



**Food and Agriculture  
Organization of  
the United Nations**



**World Health  
Organization**

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**ALINORM 10/33/30**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX ALIMENTARIUS COMMISSION**

*Thirty third Session  
Geneva, Switzerland, 5-9 July 2010*

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

*Surfers Paradise, Australia  
1-5 March 2010*

NOTE: This report contains Codex Circular Letter CL 2010/5-FICS



CL 2010/5-FICS  
March 2010

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

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

**Subject:** **Distribution of the Report of the Eighteenth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (ALINORM 10/33/30)**

The report of the Eighteenth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems will be considered by the 33<sup>rd</sup> Session of the Codex Alimentarius Commission (Geneva, Switzerland, 5-9 July 2010).

## **MATTERS FOR ADOPTION BY THE 33<sup>RD</sup> SESSION OF THE CODEX ALIMENTARIUS COMMISSION**

**Proposed draft Principles and guidelines for the conduct of assessment of foreign official inspection and certification systems** (Annex to the *Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems* (CAC/GL 26-1997)) (N07-2008) advanced to Steps 5/8 of the Codex Procedure, with the omission of Steps 6 and 7 (ALINORM 10/33/30, Appendix II). See also para. 39 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 Secretariat, 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 30 April 2010.**

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## SUMMARY AND CONCLUSIONS

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

### **Matters for the 33<sup>rd</sup> Session of the Codex Alimentarius Commission**

#### **Matters for adoption / approval**

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

The Committee agreed to forward to the Commission for adoption at Step 5/8 the renamed Principles and guidelines for the conduct of assessment of foreign official inspection and certification systems (Annex to the *Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems* (CAC/GL 26-1997) (N07-2008) (*see* para. 39 and Appendix II).

#### **Matters of interest**

The Committee agreed to return the proposed draft principles and guidelines for the national food control systems (N06-2009) to Step 2 (*see* para. 68).

### **Matters referred to other Committees / Task Forces**

#### **Committee on General Principles (CCGP)**

The Committee agreed to contribute some points to the upcoming discussion in CCGP on the merit of developing a general definition for the term “competent authority” (*see* para. 6).

**LIST OF ABBREVIATIONS USED IN THIS REPORT**

ALOP	Appropriate Level of Protection
APEC	Asia-Pacific Economic Cooperation
CAC/GL	Codex Alimentarius Commission / Guidelines
CCFICS	Codex Committee on Food Import and Export Inspection and Certification Systems
CCGP	Codex Committee on General Principles
CCMMP	Codex Committee on Milk and Milk Products
CL	Circular Letter
CRD	Conference Room Document
FAO	Food and Agriculture Organization of the United Nations
OIE	World Organisation for Animal Health
WHO	World Health Organization

## INTRODUCTION

1. The Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) held its 18<sup>th</sup> Session in Surfers Paradise, Australia, from 1 to 5 March 2010, 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 160 delegates from 66 Member countries and 1 Member organization, 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<sup>1</sup>

2. The Committee noted the division of competence between the European Union 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>2</sup>

3. The Committee adopted the Provisional Agenda as its Agenda for the Session.

### MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION, OTHER CODEX COMMITTEES AND TASK FORCES AND OTHER INTERNATIONAL ORGANIZATIONS (Agenda Item 2)<sup>3</sup>

4. The Committee noted relevant decisions of the 32<sup>nd</sup> Session of the Codex Alimentarius Commission, of the 62<sup>nd</sup> and 63<sup>rd</sup> Sessions of the Executive Committee and of other Committees, as presented in document CX/FICS 10/18/2.

5. In addition, the Committee was informed that the 9<sup>th</sup> Session of the Committee on Milk and Milk Products (CCMMP) had reviewed the *Model export certificate for milk and milk products* (CAC/GL 67-2008) to make it consistent with the *Generic model official certificate* (Annex to the *Guidelines for design, production, issuance and use of generic official certificates* (CAC/GL 38-2001)). The Committee further noted that CCMMP had recommended that CCFICS take into account the specificities of the *Model export certificate for milk and milk products* in any future revision of the *Generic model official certificate* and that, when such revision would be completed and the specificities for milk and milk products would be adequately addressed, consideration could be given to the revocation of the CAC/GL 67-2008.<sup>4</sup>

### Use of the term “competent authority”

6. The Committee noted the discussion at the 62<sup>nd</sup> Session of the Executive Committee concerning the inconsistent use of the term “competent authority” and the decision of the 32<sup>nd</sup> Session of the Commission to request the Committee on General Principles (CCGP) to look into the merit of developing a general definition for “competent authority” for inclusion in the Procedural Manual<sup>5</sup>. The Committee agreed to contribute the following points to the discussion in CCGP:

- The term “competent authority” is highly relevant to the work of CCFICS as is extensively used in 8 of the 9 texts developed by CCFICS;
- The Committee has considered defining the term at previous sessions but has concluded that the term was self-explanatory<sup>6</sup>;
- The term is defined through its use in CCFICS texts and, therefore, a general definition would impact on each of these texts; and
- The term is used by many governments and a general definition should not exclude any of these uses.

