex Committee on Food Import and Export Inspection and Certification Systems |
| CCFFP     | Codex Committee on Fish and Fishery Products                                   |
| CCFFV     | Codex Committee on Fresh Fruit and Vegetables                                  |
| CCMMP     | Codex Committee on Milk and Milk Products                                      |
| CL        | Circular Letter  |
| CRD       | Conference Room Document   |
| FAO       | Food and Agriculture Organization of the United Nations                        |
| IPPC      | International Plant Protection Convention                                      |
| ISO       | International Organization for Standardization                                 |
| OIE       | World Organisation for Animal Health   |
| SPS       | Sanitary and Phytosanitary Measures (WTO Agreement)                            |
| UN/CEFACT | United Nations Centre for Trade Facilitation and Electronic Business           |
| WHO       | World Health Organization  |
| WTO       | World Trade Organization   |

## INTRODUCTION

1. The Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) held its 16<sup>th</sup> Session in Surfers Paradise, Queensland, Australia, from 26 to 30 November 2007 at the kind invitation of the Government of Australia. Mr Gregory Read, Executive Manager, Australian Quarantine and Inspection Service, Australian Government Department of Agriculture, Fisheries and Forestry, chaired the Session. The Session was attended by delegates from 62 Member countries and 1 Member organization and 5 international governmental and non-governmental organizations. The list of participants, including the Secretariat, is given in Appendix I to this report.

### *Division of Competence*

2. The Committee noted the division of competence between the European Community and its Member States, according to paragraph 5, Rule II of the Rules of Procedure of the Codex Alimentarius Commission, as presented in CRD 1.

### **ADOPTION OF THE AGENDA (Agenda Item 1)<sup>1</sup>**

3. The Committee agreed to the proposal of the United States of America to hold an exchange of views under Agenda Item 9 (Other Business and Future Work) on issues related to intentional contamination of foods. The Committee also agreed to change the order of the agenda and to discuss Agenda Item 8 (Consistency of the draft *Model Export Certificate for Milk and Milk Products* with CAC/GL 38-2001) immediately after Agenda Item 3 (Proposed draft Appendix to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification*).

4. The Committee adopted the Provisional Agenda as its Agenda for the Session with these amendments.

### **MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION, OTHER CODEX COMMITTEES AND TASK FORCES AND OTHER INTERNATIONAL ORGANIZATIONS (Agenda Item 2)<sup>2</sup>**

5. The Committee noted the information presented in document CX/FICS 07/16/2. The Committee was also informed that the Commission had requested that in the future all project documents for new work should be prepared correctly in accordance with the provisions in the Procedural Manual<sup>3</sup>.

6. In particular the Committee commented and/or took decisions as follows:

#### ***Strategic Plan 2008-2013***

7. The Committee noted that the Commission had adopted the Strategic Plan 2008-2013 and that activities 1.4, 2.5 and 3.3 were relevant to the work of the Committee. The Committee noted the comments of the Member States of the European Community in CRD 13.

#### ***Review of Codex Committee Structure and Mandates of Codex Committees and Task Forces<sup>4</sup>***

8. Upon the request from the Commission, the Committee briefly discussed the possibility of adopting a longer interval of meetings. The Committee noted that under the current arrangements CCFICS had worked efficiently and effectively since its establishment. Some delegations expressed concern that a longer interval could lead to a proliferation of physical working groups which could be difficult to attend especially by delegations from developing countries. The Delegation of Australia, as host country to the CCFICS, explained that the current arrangements were more suitable to ensure the Government's funding of the meetings. The Committee agreed to conclude this discussion under Agenda Item 10 (Date and Place of Next Session) on the basis of the workload of the Committee (see para. 93).

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<sup>1</sup> CX/FICS 07/16/1

<sup>2</sup> CX/FICS 07/16/2; CRD 2 (Comments of Colombia, India, Kenya and Solomon Islands); CRD 13 (Comments of the European Community)

<sup>3</sup> ALINORM 07/30/REP, para. 97

<sup>4</sup> ALINORM 07/30/Rep, paras 144-156

**Draft Guidelines for the Inspection and Certification of Fresh Fruits and Vegetables for Conformity to Quality Standards at Step 5**

9. Following the request of the Commission, the Committee commented on the draft Guidelines, as presented in the Annex to CX/FICS 07/16/2.

10. Several delegations supported the text in general, while others felt that there was sufficient guidance in existing CCFICS texts and that work on this issue should preferably be done in a horizontal committee.

11. Delegations which intervened commented: that duplication and contradiction with texts of other international organizations (e.g. OECD) should be avoided; that Codex should be responsible to develop its own texts and be cautious when referencing texts of other organizations (e.g. ISO); and that consistency between some definitions used in the draft guidelines and the definitions used in existing CCFICS texts should be considered depending of the scope of the draft Guidelines.

12. Some delegations noted that the language of the draft Guidelines was overly prescriptive and stringent and this could create trade restrictions especially for countries that did not have official government bodies that could provide the relevant certification. Some other delegations also noted that the draft Guidelines applied to situations where whole consignments were inspected at the border. Different procedures might need to be applied in other situations.

13. The Committee agreed to refer the above discussion and written comments to the Codex Committee on Fresh Fruits and Vegetables (CCFFV) and invited all delegations wishing to provide any further comments to the draft Guidelines (either falling into the mandate of CCFICS or other comments) to do so in reply to Circular Letter CL 2007/20-FFV<sup>5</sup>.

**Information provided by the World Organization for Animal Health (OIE)<sup>6</sup>**

14. The Observer from the World Organization for Animal Health (OIE) informed the Committee on the collaboration between the OIE and Codex. The OIE participates in meetings of the Codex Alimentarius Commission and in various committees. At the 30<sup>th</sup> Session of the Commission, the OIE encouraged the Commission to recommend that OIE, FAO and WHO legal services work together to eventually updating their existing mutual cooperation agreements to enable the establishment of a formal agreement between OIE and Codex, thus strengthening the legal basis for the development of joint OIE/Codex standards, where appropriate. The Committee was also informed that OIE encourages its delegates to collaborate with Codex delegates at the national level and that the Codex Secretariat participates in the OIE Working Group on Animal Production Food Safety and in various *ad-hoc* groups (e.g. traceability, generic certificates).

**PROPOSED DRAFT APPENDIX TO THE GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS, AT STEP 4 (N04-2004) (Agenda Item 3)<sup>7</sup>**

15. The Chairperson recalled that considerable time had been spent by the Committee on this Appendix: the 26<sup>th</sup> Session of the Commission in 2004 had adopted the elaboration of the Appendix as new work; the Committee had had substantial discussions on this matter since its 13<sup>th</sup> Session; and three physical Working Groups had been established, respectively by the 13<sup>th</sup>, 14<sup>th</sup> and 15<sup>th</sup> Session of the Committee.

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<sup>5</sup> [ftp://ftp.fao.org/codex/Circular\\_letters/CXCL2007/cl07\\_20e.pdf](ftp://ftp.fao.org/codex/Circular_letters/CXCL2007/cl07_20e.pdf)

<sup>6</sup> CRD 10 (Update on the status of OIE work)

<sup>7</sup> CX/FICS 07/16/3; CX/FICS 07/16/3 Add. 1 (Comments of Bolivia, Brazil, Costa Rica, European Community, Kenya, Mexico, New Zealand and Peru); CRD 3 (Comments of Colombia, India, Indonesia, Republic of Korea, Solomon Islands, OIE and Consumers International); CRD 11 (Comments of Japan); CRD 12 (Comments of Thailand); CRD 14 (Comments of Norway)

16. The Delegation of the United States of America, as lead country of physical Working Group, introduced the proposed draft Appendix. She explained that the current document reflected the progress of the Working Group, which met in Brussels (Belgium) in July 2007, to address the written comments and the observations made by the 15<sup>th</sup> Session of the Committee. The Working Group had a significant discussion and found agreement on all tasks assigned to it. The Committee also recalled that the Appendix was intended to add value to the Codex *Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003) and not to paraphrase or reinterpret it and that it also made reference to the Codex *Guidelines for the Development of Equivalence Agreements Regarding Food Imports and Export Inspection and Certification Systems* (CAC/GL 34-1999).

### **General Comments**

17. The Committee congratulated the Working Group for the improved and balanced document, which added value to CAC/GL 53-2003. It was noted that the scope of the equivalence determination (i.e. single sanitary measure, set of measures or systems made up of measures) and the concept of “Objective Basis of Comparison” had been clarified.

18. The Committee agreed on the general structure of the Appendix, while recognizing the need for minor amendments to fine tune the document and to ensure consistency with CAC/GL 53-2003.

19. The Committee noted that inconsistencies in the paragraph numbering between the English, and the French and Spanish versions of CAC/GL 34-1999 had caused difficulties when commenting on certain parts of the proposed draft Appendix. The Committee was informed that these inconsistencies had been fixed on the Codex website<sup>8</sup> and in the third edition of the Codex booklet on “Food import and export inspection and certification systems”, currently in print.

20. In view of the general agreement on the structure, purpose and scope of the Appendix and to progress it in the Step procedure, the Committee agreed to consider the document paragraph by paragraph.

### **Specific Comments**

21. The Committee, in addition to some minor editorial changes, including amendments to the French and Spanish translations, agreed to the following:

#### **Paragraph 1**<sup>9</sup>

22. The Committee agreed: to amend the first sentence to clarify that the Appendix related to the equivalence determination of sanitary measures associated with food inspection and certification systems; and to refer throughout the text to the “*Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003)” as the “*Guidelines*”.

#### **Paragraph 2**

23. The Committee noted that the term “country” included regional economic integration organizations, as indicated in footnote 4 of CAC/GL 34-1999.

#### **Paragraph 4**

24. The Committee did not support a proposal of the Delegation of India to add a new point (a) on the identification of measure(s) subject to equivalence determination because it considered that the identification of measures was not a preparatory step but part of the equivalence determination itself (i.e. scoping the equivalence determination). It amended point (a) to clarify that consideration of benefits and cost/resources implications of an equivalence determination in comparison to other arrangements that meet the same outcome was a responsibility of the exporting country. The Committee added “as appropriate” at the beginning of point (b) to make the preparatory step more flexible; in the same point, it clarified that the considerations to be taken into account relating to setting priorities were those contained in paragraph 9 of CAC/GL 34-1999<sup>10</sup>.

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<sup>8</sup> [http://www.codexalimentarius.net/download/standards/362/CXG\\_034e.pdf](http://www.codexalimentarius.net/download/standards/362/CXG_034e.pdf)

<sup>9</sup> When paragraph numbers have changed as compared to the text in CX/FICS 07/16/3, Attachment 1, the new paragraph numbers in the final text in Appendix II to this report will be indicated in parentheses

<sup>10</sup> The paragraph number corresponds to the paragraph of the text of CAC/GL 34-1999 available on the Codex website [www.codexalimentarius.net](http://www.codexalimentarius.net)



25. In point (c) it deleted “assuring that” and included the term “whether” to recognise that it was difficult to assure that importing and exporting countries have access to the necessary scientific and technical resources but that there was a need to consider whether countries have access to these resources; in the same point it deleted the term “thoroughly” as overly prescriptive. In point (d) the Committee changed “practicable” with “appropriate” to emphasise that the development of a plan is not only a question of possibility but also of necessity. It amended the rest of the point to allow for more flexibility.

#### Paragraph 8

26. The Committee amended the second sentence of the paragraph to clarify the relationship and the use of “categorisation”, “organising” and “side-by-side comparison” of sanitary measures to assist the identification of measures subject to equivalence determination when the situation is not clear.

#### Paragraph 10

27. The Committee acknowledged that the purpose of the paragraph was to describe “experience, knowledge and confidence” and not to establish obligations for its determination. It amended the second sentence to clarify that the points that followed were a list of examples that might inform the importing country’s experience, knowledge and confidence.

28. Point (a) was amended to clarify that a side-by-side comparison was not a requirement. In point (d) “port of entry” was changed with “point of entry” as more appropriate. Point (f) was amended to refer to bilateral and multilateral agreements that both importing and exporting countries might have with other countries.

#### Paragraph 16 (new paragraph 13)

29. In point (a) the Committee deleted “as to whether and” to avoid that “experience, knowledge and confidence” could be used to refuse a request for a judgement of equivalence.

#### Paragraph 18

30. The Committee agreed to delete the entire paragraph because it did not provide additional value and its second part could create confusion.

31. The Committee considered several proposals including a paragraph with a definition of the Objective Basis of Comparison and whether it should be placed in the Appendix or in the CAC/GL 53-2003. Several delegations were of the opinion that the definition was not needed as paragraph 15 of CAC/GL 53-2003 adequately described an Objective Basis of Comparison. Moreover several delegations were not in favour to reopen discussion on CAC/GL 53-2003. The Committee therefore agreed not to include this definition.

#### Paragraph 19 (new paragraph 16)

32. The Committee agreed to retain the first sentence of the paragraph and to delete the remainder as it was identical to footnote (11) of CAC/GL 53-2003. A new sentence was added to highlight the important information and useful examples contained in the footnote.

#### Paragraph 20 (new paragraph 15)

33. The Committee moved the paragraph up to the beginning of the section “Objective Basis of Comparison” and amended the text to make it consistent with the introductory paragraph of other sections.

#### (New paragraphs 20 and 21)

34. The Committee added two new paragraphs with provisions aiming at limiting the requests for information and documentation to essential information related to the objective of the equivalence determination and at presenting these requests in a coordinated manner.

#### Paragraph 31 (new paragraph 30)

35. The second sentence was deleted as it repeated the information contained in paragraph 35 (new paragraph 34).

Paragraph 32 (new paragraph 31)

36. As the paragraph could lead to misinterpretation, the Committee replaced it with a new paragraph to ensure that the importing country consults the exporting country throughout the entire process and at the earliest opportunity when the preliminary assessment indicates that the application for an equivalence determination is likely to be unsuccessful.

Paragraph 33 (new paragraph 32)

37. The Committee amended the paragraph to clarify that it dealt only with favourable decisions on the judgement of equivalence.

Paragraph 34 (new paragraph 33)

38. The Committee deleted “As agreed to between the importing and exporting countries” as superfluous; at the beginning of the paragraph, it added “Within a reasonable period of time” to ensure that written reports on the findings of equivalence determination are provided to the exporting country according to timelines, where applicable.

Paragraph 36 (new paragraph 35)

39. The Committee reversed the order of the points (a) and (b) to ensure a more logical flow.

Paragraph 38 (new paragraph 37)

40. The Committee deleted the first two bullet points because they did not add useful information. A new point (g) was added referring to assistance in providing appropriate training programmes.

Others

41. The Committee considered a proposal of the Delegation of the European Community, contained in CX/FICS 07/16/3 Add.1, to add a section on maintenance of equivalence agreements in addition to the provisions in paragraphs 7 (l) and 21 of CAC/GL 53-2003. The proposal addressed three points: i) the reason for a need to update the agreement; ii) the information to be exchanged between importing and exporting country and validity of equivalence during the re-negotiation of the agreement; and iii) factors affecting the status of equivalence, underlining in particular that the equivalence determination is mainly a documentary exercise and that implementation deficiencies should not put into question the result of the equivalence determination.