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<sup>1</sup> CRD 1 (Annotated Agenda – Division of competence between the European Union and its Member States);

<sup>2</sup> CX/FICS 10/18/1

<sup>3</sup> CX/FICS 10/18/2

<sup>4</sup> ALINORM 10/33/11 para. 94

<sup>5</sup> ALINORM 10/32/REP, para. 105

<sup>6</sup> ALINORM 01/30A, para. 14

**REPORT ON ACTIVITIES OF FAO AND WHO RELEVANT TO THE WORK OF CCFICS (Agenda Item 3a)<sup>7</sup>**

7. The Representative of FAO informed the Committee of recent activities of FAO and WHO to strengthen member countries' import/export and domestic food inspection systems. Two volumes of the "risk based food inspection" manual series, the "*Risk based food inspection manual*" and the "*Guidelines for risk based fish inspection*" had recently been published in English, French and Spanish. New work related to guidance on imported food controls had been initiated. This work was complemented by the development of tools and guidance on sampling issues and food safety emergencies response. An international meeting on food safety emergencies would be organised in September 2010. The Representative further reported on specific projects in Asia and Africa having a strong inspection planning and implementation component. These projects had as a major focus to improve targeting of food inspection activities using the risk analysis framework with an emphasis on risk profiling and risk ranking. The projects would also be closely associated with the above mentioned new work on the development of guidance on imported food controls.

8. The delegation of Japan provided additional details regarding the scheduling of activities of the project in ASEAN countries funded by Japan.

**REPORT ON ACTIVITIES OF OTHER INTERNATIONAL ORGANIZATIONS RELEVANT TO THE WORK OF CCFICS (Agenda Item 3b)<sup>8</sup>**

9. The Observer from the World Organisation for Animal Health (OIE) informed the Committee of OIE work relevant to CCFICS, in particular of the activities of the OIE Working Group on Animal Production Food Safety, which was established by OIE in 2002 to manage the risks arising at the farm level and to improve coordination of the standard setting activities of OIE and Codex. The Committee noted that OIE would continue to address food safety-related issues as a high priority in its standard-setting work and to work closely with the Codex Alimentarius Commission and its subsidiary bodies and with other international bodies in promoting safe international trade in animal products. The Observer further informed the Committee that the OIE Code for Terrestrial Animals and the Code for Aquatic Animals contained standards for veterinary services and for the management of food safety hazards at the production level. The Committee noted that OIE Members had strongly supported the evaluation of the quality of veterinary services using the OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool) and that more than 100 countries had completed the evaluation.

**PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF FOREIGN ON-SITE AUDITS AND INSPECTIONS (N07-2008) (Agenda Item 4)<sup>9</sup>**

10. The delegation of Australia briefly introduced the report of the physical working group, which met in Miami in July 2009, at the kind invitation of the United States of America. The Delegation said that the proposed draft principles and guidelines aimed at replacing the existing annex to the *Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems* (CAC/GL 26-1997), providing guidance to all tools used by importing countries to assess an exporting country's official inspection and certification system.

11. Many delegations congratulated the working group on the quality of the proposed draft text in which most concerns had been resolved. They expressed the hope that this important text could be further improved editorially at the present session and progressed to steps 5/8.

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<sup>7</sup> FICS 18/INF/1; CRD 4 (Comments of Solomon Islands)

<sup>8</sup> FICS 18/INF/2

<sup>9</sup> CX/FICS 10/18/3; CX/FICS 10/18/3 Add. 1 (Comments of Brazil, Canada, Costa Rica, European Union, France, Indonesia, Mexico, New Zealand, Panama, Philippines, South Africa, United States of America and OIE); CX/FICS 10/18/4 Add. 2 (Comments of Japan, Norway and Panama); CRD 2 (Comments of Colombia, Ghana, India, Jamaica, Kenya, Mali, Norway, Solomon Islands, Uruguay and Thailand)

### **Specific comments**<sup>10</sup>

12. The Committee reviewed the proposed draft text paragraph by paragraph and, additionally to editorial changes to improve clarity, including corrections to the French and Spanish versions of the text, agreed to the following amendments:

#### **Section 1 – Introduction**

##### *Paragraph 1*

13. The Committee agreed to delete the words “In the context of a relationship between two countries” at the beginning of the paragraph as the context of the guidance was already given in the parent document CAC/GL 26-1997. The Committee also agreed to delete the words “or verify” as verification was one of the tools that can be used in an assessment. The Committee further agreed to clarify in the last sentence of the paragraph that the annex was not meant to mandate use of assessments but to provide guidance when they were used.

##### *Paragraph 2*

14. The Committee clarified that assessment should concentrate on systems rather than on specific commodities or establishments and that when determining the appropriate assessment tool should include whether on-site visits were required.

##### *Paragraph 3*

15. The Committee clarified that relevant sections of the OIE PVS Tool should be considered where appropriate.

#### **Section 3 – Principles**

##### *Paragraph 5*

16. The Committee highlighted the overarching principle that an importing country’s competent authority may conduct an assessment of foreign official inspection and certification systems only with the agreement of the exporting country. The Committee deleted the reference to audits and inspection as they were part of assessment.

##### Principle C

17. The Committee amended Principle C to clarify that the tool to be used for the conduct of the assessment should be agreed by the importing and exporting countries prior to the commencement of the assessment. While recognising that “audit” was the preferred approach for the conduct of an assessment, the Committee agreed to delete the term in the second sentence noting that paragraphs 16-19 provided adequate guidance on the identification of the tool.

##### Principle E

18. The Committee clarified that the competent authority of the exporting country should not only be notified by the competent authority of the importing country but also agree to the plan for the assessment of the official inspection and certification system. The Committee agreed to refer to a “reasonable period of time prior to the commencement of the assessment” rather than “well in advance of undertaking the assessment” to indicate more precisely the timeframe by which the plan should be notified and agreed by the exporting country’s competent authority and for consistency with the language used in other CCFICS texts.

#### **Section 4 - Conduct of Assessment**

##### *Paragraph 6*

19. The Committee included the term “competent authority” for consistency.

##### *Paragraph 7*

20. The Committee highlighted the need to avoid duplication of effort on the part of the exporting country through coordination of assessments by multiple competent authorities of an importing country.

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<sup>10</sup> Paragraph numbers listed below are related to document CX/FICS 10/18/3 (and not to the finalised document as presented in Appendix II to this report)



*Paragraph 8*

21. The Committee emphasised the need for the competent authority or authorities of the exporting country to cooperate, coordinate and assist in the implementation of the assessment in order to achieve the assessment's results.

*Paragraph 10*

22. The Committee clarified that it was the responsibility of the competent authority to ensure that their auditors, inspectors or auditing organizations were impartial.

*Paragraph 11*

23. The Committee agreed to replace "commercial confidential information" and "intellectual property rights" with "confidential information" and clarified that the competent authority should ensure that confidential information is protected and that, when countries have specific legislation on confidentiality in place, they should agree how the laws will be adhered to.

*Paragraph 13*

24. The Committee deleted reference to costs of translators as the responsibility for these costs should be agreed by both parties and noted that paragraph 35 provided for agreement of the parties regarding translations and availability of interpretations and resources.

*Paragraph 20*

25. The Committee clarified that the audit tool was often described as "systems based audit".

*Paragraph 24*

26. The Committee revised and simplified the entire paragraph by specifying that the inspection tool may be used in some instances to confirm the effectiveness of the controls by the competent authority(ies) of the exporting countries. The Committee recognised that paragraph 25 provided examples of the use of the inspection tool.

*Paragraph 29*

27. Some delegations were of the view that paragraph 29 should include guidance on frequency of assessments to be decided by the importing country in agreement with the exporting country.

**Section 5 - Assessment Process***Paragraph 30*

28. The Committee agreed to move paragraph 39 before paragraph 30 as its content was a general statement applicable to all types of assessments and not specific to a particular tool.

29. The Committee specified the timeframe for exchanging the information related to notification and amended: bullet (a) by replacing "adequacy" with "capability to meet requirements" and bullet (c) by deleting the last part of the sentence, which was redundant.

*Paragraph 31*

30. The Committee agreed to add a new paragraph 31bis to ensure that the importing country responds in a timely manner to requests for assessment from an exporting country providing a commitment to conduct the assessment.

*Paragraph 32*

31. The Committee added the term "assessment tool" and replaced "well in advance" with "within a reasonable period of time" for consistency with Principle E. In addition, the Committee: in bullet (e) replaced the term "specialists" with "with technical experts and translators" as more appropriate; added a new bullet (e)bis referring to the language to be used during the assessment; revised bullet (f) to refer to "offices, laboratories or other facilities" as examples of locations to be visited and to ensure that the plan assigns the responsibility for the notification; clarified in bullet (h) that travel schedules and other logistics only apply in the case of an assessment visit; and amended bullet (i) for consistency with the amendment to paragraph 11.

*Paragraphs 33/34*

32. The Committee replaced party(ies) with competent authority(ies) to clearly recognise the governments' responsibility in preparing the assessment plan.

*Paragraph 36*

33. The Committee deleted in bullet (c) the terms "auditee" and "auditor" in order not to introduce any new terms and specified that bullet (d) only applied in case of on-site visits.

*Paragraphs 40/41/42*

34. The Committee noted that bullets (a) of paragraphs 41 and 42 clarified who is responsible for designation of the place where entry/exit meetings will take place.

35. The Committee specified that the paragraphs only related to assessments involving on-site visits. The Committee revised bullet (b) of paragraph 42 to clarify that the assessment team should: summarise main findings and preliminary conclusions; identify any non-conformities; and outline the objective evidence to support conclusions. It added "including a follow-up assessment if required" for clarity.

36. The Committee agreed to move paragraph 47 after paragraph 43 as this was a more logical flow.

*Paragraph 46*

37. The Committee replaced "commercial confidentiality" with "confidential information" for consistency with previous decisions.

*Paragraph 48*

38. The Committee amended the paragraph to emphasize that the publication of the report was not mandatory.

**Status of the proposed draft Principles and guidelines for the conduct of foreign on-site audits and inspections (N07-2008)**

39. The Committee agreed to forward the renamed proposed draft Principles and guidelines for the conduct of assessment of foreign official inspections and certification systems (Annex to *Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems* (CAC/GL 26-1997)) to the 33<sup>rd</sup> Session of the Commission for adoption at Steps 5/8, with the recommendation to omit Steps 6 and 7 (*see* Appendix II). The Committee recommended to the Commission that the proposed draft Guidelines and Principles replace the current Annex "Guidelines on procedures for conducting an assessment and verification by an importing country of inspection and certification systems of an exporting country" of CAC/GL 26-1997.

**PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR NATIONAL FOOD CONTROL SYSTEMS (N06-2009) (Agenda Item 5)<sup>11</sup>**

40. The delegation of Australia introduced the report of the physical working group, which met in Miami in July 2009 at the kind invitation of the United States of America. The delegation stated that the working group had acknowledged the importance of the document to both developed and developing countries. The delegation further said that it was important that the principles and guidelines be developed as a stand-alone document that countries could use to develop and enhance their national food control systems.

**General comments**

41. The Committee congratulated the working group on the initial draft and recognised the importance for CCFICS to develop this document, which was needed both by developed and developing countries.

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<sup>11</sup> CX/FICS 10/18/5; CX/FICS 10/18/5 Add. 1 (Comments of Brazil, Bolivia, Canada, Costa Rica, Mexico, New Zealand, Panama, Philippines, South Africa, United States of America, FAO and OIE); CX/FICS 10/18/5 Add. 2 (Comments of European Union); CX/FICS 10/18/5 Add. 3 (Comments of Japan and Norway); CRD3 (Comments of Colombia, Dominica, Ghana, India, Jamaica, Kenya, Mali, Norway, Solomon Islands, Thailand and Uruguay); CRD 5 (Revised Proposed draft Principles and guidelines for national food control systems, prepared by the Australian Secretariat taking into account comments submitted at Step 3)

42. The Committee noted that the document still required substantial work and that it would be necessary not only to consider the completeness of the framework but also to consider the document in the context of CCFICS and other relevant texts.

43. The following main comments were made: the document was needed to assist countries in using Codex texts; the document should establish a common understanding of national food control systems; the document should be a stand-alone document and draw from existing Codex texts and modified as necessary; the document should provide the broad framework and high level principles guiding countries in the development and enhancement of their national food control systems.

44. The Representative of FAO stated that in FAO and WHO guidance documents, food control systems were referred to as the integration of a mandatory regulatory approach with preventive and educational strategies that protect the whole food chain. The Representative recommended that information, education and communication be given due recognition, when describing the components of a food control system.

### **Specific comments**

45. The Committee agreed to base its discussion on CRD 5, which presented a revised framework and structure of the document based on comments submitted.

46. After a general discussion on the structure the Committee agreed that the document should contain the following sections: introduction; scope; objective of a national food control system; principles of a national food control system; framework for the design and operation of a national food control system – guidance for competent authorities including sub-sections on: characteristics/components; infrastructure; and system management.

47. The Committee considered the content of each of the above sections to provide guidance for their further development by a working group (*see* para. 67).

### **Introduction**

48. The Committee agreed that the introduction should lead the reader logically from all components of food safety, as contained in a national food safety system, to those that would be covered in a national food control system. The Committee agreed that the focus of the document should be guidance on national food control systems for competent authorities.

49. The Committee developed the following text for consideration as part of the introduction: “*An integrated effort from all participants to achieve food safety and ensure fair practices in the food trade including consumers making informed decisions, the actions of business across the food chain to comply with requirements, the actions of governments to develop science based standards and promote food safety, to monitor and verify compliance and taking corrective and enforcement action as needed.*”

50. The Committee further agreed that the introduction should include a paragraph that would be constructed from drawing on the following high level principles :

- *the whole food chain approach;*
- *transparency;*
- *primary / shared responsibility of food business operators (including producers, processors, wholesalers, distributors and retailers) for complying with requirements and ensuring safe food on those aspects of food under their control. Responsibility of consumers (national and international) to manage food safety risks complementing food business responsibility;*
- *consistency and impartiality;*
- *incorporation of risk based, science based and evidence based decision making;*
- *cooperation and coordination between multiple competent authorities.*

51. The Committee agreed that there was a need to have a common understanding of what is meant by “national food control system” and developed the following text:

*“Integrated structure comprised of 2 principal parties*

*Competent Authority*

- *establishes and enforces science based regulatory infrastructure that promotes food safety*
- *supports and enables fair trade in food*
- *advances/fosters knowledge, science, research, education related to food safety*

*Industry*

- *primary responsibility for producing safe food and adhering to the established regulatory requirements*
- *advances/fosters knowledge, science, research, education related to food safety*

52. The Committee recognised that other parties involved in consumer protection were “academia” and “consumers”, though with limited responsibility.

53. An alternative definition of national food control system for consideration by the working group was proposed as follows: *“The national food control system is an action plan of the government strategy to ensure the production of safe food and to achieve food safety it is based on public private cooperation, regulatory requirements, educational programs and enforcement actions.”*

**Scope**

54. The Committee agreed that the scope of the document should be the following: *“This document provides principles and guidelines to assist the competent authority(s) of national governments in the development, operation and improvement of a national food control system.”*

**Objective of a national food control system**

55. The Committee agreed that: *“The objective of a national food control system is to protect the health of consumers and ensure/enable fair practices in the food trade in a transparent and consistent manner.”* (This text has been adapted from CAC/GL 20-1995 Para 5 and 6.).