42. Several delegations generally supported the proposal and considered that it could be included in the Appendix to add further value to CAC/GL 53-2003; other delegations, while not opposing the proposal in principle, were concerned with including such a long new text with complicated and potentially controversial points at this late stage of the development of the Appendix. They were of the opinion that the proposal needed to be considered more carefully. Another delegation suggested to put the section into square brackets and to consider it at the next session at Step 6 which was not supported by the Committee.

43. The Committee concluded that a section on maintenance would not be included at this time but that there was potential benefit for new work in this area and noted that some delegations were of the view that this work needed to be urgently addressed.

**Status of the proposed draft Appendix to the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (N04-2004)**

44. The Committee agreed to forward the proposed draft Appendix, as amended above and with some editorial changes, to the 31<sup>st</sup> Session of the Commission for adoption at Steps 5/8, with the recommendation to omit Steps 6 and 7. The proposed draft Appendix is presented in Appendix II to this report.

**DISCUSSION PAPER ON THE NEED TO REVISE CAC/GL 20-1995 AND CAC/GL 26-1997 (Agenda Item 4)<sup>11</sup>**

45. The Delegation of New Zealand in introducing the document recalled the request of the 15<sup>th</sup> Session of the Committee to prepare a comprehensive discussion paper to justify the need for the revision Codex *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995) and the Codex *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997) and to identify the elements of the two documents to be revised, for consideration at its next session, including a project proposal for new work if appropriate.<sup>12</sup>

46. The Delegation reaffirmed the need to revise these documents. However, it noted that the Committee was currently considering important work and new proposals, which could have considerable impact on CCFICS texts. Therefore, New Zealand could not develop the discussion paper to the level of detail requested and recommended to defer consideration of this matter until further notice.

47. The Committee agreed to this proposal.

**DISCUSSION PAPER ON THE NEED FOR GUIDANCE FOR NATIONAL FOOD INSPECTION SYSTEMS (Agenda Item 5)<sup>13</sup>**

48. The Delegation of Australia introduced CX/FICS 07/16/5, which examined: (i) whether the existing Codex and/or CCFICS texts provided sufficient guidance for national food inspection systems and alignment with international standards; and (ii) reviewed the CCFICS Terms of Reference to examine whether the scope included national food inspection systems.

49. With regard to the benefits in developing principles and guidelines for national food control systems, several delegations<sup>14</sup> were of the opinion that the guidance contained in existing CCFICS texts was sufficient and that their broader use should be encouraged before developing new texts. It was mentioned that WTO members had the obligation not to differentiate between national and imported food products in their legislations and, consequently food control systems for national and imported food products needed to be harmonised.

50. It was also mentioned that Codex already provided guidance for national food inspection in texts such as the *General Principles for Food Hygiene* (CAC/RCP 1-1969) and the *Code of Practice for Meat Hygiene* (CAC/RCP 58-2005). FAO and WHO had discussed national food inspection systems in the framework of the Global Forum of Food Safety Regulators and developed relevant guidelines for national governments<sup>15</sup>.

51. These delegations recognised that the development of guidance for national food control systems was useful in principle, however they felt that further discussion was necessary before work could proceed and that duplication of work should be avoided.

52. Other delegations<sup>16</sup> strongly supported work on guidance for national food inspection systems as these, together with the import and export systems, were parts of the food control system. In many countries Codex standards were used as the base for national food legislation and often products initially intended for domestic markets were exported. The safety of exported foods was thus directly linked to the national food control system of exporting countries. Smaller countries could gain access to international markets by improving their national food inspection systems. The discussion on the *Code of Ethics* was recalled and the problems faced by countries lacking adequate food inspection system.

53. These delegations were of the opinion that guidance was needed on how to combine national application of Codex standards and related texts into a system.

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<sup>11</sup> CX/FICS 07/16/4; CRD 4 (Comments of Indonesia, Kenya, Republic of Korea, the Philippines and Solomon Islands)

<sup>12</sup> ALINORM 07/30/30, paras 68-70

<sup>13</sup> CX/FICS 07/16/5; CRD 5 (Comments of Indonesia, Kenya, Republic of Korea, the Philippines and Solomon Islands); CRD 11 (Comments of Japan); CRD 13 (Comments of the European Community)

<sup>14</sup> European Community and its Member States (14), Japan, Brazil, Thailand

<sup>15</sup> Guidelines for Strengthening National Food Control Systems, FAO Food and Nutrition Paper 76

<sup>16</sup> Australia, Argentina, Mexico, Costa Rica, Cuba, New Zealand, United States of America, Philippines, Chile

54. The Observer from the OIE welcomed the initiative to develop guidance on national food inspection systems and encouraged CCFICS to take into account the guidance provided in the OIE Terrestrial Animal Code. The OIE had recently developed a document on the role of veterinary services in food safety. This document had been provided to OIE Members for comments and was expected to be adopted in 2008.

55. With regard to the current Terms of Reference, the Committee recognised that they were sufficiently broad. In particular point (g) “to consider other matters assigned to it by the Commission in relation to food inspection and certification systems” allowed work on the development of guidance on national food control systems. One delegation stated that the addition of a specific term of reference relating to work on national food control systems might be appropriate.

56. With regard to the appropriateness of CCFICS to carry out this work, several delegations considered it necessary to better clarify the scope of the work before taking a decision, considering the horizontal nature of this work which might include aspects which could better fall under the responsibility of other committees.

57. In concluding the discussion, the Chairperson recognised that while there was general support for new work in this area there was not enough consensus to commence it at this moment. He said that the discussion paper needed to be revised: to clarify the scope of the work; to identify the gaps in existing CCFICS texts and how to link these texts together, thus providing a framework for national food control systems; and to justify why this work should be done by CCFICS.

58. The Committee agreed to establish an electronic Working Group, led by Australia, open to all Members and Observers and working in English only, to revise the discussion paper for consideration at its next session. The revised paper should take into account the above discussion, all written comments as well as existing guidance provided by FAO, WHO and other relevant international organizations such as OIE.

59. The delegations of Mexico and Argentina expressed their concern that work on this important matter could not start immediately.

#### **DISCUSSION PAPER ON THE DEVELOPMENT OF GUIDELINES FOR THE CONDUCT OF FOREIGN AUDIT TEAM INSPECTIONS (Agenda Item 6)<sup>17</sup>**

60. The Delegation of Australia introduced CX/FICS 07/16/6 on the scope, justification and rationale for new work on the development of principles and guidelines for the conduct of foreign on-site audits and inspections. The proposed work aimed at developing guidance for the conduct of foreign on-site audits and inspections, thus providing a transparent and consistent framework in which exporting country food inspection and certification are assessed. The work was justified by the increasing use of foreign on-site audits and inspections and assessments of compliance with equivalence determinations or agreements of those systems.

61. The Committee unanimously expressed support for this new work.

62. The Committee considered the project document for new work (CX/FICS 07/16/6 Attachment 2) in detail. It made some amendments to make the project document more consistent with the format set out in the Procedural Manual and to provide sufficiently detailed relevant information, as requested by the 30<sup>th</sup> Session of the Codex Alimentarius Commission (see para. 5).

63. During the round of comments on the proposed outline of the document (CX/FICS 07/16/6 Attachment 1) delegations noted that: “system-based approach” should be explained; consideration should be given to develop definitions for terms used in foreign on-site visits and inspections (e.g. on-site visit, on-site verification, access); the use of terms “inspection”, “audits” and “assessments” should be clarified; the responsibility for costs should be clarified attention should be given to find mechanisms to minimise the numbers of visits; pre-audit activities and provisions for the use of on-site audits and inspections’ reports should be addressed; consideration should be given to avoid countries being subject to consecutive multiple and identical audits and inspections. One delegation mentioned that “audit” should be a primary focus of the guidelines and that there was need to clarify the relationship with existing texts (e.g. Annex to CAC/GL 26-1997)

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<sup>17</sup> CX/FICS 07/16/6; CRD 6 (Comments of Indonesia, Kenya, Republic of Korea, Peru, the Philippines and Solomon Islands); CRD 11 (Comments of Japan); CRD 13 (Comments of the European Community)

64. The Committee agreed to forward the project document as amended (see Appendix III) to the 61<sup>st</sup> Session of the Executive Committee for critical review and to the 31<sup>st</sup> Session of the Commission for approval as new work.

65. It further agreed to establish a physical Working Group<sup>18</sup>, led by Australia, open to all Members and Observers and working in English, French and Spanish, which would prepare a proposed draft principles and guidelines document for circulation at Step 3 and further consideration at Step 4 at its next session.

66. It was agreed that the physical Working Group would meet as early as possible to allow timely circulation of the proposed draft. It was also agreed that, in order to facilitate the initial work of the Working Group, Codex members and observers be invited to electronically submit elements for the proposed draft document to the Delegation of Australia.

67. The Committee noted that consideration of the proposed draft at Step 4 was subject to approval of the proposed new work by the Commission in July 2008.

#### **DISCUSSION PAPER ON THE NEED FOR FURTHER GUIDANCE ON TRACEABILITY/PRODUCT TRACING (Agenda Item 7)<sup>19</sup>**

68. The Delegation of Norway introduced CX/FICS 07/16/7 which provided an overview of the current situation regarding traceability/product tracing, including information on existing guidance to governments and food industry. The document highlighted the importance of using traceability/product tracing to assist in containing food safety problems and in improving the reliability of consumers' information. In Norway's experience, traceability/product tracing had proved to be very efficient in ensuring targeted, accurate and cost-efficient withdrawals of products when needed. The Delegation noted that a number of countries had incorporated traceability into their legislation with different levels of detail in their requirements with the potential to create barriers to trade. They were of the opinion that the development of guidelines to complement the Codex Principles for traceability/product tracing could assist countries in implementing this tool in an efficient and harmonised way. The Delegation further stated that the experience of countries that have developed traceability systems, especially the challenges faced and the solutions found, could be of great benefit in the elaboration of the guidelines.

69. The Committee recognised the importance of traceability/product tracing and most members supported the development of further guidance. However, many delegations felt that starting new work at present would be premature. They considered that countries and industry needed more experience with the implementation of the Codex Principles, adopted in 2006, to identify specific areas where additional guidance was needed and noted the ongoing work by the food industry to develop data systems.

70. Other delegations were of the opinion that guidance was necessary to promote the harmonised use of traceability/product tracing and avoid possible trade problems due to the proliferation of diverging systems. It was also noted that the scope of new work should be clearly defined and the document should explain in detail how exactly further guidance would assist in the implementation of traceability /product tracing.

71. The Observer from the OIE informed the Committee of the status of the OIE work on animal identification and traceability, as presented in CRD 10, and of the plan to hold in collaboration with Codex an international Conference on animal identification and traceability in 2009.

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<sup>18</sup> Argentina, Brazil, Canada, Chile, China, Costa Rica, European Community, France, Germany, India, Italy, Jamaica, Japan, Kenya, Malaysia, Mexico, Netherlands, New Zealand, Nigeria, Norway, South Africa, Switzerland, Sweden, Tanzania, Thailand, United States of America, Zambia and Zimbabwe expressed their willingness to take part in the Working Group

<sup>19</sup> CX/FICS 07/16/7; CRD 7 (Comments of India, Indonesia, Kenya, Republic of Korea, the Philippines and Solomon Islands); CRD 10 (Comments of OIE); CRD 13 (Comments of the European Community)

72. The Committee agreed to continue discussion on this matter at its next session and to establish an electronic Working Group<sup>20</sup>, led by the Delegation of Norway, open to all Members and Observers and working in English only, to prepare a revised discussion paper for consideration at its next session. The revised paper should consider the above discussion and written comments; it should clearly describe the present gaps in the implementation of traceability/products tracing, identify the key elements of the guidelines that would address these gaps and consider the technical and economical feasibility of countries to implement traceability/product tracing. It was agreed that the Working Group would start working as early as possible to allow an ample debate on this matter. The Delegation of Norway said that the active participation of members of the Working Group, contributing their experience, was necessary to successfully complete this task.

**CONSISTENCY OF THE DRAFT MODEL EXPORT CERTIFICATE FOR MILK AND MILK PRODUCTS WITH CAC/GL 38-2001 (Agenda Item 8)<sup>21</sup>**

73. The Australian Secretariat presented their review of the consistency of the proposed draft Model Certificate for Milk and Milk Products with the Codex *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* (CAC/GL 38-2001). They had found the text generally consistent with CAC/GL 38-2001 and recommended several amendments to further improve its alignment with the Guidelines.

74. The Committee generally concurred with the analysis of the Australian Secretariat. It agreed with all recommendations in CX/FICS 07/16/8 except those in paragraphs 11 and 13 because these were not appropriate. Consequently the recommendation in paragraph 15 was amended. The Committee agreed to forward the recommendations, as contained in Appendix IV to this report, to the 8<sup>th</sup> Session of CCMMP for its consideration.

75. It further agreed to refer the individual comments below along with the written comments submitted at its current and previous sessions<sup>22</sup> to CCMMP for its consideration.

Recommendation on Section “Definition” (CX/FICS 07/16/8, paragraph 8)

76. The Delegation of the European Community suggested to delete the entire section on definitions and to refer to CAC/GL 38-2001, which contained all definitions, including that for consignment.

Recommendation on Section “Use of Model Export Certificates for Milk and Milk Products” (CX/FICS 07/16/8, paragraphs 9-10)

77. The Delegation of New Zealand proposed that the container’s seal number should be recorded as a separate item on the model certificate and that the explanation in regard to the signature should read: “The official signature should appear at the end of the certificate. The official stamp should be applied at the end of the certificate, or at the end of each page in the case of multiple-page certificate”. The Delegation of India noted that it was not appropriate to include information on the container seal number since often certificates were issued before this information was available; they also suggested referring to “seal” only instead of “seal number” as some seals might not have numbers.

Recommendation on Section I “Details identifying milk and milk products” (CX/FICS 07/16/8, paragraphs 11-13)

78. With regard to the recommendation in paragraph 12, the Delegation of New Zealand proposed to amend the section to read “Identification is the identification of the lot(s) to which the certificate uniquely relates, to facilitate the traceability/product tracing of the lot(s)”. The Delegation of the European Community suggested referring to “lot number” or “date coding” to allow establishing a direct link between the consignment and the certificate.

<sup>20</sup> Australia, Austria, Brazil, Canada, Chile, China, European Community, France, Hungary, India, Indonesia, Italy, Japan, Kenya, Mexico, Netherlands, New Zealand, Norway, Philippines, South Africa, Switzerland, Sweden, Thailand, United States of America and ICGMA expressed their willingness to take part in the Working Group

<sup>21</sup> CX/FICS 07/16/8; CRD 8 (Comments of India, Indonesia, Kenya and OIE); CRD 13 (Comments of the European Community)

<sup>22</sup> CRD 9 (Comments of the European Community)

Recommendation on Section II “Provenance of milk and milk products” (CX/FICS 07/16/8, paragraph 14)

79. The Delegation of Kenya suggested including information on “country of origin” in addition to “country of dispatch”.

**OTHER BUSINESS AND FUTURE WORK (Agenda Item 9)**

**FUTURE WORK**

*Discussion Paper on the Development of a Generic Template for Health Certificates*<sup>23</sup>

80. The Delegation of the European Community presented CX/FICS 07/16/9 and said that the development of a generic template (model format) was a logical follow-up to the recently completed revision of the Codex *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* (CAC/GL 38-2001). The Delegation felt that Principle E of the guidelines should be made explicit by developing a harmonised template that could facilitate procedures in international trade and the task for those in charge of checking certificates. They said that similar work was either completed or ongoing in other international bodies such as OIE and IPPC.