**Principles of a national food control system**

56. The Committee agreed that the overarching principle of *“precedence to protection of consumers”* should be contained in an introductory statement leading to the principles of a national food control system. It also agreed that the introductory statement should link the objective of a national food control system to the principles.

57. The Committee agreed on the following high priority principles around which a national food control system should be developed:

- *the whole food chain approach;*
- *transparency;*
- *primary / shared responsibility of food business operators (including producers, processors, wholesalers, distributors and retailers) for complying with requirements and ensuring safe food on those aspects of food under their control. Responsibility of consumers (national and international) to manage food safety risks complementing food business responsibility;*
- *consistency and impartiality;*
- *incorporation of risk based, science based and evidence based decision making;*
- *cooperation and coordination between multiple competent authorities (articulation of responsibilities of different competent authorities including delegated to third parties);*

58. The Committee agreed that the working group would expand the above high priority principles taking into account language contained in CCFICS texts and relevant working documents of the present session. The Committee agreed that the working group should review the following remaining principles and consider whether they should be kept in this section or could be better addressed in different sections:

- *preventive measures;*
- *harmonisation with international standards;*
- *resources to meet its objectives;*
- *self assessment and review procedures to ensure it maintains its fitness for purpose;*
- *independence/objectivity of the system (comment: stakeholders usually have vested commercial interests – the competent authority has to discharge its obligations free from outside interference on decisions made regarding enforcement) fitness for purpose, cooperation, communication with stakeholders is still important but to carry out enforcement it must be independent;*
- *legislative and regulatory framework (comment: is this a tool rather than principle?)/ accreditation of third parties;*
- *equivalence/recognition of systems;*
- *inspection and control procedures to achieve consumer protection; and*
- *framework of how to achieve consumer protection.*

#### **Framework for the design and operation of a national food control system guidance for competent authorities**

59. The Committee agreed that this section should encompass what the competent authority should take into account when building the national food control system.

60. The Committee agreed that the section should include:

- *an introductory paragraph that explains that there are a number of components of a national food control system and either list those components or organise them under three main headings: how the system looks from outside; what is its structure/static components i.e. infrastructure; and how it is working i.e. system management; and*
- *a paragraph that deals with roles and responsibilities of the competent authority.*

61. The Committee agreed that the working group should:

- *consider the need to reflect again the need for the national food control system to address outcomes in regard to protection of consumers and ensure fair practices in food trade including fit for purpose; and*
- *take into account Section 6 of CAC/GL 26-1997 and adapt language from other CCFICS texts to fit national food control systems.*

#### Characteristics / components

62. The Committee agreed that the working group should consider whether the following characteristics/components could be captured in principles or reflected in other parts of the document, notwithstanding that it could be justified that certain elements be captured within this sub-section:

##### *Characteristics/components outlining the behaviour of the system*

- *precedence to the protection of consumers;*
- *risk-based and proactive;*
- *based on prevention, intervention and response;*
- *clearly defined and transparent legislation, regulations, guidelines, policies and procedures;*
- *clearly defined roles and responsibilities for the competent authorities;*
- *uniform national implementation;*

- *sufficient infrastructure and resources;*
- *adequate performance and enforcement capabilities;*
- *means to identify food safety problems;*
- *means to respond to food safety emergencies;*
- *adaptive, responsive to change with mechanisms to review and update the food control systems;*
- *use of harmonized international standards to the extent possible.*

*Characteristics/components outlining situational awareness of the system*

- *statistical data on production, trade and consumption;*
- *knowledge of operators at various stages of the food chain;*
- *typical and atypical use of products, raw materials and by-products;*
- *structure of production and supply chains; and*
- *production technologies, processes and practices;*
- *consumer practice on selection, storage and handling of products; and*
- *food safety hazards associated with each productions and epidemiological data on foodborne disease*

*Proactivity*

*Capability to learn*

Infrastructure

63. The Committee agreed that this sub-section should address: *legislative framework; program design; resources, laboratories, personnel, facilities, equipment, transportation and communication.*

System management

64. The Committee agreed that this sub-section should address: *design and implementation; operations; verification, maintenance and improvement.*

65. The Committee noted that the above sections would likely contain aspects of other CCFICS texts, in particular of Section 6 of CAC/GL 26-1997.

Conclusions

66. The Committee was of the opinion that good progress had been made in improving the understanding of the scope and objective of the document, formulating a high-level statement, defining the structure of the document and agreeing on the high priority principles of a national food control system.

67. In order to facilitate the further development of the document at its next session, the Committee agreed to establish a physical working group, chaired by Australia, open to all members and observers and working in English, French and Spanish and in accordance with the *Guidelines on physical working groups*<sup>12</sup> to prepare revised proposed draft principles and guidelines. The working group should expand and elaborate around the guidance provided by the Committee as contained in the paragraphs above. The meeting of the working group was tentatively scheduled for the beginning of 2011.