81. Many delegations supported the proposal in principle in view of the advantages that a harmonised certificate would have such as: avoiding different interpretations; being easier to produce and read; reducing the number of certificates thereby facilitating trade. Additional comments were made as follows: the work should be consistent with the work done by IPPC and OIE; the template should be flexible enough to support future electronic certification while taking into account countries’ technical capacities and resources; the template should allow for multiple attestations; the experience of those Committees that have already developed certificates should be used (i.e. Codex Committees on Fish and Fishery Products and on Milk and Milk Products).

82. The Observer from the OIE informed the Committee that the OIE *ad hoc* Group on the Revision of the OIE Model Veterinary Certificates had developed four model veterinary certificates and would continue this work in 2008. The OIE certificate for products of animal origin was compatible with the model certificate under development in CCMMP. The Observer said that continued cooperation between Codex and OIE on the work of model certificates was necessary.

83. Some delegations recognised the burden caused by too many certificates, however they were of the opinion that before starting new work it was necessary to consider other initiatives in this area such as those of the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT). UN/CEFACT is responsible for the UNeDocs standards, the UN Layout Key for Trade Documentation, standards for data elements used in international trade and the single window approach.

84. The Committee considered in detail the project document for new work (CX/FICS 07/16/9 Annex 1). The Committee added references to the work of other international organizations and to the need to ensure consistency and avoid duplication with their work. References to a data processing interface were deleted. The Committee clarified that this work would focus on the data elements and their spatial layout in a paper certificate with explanatory notes providing information for each field. The Committee also made some amendments to make the project document more consistent with the format set out in the Procedural Manual and to provide sufficiently detailed relevant information in particular in the section on the assessment against the *Criteria for the Establishment of Work Priorities*, as requested the 30<sup>th</sup> Session of the Codex Alimentarius Commission (see para. 5).

85. The Committee agreed to forward the project document as amended (see Appendix V) to the 61<sup>st</sup> Session of the Executive Committee for critical review and to the 31<sup>st</sup> Session of the Commission for approval as new work.

86. It further agreed to establish a physical Working Group, lead by the European Community, open to all Members and Observers and working in English, French and Spanish, which would prepare a proposed draft Generic Model Health Certificate for circulation at Step 3 and further consideration at Step 4 at its next session.

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<sup>23</sup> CX/FICS 07/16/9; CRD 9 (Comments of Colombia, India, Indonesia, Kenya, the Philippines and Solomon Islands); CRD 10 (Comments from OIE)

87. It was agreed that the physical Working Group would meet around June/July 2008. It was also agreed that, in order to facilitate the initial work of the Working Group, Codex members and observers be invited to electronically submit elements for the proposed draft document to the Delegation of the European Community.

88. The Committee noted that consideration of the proposed draft at Step 4 was subject to approval of the proposed new work by the Commission in July 2008.

89. Noting that two physical Working Groups had been established, the Committee invited the leading delegations of the Working Groups to explore possibility for arranging their physical meetings back-to-back in a same venue to facilitate participation of members and observers.

## **OTHER BUSINESS**

### ***Intentional contamination of foods***

90. The Delegation of the United States of America explained that intentional food contamination was related to, but distinct from, traditional food safety and had a greater potential to result in market disruption and human death. Over the past years many food control authorities, industries and international organizations, such as WHO, had been engaged in the development of guidance to minimize the risk due to intentional contamination of food, e.g. intentional tampering, unsafe economic adulteration. They noted that although some Codex texts provided elements of guidance that could be applied when assessing intentional contamination, currently there was none providing substantial comprehensive guidance.

91. The Delegation stated that it would be helpful for Codex to consider developing such guidance, particularly with respect to systems assessing the vulnerability to and controlling intentional contamination. Therefore, they proposed to develop a discussion paper that would address: i) the nature of intentional contamination of food; ii) the nature and extent of guidance that has been developed by governments, industry and international organizations; iii) an analysis of existing Codex texts, especially those related to intentional contamination, to identify gaps; and iv) an assessment of specific work that CCFICS might develop in this area, including an analysis of why CCFICS would be the appropriate venue for such work.

92. Several delegations recognised that intentional contamination was an important subject for discussion and that countries should assess their vulnerability to it and their capacity to control it. Concern was expressed as to whether CCFICS was the appropriate venue to develop such guidance since the control of intentional contamination fell within multiple jurisdictions. In view of the general support for continuing the discussion on this subject, the Committee agreed to the proposal of the Delegation of the United States of America to develop the discussion paper, as described above, for consideration at its next session.

## **DATE AND PLACE OF NEXT SESSION (Agenda Item 10)**

93. Following the discussion under Agenda Item 2 (see para. 8) and relevant decisions concerning new work and discussion papers, the Committee decided to maintain annual meetings for the time being.

94. The Committee noted that its 17<sup>th</sup> Session was tentatively scheduled to be held from 24 to 28 November 2008, subject to further discussion between the Codex and Australian Secretariats.



## SUMMARY STATUS OF WORK

| Subject Matter   | Step         | Action by:   | Document Reference<br>(ALINORM 08/31/30) |
|--|--------------|--|--|
| Proposed draft Appendix to the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (N04-2004)  | 5/8          | Comments<br>31 <sup>th</sup> CAC   | Para. 44 and<br>Appendix II              |
| Proposed draft Guidelines for the Conduct of Foreign Audit Team Inspections  | 1/2/3/4      | Physical WG<br>61 <sup>st</sup> CCEXEC,<br>31 <sup>st</sup> CAC<br>Comments<br>17 <sup>th</sup> CCFICS | Paras 64-66 and<br>Appendix III          |
| Proposed draft Generic Template for Health Certificates  | 1/2/3/4      | Physical WG<br>61 <sup>st</sup> CCEXEC,<br>31 <sup>st</sup> CAC<br>Comments<br>17 <sup>th</sup> CCFICS | Paras 85-87 and<br>Appendix V            |
| Discussion Paper on the Need for Guidance for National Food Inspection Systems   | -            | Electronic WG<br>17 <sup>th</sup> CCFICS   | Paras 57-58                              |
| Discussion Paper on the Need for Guidance on traceability/product tracing  | -            | Electronic WG<br>17 <sup>th</sup> CCFICS   | Para. 72                                 |
| Discussion Paper on the consistency of the draft <i>Model Export Certificate for Milk and Milk Products</i> with the proposed draft Guidelines for Generic Official Certificate Formats and the Design, Production, Issuance and Use of Certificates   | -            | 8 <sup>th</sup> CCMMP  | Para. 74                                 |
| Discussion Paper on the revision of the Codex <i>Principles for Food Import and Export Inspection and Certification</i> (CAC/GL 20-1995) and the Codex <i>Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems</i> (CAC/GL 26-1997) | discontinued | -  | Para. 47                                 |

**Appendix I**

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LISTE DES PARTICIPANTS  
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**Appendix II****PROPOSED DRAFT APPENDIX TO THE GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION (N04-2004)****(At Steps 5/8 of the Elaboration Procedure)****ADDITIONAL GUIDANCE TO ASSIST EXPORTING AND IMPORTING COUNTRIES IN UNDERTAKING AN EQUIVALENCE DETERMINATION OF SANITARY MEASURES**

1. This Appendix relates to the equivalence determination of sanitary measures associated with a food inspection and certification system and clarifies certain aspects of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* (CAC/GL 53-2003 referred to below as “*the Guidelines*”).

**PRELIMINARY CONSIDERATIONS RELATING TO UNDERTAKING AN EQUIVALENCE DETERMINATION**

2. There is a broad spectrum of circumstances where an exporting country may wish to seek an equivalence determination with an importing country. While each circumstance will likely need to be considered on a case-by-case basis, it can vary from seeking equivalence for a set of sanitary measures making up a food control system associated with a certain type of food or group of foods (e.g. dairy products) to seeking equivalence for a sanitary measure (e.g. analytical method).

3. Factors that may facilitate the equivalence determination of sanitary measures could include the following:

- a) The experience, knowledge and confidence the importing country has with the exporting country's food control system (see paragraphs 9 to 14 below);
- b) The prior history in food trade between the importing and exporting countries;
- c) The level of compliance of the exporting country's food products with the importing country's requirements;
- d) The level of cooperation that exists between the food safety competent authorities of the importing and exporting countries;
- e) The extent to which importing and exporting countries' food control systems are similar (e.g., the similarity of food laws and regulations, the capabilities of professional staff and laboratories, the similarity of inspection and monitoring programs);
- f) Being well prepared to undertake an equivalence determination, including that the importing and exporting countries have access to the necessary resources such as the scientific and technical capabilities;
- g) Consideration of the relevance of any previous equivalence determinations made by the importing country.

**Preparatory steps to undertaking an equivalence determination**

4. Preparatory steps, that should be considered include:

- a) The exporting country considering the benefits and cost/resource implications of an equivalence determination in comparison to other arrangements that meet the same outcome;

- b) As appropriate, taking into account the considerations relating to setting priorities contained in Section 5 Paragraph 9, “Considerations before entering into bilateral or multilateral discussions”, of the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999)*;
- c) Whether the importing and exporting countries have access to the necessary scientific and technical resources to carry out an equivalence determination, recognizing that a proposal for equivalence will need to be well considered and documented;
- d) Where appropriate the importing and exporting country should at an early stage in the equivalence determination process develop a plan containing objectives, milestones, timelines and/or expected outcomes.

## **GUIDANCE ON UNDERTAKING AN EQUIVALENCE DETERMINATION**

### **Scoping the equivalence determination**

- 5. The exporting country should appropriately scope the request for an equivalence determination by identifying the sanitary measures and food commodity combination to be submitted for consideration.
- 6. The exporting country must decide on which of the importing country’s measures it will meet by compliance and for which measures it will seek equivalence.
- 7. In some situations it will be clear as to the specific measure or group of measures that are the subject of the equivalence determination.
- 8. In other situations the scope of the equivalence determination may not be clear and categorization of sanitary measures as referred to in paragraphs 13 and 14 of *the Guidelines* may assist in determining the scope of the equivalence determination. Specifically, categorisation may assist with organising sanitary measures, carrying out side-by-side comparisons of those measures where appropriate, and identifying which measures will be the subject of the equivalence determination.

### **Experience, knowledge and confidence**

- 9. The following section expands on information presented in paragraph 10-12 of *the Guidelines* and provides additional guidance relating to what constitutes experience, knowledge and confidence.
- 10. Experience, knowledge and confidence in an exporting country’s food inspection and certification system by an importing country includes the history of food trade between the two countries and the history of compliance of foods with the importing country’s requirements, particularly the food products involved in the equivalence determination. Other examples that may inform the importing country’s experience, knowledge and confidence could include:
  - a) General knowledge of the exporting country’s food control system which may be demonstrated by, among other things, a side by side comparison;
  - b) Results of audits/inspections/field examinations by the importing country, exporting country, other countries, or other officially recognized third party organizations;
  - c) Knowledge of the exporting country’s application and implementation of the risk analysis principles in their food control system;
  - d) Point of entry inspection and test results, including records of import rejections and alerts by the importing country as well as from other trading partners;
  - e) Agreements the importing country may already have with the exporting country, including equivalence agreements;
  - f) Bilateral or multilateral agreements on recognition of equivalence that either importing or exporting countries may have with other countries;
  - g) Impact on food control systems as a consequence of organisational/structural/administrative changes in the exporting countries competent authority/ies;

- h) Contingency plans for containing and mitigating the effects of food safety emergencies;
  - i) Food borne disease surveillance data associated with the food product;
  - j) The degree to which industry in the exporting country uses appropriate processing controls;
  - k) Adequacy of the exporting country's legislation and, as appropriate, quality control systems;
  - l) Level/form of oversight of the food production system by the exporting country's certifying authority;
  - m) Acknowledgement and evaluation of pre-existing certification systems conducted or carried out by the exporting country;
  - n) Any specific export control system in operation.
11. The importing country can apply such experience, knowledge and confidence at any point throughout the equivalence determination process.
12. Experience, knowledge and confidence may assist in facilitating familiarity with the information provided by the exporting country and therefore reduce the resources required to form a judgement of equivalence of the measures proposed.
13. Situations where experience, knowledge and confidence can assist include:
- a) In making a decision how to proceed with a request for a judgement of equivalence;
  - b) In setting priorities, as may be appropriate (reference should also be made to Section 5, "Considerations Before Entering into Bilateral or Multilateral Discussions", of the *Codex Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999)*);
  - c) In informing the process of comparing the exporting country's relevant sanitary measures with the importing country's sanitary measures;
  - d) In reducing the number of sanitary measures that are to be the subject of a detailed examination;
  - e) In reducing the extent of the scientific evidence required to determine equivalence.
14. In applying experience, knowledge and confidence to a determination of equivalence, transparency is essential so that the use and application of this information is clear to all parties.

### **Objective Basis of Comparison**

15. The following section expands on information presented in paragraphs 15 and 16 of the *Guidelines* and provides additional guidance relating to what constitutes the development of an objective basis of comparison.
16. An objective basis of comparison is a tool that may be quantitative and/or qualitative in nature. The information in footnote 11 of the *Guidelines* is particularly relevant in explaining this point and provides some useful examples.
17. Depending on the scope of the equivalence determination there may be more than one OBC.
18. When developing OBC(s) the importing country should gather and assess scientific data and other information<sup>1</sup> and enter into a dialogue with the exporting country to seek agreement on the OBC(s). The OBC development process should, as appropriate:
- a) Ensure sufficient data to provide valid support for conclusions;
  - b) Ensure the adequacy and accuracy of the data;
  - c) Utilize risk assessments, as available; and
  - d) Ensure sufficient knowledge and technical expertise of the subject matter experts.

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<sup>1</sup> In the context of this appendix data is taken to mean both quantitative and qualitative data and other information.