**Status of the proposed draft Principles and guidelines for national food control systems (N06-2009)**

68. The Committee agreed to return the proposed draft principles and guidelines to Step 2 for redrafting by a physical working group, circulation for comments at Step 3 and further consideration at Step 4 at the next Session of CCFICS.

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<sup>12</sup> Procedural Manual of the Codex Alimentarius Commission

**OTHER BUSINESS AND FUTURE WORK (Agenda Item 6)<sup>13</sup>**

69. The Delegation of the United States of America informed the Committee of the conclusions of an APEC (Asia-Pacific Economic Cooperation) Export Certification Roundtable, which was held from 25-26 February 2010 in Surfers Paradise (Australia). The Committee noted that one of the conclusions of the meeting was the consideration to propose that CCFICS consider additional work on incorporating appropriate attestations in the *Generic model official certificate* (Annex to CAC/GL 38-2001). The delegation proposed to prepare a discussion paper on this issue for consideration at the next session of the CCFICS.

**DATE AND PLACE OF NEXT SESSION (Agenda Item 7)**

70. The Committee noted that its 19<sup>th</sup> Session was tentatively scheduled to be held in Australia, from 17-21 October 2011, subject to further discussion between the Codex and Australian Secretariats.

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<sup>13</sup> CRD 6 – Summary of APEC Export Certification Roundtable

## SUMMARY STATUS OF WORK

<b>Subject Matter</b>	<b>Step</b>	<b>Action by:</b>	<b>Document Reference (ALINORM 10/33/30)</b>
Proposed draft Principles and guidelines for the conduct of foreign on-site audits and inspections (N07-2008) (Annex to the <i>Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems</i> (CAC/GL 26-1997))	5/8	33 <sup>rd</sup> CAC	Para. 39 and Appendix II
Proposed draft Principles and Guidelines for National Food Control Systems (N06-2009)	2/3	Physical WG 19 <sup>th</sup> CCFICS	Para. 68
Discussion paper on further guidance regarding attestation in generic model official certificate	-	USA	Para. 69



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**Appendix II****PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF ASSESSMENTS OF FOREIGN OFFICIAL INSPECTION AND CERTIFICATION SYSTEMS**

(Annex to the Codex *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997))

(NO7-2008)

(At Step 5/8)

**SECTION 1- INTRODUCTION**

1. An importing country may determine that it is necessary to assess an exporting country's official inspection and certification systems<sup>1</sup>. This annex is not intended to mandate the use of such assessments but to provide guidance that should be taken into account where they are used.
2. These assessment activities should concentrate primarily on evaluating the effectiveness of the official inspection and certification systems rather than on specific commodities or establishments in order to determine the ability of the exporting country's competent authority(s) to have and maintain control and deliver the required assurances to the importing country. A number of tools are available for the conduct of an assessment of an exporting country's official inspection and certification system these include, but are not limited to, audits, inspections and visits. The level of experience, knowledge and confidence<sup>2</sup> the importing country has in the exporting country's official inspection and certification system is important in determining the appropriate tool to undertake the assessment, including whether a visit to the country is required.
3. This annex is to be read in conjunction with section 9 - Assessment and verification of inspection and certification systems of *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997). In addition, the relevant sections of the *OIE Performance of Veterinary Service Tool for Evaluation of Veterinary Services, Chapter 3.2 of the OIE Terrestrial Animal Health Code* should be considered where appropriate

**SECTION 2 - SCOPE**

4. This annex provides guidance for use by competent authorities of both importing and exporting countries to ensure an effective, efficient, transparent<sup>3</sup>, and consistent approach when using audits or inspections for assessment of an exporting country's official inspection and certification system(s), or component thereof. This annex should also apply to any other visit or request for information that may be part of an assessment which has the ability to impact on the exporting country.

**SECTION 3 - PRINCIPLES**

5. The overarching principle of this annex is that the competent authority of an importing country may conduct an assessment of an exporting country's official inspection and certification system with the agreement of the exporting country. In conducting assessments of an exporting country's official inspection and certification systems, the following additional principles apply.

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<sup>1</sup> *Official inspection and certification systems* refers to both 'Official inspection systems and official certification systems' and 'Officially recognized inspection systems and Officially recognized certification systems' as defined in the parent document.

<sup>2</sup> 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 two countries and the history of compliance of foods with the importing country's requirements, particularly the food products involved. Further examples that may inform the importing country's experience, knowledge and confidence are listed in paragraph 10 points (a) to (n) in CAC/GL 53-2003.

<sup>3</sup> CAC/GL 20 1995, paragraphs 13-16, and CAC/GL 26-1997, paragraph 58.



**Principles A to C apply to the conduct of the competent authorities of the importing and exporting countries throughout the assessment process**

- A. Assessments should be outcome focused, transparent, evidence-based and conducted in a cooperative, ethical and professional manner respecting confidential information, where appropriate.**
- B. The importing and exporting countries should have an agreed process to address any issues that may arise throughout the assessment process.**
- C. The importing and exporting countries should agree on an appropriate tool for the conduct of the assessment prior to its commencement based on the agreed scope and objectives. In most cases the preferred assessment approach would consider the official inspection and certification system as a whole or part.**

**Principles for the assessment process are provided in Principles D to G**

- D. The assessment process should be planned, systematic, transparent, consistent, fully documented and well communicated.**
- E. The plan incorporating rationale, objective, scope, assessment tools and, requirements against which the exporting country's official inspection and certification system is assessed should be clearly identified by the importing country, notified to and agreed by the exporting country's competent authority(s), within a reasonable period of time prior to the commencement of the assessment..**

**Principles F and G cover assessment reporting**

- F. Agreed corrective actions, timeframes and follow-up verification procedures should be clearly established and documented.**
- G. The final assessment report should be accurate and transparent and may be published respecting confidentiality of information, where appropriate.**

**SECTION 4 - CONDUCT OF ASSESSMENTS**

**Principle A**

**Assessments should be outcome focused, transparent, evidence-based and conducted in a cooperative, ethical and professional manner, respecting confidential information where appropriate.**

6. The importing country's competent authority should be able to demonstrate that its assessment findings, conclusions and recommendations are primarily focused on whether the required outcomes are likely to be achieved by the system and that they are supported by objective evidence or data which can be verified as accurate and reliable.
7. Where there are multiple competent authorities in an importing country, these authorities should coordinate their assessments in order to avoid any duplication of effort on the part of the exporting country .
8. The exporting country's competent authority or authorities should cooperate, coordinate and assist in the performance of the assessment so that the assessment objectives are achieved.
9. Throughout the course of the assessment, all issues arising should be dealt with in a cooperative, ethical and professional manner by the competent authorities.
10. The importing country's competent authority should ensure the impartiality of their auditors, inspectors or auditing organization. The assessors should have the appropriate qualifications, experience and training both in the relevant area of technical expertise and in audit techniques.
11. In conducting an assessment importing countries should ensure that confidential information is protected. For countries with specific laws relating to confidentiality, an agreement between the two parties should be reached as to how the laws will be adhered to, in order to proceed.
12. The anticipated costs for undertaking the assessment should be understood by both competent authorities in advance of undertaking the assessment.

13. The costs incurred in undertaking an assessment, including all travel costs, costs of technical experts and auditors or inspectors, and costs of support staff should normally be borne by the competent authority of the importing country except as may otherwise be agreed.

14. The costs incurred by the competent authority of the exporting country, in supporting the assessment, for support staff and technical experts in the exporting country should normally be borne by the competent authority of the exporting country except as may otherwise be agreed.

### **Principle B**

**The importing and exporting countries should have an agreed process to address any issues that may arise throughout the assessment process.**

15. Prior to the commencement of the assessment the key elements of a process to address issues that may arise throughout an assessment should be agreed. Where they are available, the competent authorities of the importing and exporting countries should use existing processes to resolve issues arising from the assessment to the extent possible. The competent authorities of the importing and exporting country should aim to resolve any issues which may arise in the course of the assessment in an open, transparent and cooperative manner. If any issues remain outstanding they should be indicated in the assessment report with appropriate justification.

### **Principle C**

**The importing and exporting countries should agree on an appropriate tool for the conduct of the assessment prior to its commencement based on the agreed scope and objectives. In most cases the preferred assessment approach would consider the official inspection and certification system as a whole or a part.**

16. The most efficient and effective tool that can assess the effectiveness of the exporting country's official inspection and certification system including the exporting country's competent authority(s) ability to have and maintain control and deliver the required assurances to the importing country should be selected.

17. In selecting the assessment tool, it is important to consider the reason the assessment is being undertaken. Assessments can, for example, be part of a risk analysis prior to commencement of trade, can assess the official inspection and certification system, or controls for a particular component e.g. commodity (e.g. dairy, fish or meat) or controls for a particular element (e.g. chemical residues) or specific exporting establishments.

18. The importing country's experience, knowledge and confidence<sup>4</sup> in an exporting country's official inspection and certification systems, should be considered in selecting an assessment tool.

19. In general, the preferred assessment tools would be audits of all or part of an exporting country's official inspection and certification system including the ability of the competent authority. Inspections can also be an appropriate assessment tool. Where competent authorities use other terms to describe assessment activities, e.g. visits, information exchanges, such activities should also be subject to these guidelines.

### **Audit Tools**

20. The audit tool, often described as 'systems based audit' should focus on assessing whether the implementation of the official inspection and certification system or components thereof in operation in the exporting country is capable of meeting its objectives.

21. Systems-based audits rely on the examination of a sample of system procedures, documents or records and, where required, a selection of sites within the scope of the system under audit, as opposed to examining all procedures.

22. A system-based approach focuses on the control system(s) and recognizes that any compliances/non-compliances found must be viewed in the context of the over-all system.

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<sup>4</sup> Paragraphs 9-14 of the Appendix to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003) provides additional guidance relating to what constitutes experience, knowledge and confidence and expands on information presented in paragraph 10-12 of that Guideline.

23. In conducting a systems-based audit, the audit may involve examination of the elements as contained in Section 6, Inspection and Certification System Infrastructure or other elements as appropriate.

### **Inspection Tool**

24. The inspection tool may be used in some instances to confirm the effectiveness of controls by the competent authority(s) in the exporting country.