### **Information and Documentation Contained in Submissions for Evaluation of a Request for an Equivalence Determination**

19. The following section provides additional guidance on what information should be contained in a country's submission for an equivalence determination.
20. Information and documentation required by the importing country should be confined to essential information that is related to the defined objective for the determination of equivalence.
21. Requests for information from the importing country should be presented in a coordinated manner.
22. Paragraphs 16-20 of Section 7 "Consultative process for equivalence agreements" of the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999) provide guidance and the type of information that may need to be included in a submissions package.
23. Before forwarding a submission package to the importing country, an exporting country should initiate an official request for the determination of equivalence, including identifying the food products or group of food products concerned, and have made appropriate contact with its counterpart in the importing country.
24. The submission package should specify the measure(s) for which equivalence is sought.
25. It may often be the case that a submission package is done in steps. For example the exporting country provides the measures for which an equivalence determination is sought. The importing country then provides the OBC if required.
26. Depending upon the nature of the OBC ( see the section on Objective Basis of Comparison in this appendix), exporting countries should provide the following information and data:
  - a) For a qualitative OBC, references to pertinent scientific information should be provided. The submission package should also contain a written analysis by the exporting country's subject matter experts explaining how they arrived at their conclusion that the exporting country's measures are equivalent to the importing country's measures.
  - b) For a quantitative OBC, the submission package should include: the data used to assess the equivalence of the measure; the methodology used to obtain the data; the methodology used to assess the data including, as appropriate, the risk assessment models employed, and the assumptions made and the nature and extent of uncertainty of the findings. The submission package should also contain a written analysis that clearly shows how the exporting country arrived at the conclusion that its measure(s) are equivalent to the importing country's measure(s).

### **Details on Judgement of Equivalence**

27. The following expands on Sections 7 and 8 of the *Guidelines*.
28. In the process of judging equivalence the importing country should focus on those measures or groups of measures which the exporting country and importing country have mutually agreed will be the subject of the equivalence determination.
29. Ongoing communication between the importing and exporting countries may assist with the judgement of equivalence process to, among other things, clarify technical points and respond to the need for additional information.
30. Importing countries may undertake to judge equivalence based only on a review of the data and information. Subject matter experts in the importing country may also be utilised especially in reviewing the conclusions of the exporting country.
31. Throughout the process of judgement and at the earliest opportunity the importing country should consult the exporting country if preliminary assessment indicates that the application is likely to be unsuccessful.

32. A favourable decision regarding the judgement of equivalence based on the assessment of available information taking into account experience, knowledge and confidence can be made at any point in the process including:

- a) At initial contact by the exporting country;
- b) Following review of the submission package by the importing country, including the opinions of subject experts where necessary;
- c) Following an assessment based on an objective basis of comparison.
- d) Following an assessment of the information gathered during onsite visits by the importing country;
- e) Following the resolution of outstanding issues.

33. Within a reasonable period of time the importing country should provide to the exporting country a written report as to whether or not equivalence has been found. Where equivalence is not found, the reasoning for this should be given to the exporting country and should be included in the written report with suggestions for solutions where possible.

#### **Use of On-site visits**

34. To complement the documentary review by the importing country, the use of on-site visits may be beneficial in clarifying information provided by the exporting country. The rationale for on-site visits related to the determination of equivalence may include:

- a) To help clarify information provided by the exporting country relevant to its sanitary measures subject to the equivalence determination;
- b) To gather additional information on the exporting country's proposed measures that may be required by the importing country to undertake a judgement of equivalence;
- c) To improve knowledge and confidence in the exporting country's food control system.

35. In preparing for an on-site visit, both the importing and exporting country should consider:

- a) The development of a protocol for the on-site visit.
- b) Limiting the scope of on-site visits to the food product or group of food products and the associated sanitary measures that are the subject of the equivalence determination

#### **Provision of Technical Assistance**

36. The following expands on paragraph 7 (n) of *the Guidelines* the principle relating to technical assistance, and provides additional guidance relating to the provision of technical assistance. It is possible that technical assistance may be needed by importing and exporting countries in carrying out equivalence determinations.

37. Countries considering the need for technical assistance with respect to equivalence determinations or countries considering providing technical assistance, may wish to consider the following:

- a) Assistance in evaluating which measures would be the subject of an equivalence determination;
- b) Assistance with the preparation of documentation, including the submittal package;
- c) Assistance in undertaking necessary risk assessments;
- d) Assistance with data analysis;
- e) Assistance in assessing whether measures meet the importing country's stated objective basis of comparison;
- f) Exchange of technical expertise between the importing and exporting countries; and
- g) Assistance in providing appropriate training programs.

**Appendix III****PROJECT DOCUMENT****Proposal for New Work – Codex Committee on Food Import and Export Inspection and Certification Systems****PROPOSAL TO DEVELOP PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF FOREIGN ON-SITE AUDITS AND INSPECTIONS****1. The purposes and scope of the proposed standard**

The purpose of the proposed standard would be to identify existing texts on the conduct of foreign on-site audits and inspections and to develop principles and guidelines for these activities.

**2. Its relevance and timeliness**

Foreign on-site audits and inspections are increasingly being used by importing countries to assess inspection and certification systems in exporting countries and reports of these evaluations are sometimes used by third countries to inform their own assessment of exporting country systems.

The concept of foreign on-site audits and inspections to evaluate whether activities and related results comply with the objectives or associated technical or sanitary measures is mentioned in many adopted Codex texts, however internationally no guidance exists for the conduct of these types of on-site evaluations to ensure consistency of approach and transparency in application.

**3. The main aspects to be covered**

The development of principles and guidelines for the conduct of foreign on-site audits and inspections with reference to existing Codex texts and other international standards. The document will provide a consistent framework for the conduct of foreign on-site audits and inspections.

**4. An assessment against the *Criteria for the Establishment of Work Priorities***

The proposal is consistent with the criteria as follows:

***General Criterion***

Consumer protection from the point of view of health, food safety, ensuring fair practice in food trade and taking into account the identified needs of developing countries: Given the importance and prominence of these importing country assessments in order to ensure consistency of approach, Codex development of principles and guidelines will contribute to the protection of consumers' health and the promotion of fair practices in the food trade.

***Criteria applicable to general subjects***

(a) Diversification of national legislations and apparent resultant or potential impediments to international trade: Several countries or groups of countries have developed their own legislative frameworks regarding foreign on-site audits and inspections. The envisaged guidelines would provide essential guidance on the consistent conduct of foreign on-site audits and inspections to the benefit of both exporting and importing countries and international trade. The potential for diverse conduct of such evaluations may impede international trade.

(b) Scope of work and establishment of priorities between the various sections of the work: The proposed Guidelines the Committee will identify the rationale (or objective) for conducting foreign on-site audits and inspections of food inspection and certification systems and the process and procedures to be agreed between the importing and exporting country before, during and after the evaluation has been conducted.

(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies): In developing these guidelines CCFICS will take into consideration other international standards.

## 5. Relevance to Codex Strategic Objectives

The proposal is consistent with:

**Goal 1: Promoting Sound Regulatory Frameworks** (Activity 1.4: Review and development Codex standards and related texts for food inspection and certification, and methods of sampling and analysis) which states:

- In strengthening the strategic focus of Codex in the development of risk-based, performance-based standards and related texts for broad application across a range of commodities, the CAC must give priority to establishing a coherent and integrated set of food standards covering the entire food chain. Such an approach can serve as a model for the members of CAC to pursue food regulatory systems that provide consumers with safe food and ensure fair practices in the food trade.

This work also supports the premise in the Strategic Plan that successful negotiation of bilateral mutual recognition and equivalence of food control systems depends on the abilities of countries to assure each other of the integrity and international conformity of their regulatory systems.

The work will benefit countries by providing them with the necessary tools and information to ensure that the assessment of their systems is consistent and transparent.

## 6. Information on the relation between the proposal and other existing Codex documents

CCFICS has already included provisions for the conduct of foreign on-site audits and inspections in several of its documents. To complement this work and assist in implementation of existing guidance there is a need to develop a document that will provide a framework for the conduct of these activities which in turn will improve their transparency.

The concept of evaluating inspection and certification systems to determine whether activities and related results comply with the objectives or associated technical or sanitary measures is mentioned in many adopted Codex texts for example, *Guidelines for Food Import Control Systems* (CAC/GL 47-2003), *Guidelines for the Design, Operation, Assessment and Accreditation of Food Inspection and Certification Systems* (CAC/GL 26-1997), *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999), *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003) and the *Principles and Guidelines for Imported Food Based on Risk* (adopted in 2006).

## 7. Identification of any requirement for and availability of expert scientific advice

None required

## 8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

None required

## 9. The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years

Subject to Commission approval at its 31<sup>st</sup> session in 2008, it is expected that this work can be completed in four years with:

- Consideration at Step 3 by CCFICS 17;
- Consideration at Step 5 by CCFICS 18; and
- Adoption of the proposed Guidelines by the Commission within 4 years.



**Appendix IV****RECOMMENDATIONS OF 16<sup>TH</sup> CCFICS TO THE 8<sup>TH</sup> CCMP****PROPOSED AMENDMENTS TO *PROPOSED DRAFT MODEL EXPORT CERTIFICATE FOR MILK AND MILK PRODUCTS*****Section GENERAL REMARKS CONCERNING THE PRODUCTION AND ISSUANCE OF CERTIFICATES**

To better align paragraph 12 with paragraph 22 of the *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* add the following at the end of the existing paragraph 12:

Certificates should be in a language or languages fully understood by the certifying officer in the exporting country, in transit countries where appropriate, by the receiving authority in the importing country or those countries in which the inspection of food takes place. Where required the certificate can be accompanied by official translations.

**References to *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates***

Amend all references to the title of the Guidelines (*Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates* (CAC/GL 38-2001)) to reflect the new title of the Guidelines (*Guidelines for Design, Production, Issuance and Use of Generic Official Certificates*).

**Section DEFINITION**

For consistency between the two texts the definitions section should be aligned with Section 3 – Definitions of the *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates*, in particular the definitions of Certifying bodies, Certifying officers and Official certificates, and inclusion of a definition for Consignment.

**Section USE OF MODEL EXPORT CERTIFICATES FOR MILK AND MILK PRODUCTS**

In paragraph 14, modify the current text as follows:

**Page numbering** should be used where the certificate occupies more than one sheet of paper. Add a new sentence which reads “For multiple page certificates the certifying officer should ensure that it is clear that the pages constitute a single certificate including official translation(s) when appropriate (e.g., each page is numbered with the same unique certificate number so as to indicate it is a particular page in a finite sequence).”

Add wording (underlined) to the paragraph which aims to minimise the use of fraudulent certificates.

**Seal number(s), official stamp (official identifier of the competent authority) and signature** should be applied in a manner that minimises the risk of fraud.

**Section I. DETAILS IDENTIFYING MILK AND MILK PRODUCTS**

Replace the paragraph **Lot identification/Date code** with the following paragraph:

**Identification** A description of the commodity and consignment to which the certificate uniquely relates, e.g., lot identifier or date coding, facilitating the traceability/product tracing of the product in the event of public health investigations and/or recalls.

**Section II. PROVENANCE OF MILK AND MILK PRODUCTS**

Modify as follows:

**Country of Dispatch** For the purposes of the Model Export Certificate for Milk and Milk Products, the country of dispatch designates the name of the country of the competent authority which has the competence to verify and certify the conformity to the attestations. A part of the country may be mentioned where this relates to specific attestations.

**MODEL EXPORT CERTIFICATE FOR MILK AND MILK PRODUCTS**

For consistency with the main document replace “Lot(s)” with “Identification”.

**Appendix V****PROJECT DOCUMENT****Proposal for New Work – Codex Committee on Food Import and Export Inspection and Certification Systems****PROPOSAL TO DEVELOP A GENERIC MODEL HEALTH CERTIFICATE****1. The purposes and scope of the proposed standard**

The objective of the project is to develop an Annex to the *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* which would contain a generic model health certificate that may be applicable to all types of commodities.

**2. Relevance and timelines**

The Codex Alimentarius Commission adopted during its 30<sup>th</sup> Session a revised version of the *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* (CAC/GL 38-2001). This revision was initiated with the objective of clarifying the use of export certificates and simplifying their use by eliminating those attestations which were identified as redundant, unnecessarily burdensome or discriminatory. The logical complement to these Guidelines would be a generic model health certificate applicable to all food commodities. There is significant parallel work going on under the United Nations system (e.g. United Nations Centre for Trade Facilitation and Electronic Business – UN/CEFACT) and there is a need for this work to be appropriately incorporated and referenced to avoid duplication and to ensure consistency.

The harmonization of a generic model health certificate at an international level would allow a reinforced cooperation and a better understanding between competent health authorities. It would make the reading of certificates easier, would standardize the interpretation of administrative information regarding the certificates.

**3. The main aspects to be covered**

The proposed generic model health certificate will focus on the data elements and their spatial layout in a paper certificate. Explanatory notes will be provided to clarify details on information for each field should the importing country consider it necessary.

**4. An assessment against the *Criteria for the Establishment of Work Priorities***

The proposal is consistent with the criteria as follows:

***General criterion***

Consumer protection from the point of view of health, food safety, ensuring fair practice in food trade and taking into account the identified needs of developing countries: This work could improve protection against fraudulent practices and enhance consumer protection by harmonising the models used for health certificates thereby facilitating the clearance process.

***Criteria applicable to general subjects***

(a) Diversification of national legislations and apparent resultant or potential impediments to international trade: This work addresses the fact that a considerable number of models for health certificates have been developed by countries or groups of countries leading to impediment to international trade.

(b) Scope of work and establishment of priorities between the various sections of the work: This work will complement the revised Codex *Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates*, adopted by the 30<sup>th</sup> Session of the Codex Alimentarius Commission.

(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies): There is significant parallel work ongoing under the United Nations system (e.g. UN/CEFACT) and there is a need for this work to be appropriately incorporated and referenced to avoid duplication and to ensure consistency. This work will be developed in close cooperation with the relevant United Nations bodies, World Customs Organization and the World Organisation for Animal Health (OIE) to avoid contradictions, gaps and duplications.

#### **5. Relevance to Codex strategic objectives**

This proposal is consistent with:

Goal 1: Promoting Sound Regulatory Frameworks (Activity 1.4: Review and development Codex standards and related texts for food inspection and certification, and methods of sampling and analysis). This work is consistent with the strategy of the Codex Alimentarius Commission regarding the periodic review and harmonisation of standards, taking into account the horizontal nature of the provisions foreseen, which would provide consistency across a wide range of products.

In addition this work is in line with Goal 4: Promoting cooperation between Codex and other relevant international organisations.

#### **6. Information on the relation between the proposal and other existing Codex documents**

This new work is proposed to be an Annex to the "*Guidelines for Design, Production, Issuance and Use of Generic Official Certificates*"(CAC/GL 38-2001) .

The Codex Committee on Fish and Fishery Products has developed a "*Model Certificate for Fish and Fishery Products*" (CAC/GL 48-2004) and the Codex Committee on Milk and Milk Products is currently developing a "*Model Export Certificate for Milk and Milk Products*", currently at Step 5 of the Codex Procedure. These model certificates currently only cover fishery and milk products and have not a harmonised approach and presentation.

#### **7. Identification of any requirement for and availability of expert scientific advice**

None required

#### **8. Identification of any need for technical input to the standard from external bodies**

Relevant United Nations bodies (e.g. UN/CEFACT), World Customs Organization and the World Organisation for Animal Health (OIE)

#### **9. The proposed time-line for completion the new work**

- Consideration of the draft proposal at Step 3 by CCFICS17.
- Consideration of the proposal at Step 5 by CCFICS18.
- Adoption of the standard by the CAC at Step 8: July 2010 (on the condition that the interval between CCFICS sessions is not modified).