25. Inspections may involve the examination of:

- a) How establishments meet requirements, including review of specific activities and product specifications, observation and review of establishment operations and appropriate operating records;
- b) Establishment's personnel capabilities, when specified in requirements;
- c) Inspectors' capability, if specified in requirements.

## **SECTION 5 - ASSESSMENT PROCESS**

### **Principles D to G cover the assessment process.**

#### **Principle D**

**The assessment process should be planned, systematic, transparent, consistent, fully documented and well communicated.**

26. The transparency and consistency of the assessment process may be facilitated by good documentation and communication. Documents supporting findings, conclusions and recommendations should be standardised as much as possible in order to make the performance of the assessment and the presentation of its outcome uniform, transparent and reliable.

27. In order to prepare and carry out an assessment, ongoing and transparent communication is required. Consultation should occur between the competent authorities of the importing and exporting countries at all points in the process, from developing the assessment plan through to final reporting and resolution of any issues arising during the assessment. To ensure ongoing and transparent communication the competent authorities of the importing and exporting country should designate responsible contact persons or contact points for assessments.

28. Processes and protocols for addressing assessment findings and recommendations should be documented and agreed prior to the assessment.

#### **Principle E**

**The plan incorporating the rationale, objective, scope, assessment tools and requirements against which the exporting country's official inspection and certification system is assessed, should be clearly identified by the importing country, notified to and agreed by the exporting country's competent authority(s), within a reasonable period of time prior to the commencement of the assessment**

29. When establishing the rationale, objective, scope, frequency of assessment and assessment tools, the importing country's competent authority should take into account the established level of experience, knowledge and confidence together with the history of previous assessments, the period since the last assessment and any other relevant factors.

30. A systematic evaluation procedure for undertaking the assessment should be used based on a predetermined and structured program consistent with the purpose of the assessment.

#### **Notification**

31. The following information should be exchanged during the initial request and prior to commencing an assessment of a country's official inspection and certification system:

- a) The rationale or need to conduct an assessment may arise from a number of reasons including, an importing country's legal obligations or the need to understand the respective roles of the competent authorities in both importing and exporting countries or the need to verify the

capability of an exporting country's system or food production/processing facilities to meet requirements.

- b) The objective of the assessment, for example is; to verify the effective application/implementation of specific measures or technical requirements of the exporting country's inspection and certification system; to verify compliance with measures of the importing country that the exporting country is implementing; to assess compliance with equivalency agreements or other types of mutual acceptance of systems, conduct an investigation of outbreaks of foodborne diseases related to imported/exported food and to follow up corrective action resulting from previous assessments or of situations derived from food safety issues. The risk assessment component of an exporting country's food control system may be audited where it is necessary to support a risk management approach.
- c) The scope of the assessment, that is, whether the assessment is to cover a whole system or its sub-components, measures, technical requirements, or products should be defined.
- d) The assessment tool intended to be used including the requirements against which the official inspection and certification system of the exporting country will be assessed should be identified.

32. In all cases, the competent authority of the importing country should provide the competent authority of the exporting country with sufficient notice of the intended assessment, in order to enable it to make the necessary arrangements such as logistics and information gathering. If the rationale for the assessment is a critical public health issue the advance notice should reflect the urgency related to the public health risk.

33. In the case of a request for assessment from an exporting country, the importing country should respond in a timely manner providing a commitment to conduct the assessment<sup>5</sup>.

#### ***Assessment Preparation***

34. A plan for undertaking the assessments, including the assessment tool, timeframes and exchange of required information should be prepared and communicated to the exporting country's competent authority within a reasonable period of time. The plan should include the following:

- a) Objective and scope of the assessment including whether it is a stand alone assessment or related to another assessment (e.g. follow-up of previous assessment) or series of assessments;
- b) Items/ elements to be reviewed/ undertaken which may include records and assessment checklists;
- c) The anticipated timeframe within which the assessment will be conducted and reported;
- d) Criteria against which the assessment of the exporting country's official inspection and certification system will be carried out;
- e) A contact person for the assessment team who can negotiate the details of the assessment plan and if required , assessment team members including foreign auditors/inspectors, the lead auditor/inspector, technical experts and translators;
- f) The language that will be utilised during the assessment including, translation, availability of impartial and knowledgeable interpretation and resources.
- g) An indication of the type or where possible/relevant the identity of locations to be visited (e.g. offices, laboratories or other facilities) and the timing and responsibility for the notification to the sites where necessary (although this task may be completed at the audit opening/entry meeting);
- h) The dates for the conduct of the assessment, the dates of the opening and closing meeting and the anticipated date for reporting the observations of the assessment;
- i) Travel schedules and other logistics, as necessary for an assessment visit; and
- j) Provisions to protect confidential information.

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<sup>5</sup> CAC/GL 20-1995 para 18.

35. While efforts should be made to adhere to the assessment plan it should be designed to be flexible in order to permit changes in emphasis based on information gathered prior to, or during the audit. Proposed significant amendment(s) to the assessment plan should only be made in extenuating circumstances and should be communicated by the proposing competent authority to the other competent authority as soon as possible.

36. As part of the assessment plan, the competent authorities of both countries should reach agreement on how the results of the evaluation will be conveyed to the exporting country, such as findings, non-compliance and recommendations.

37. Advanced agreement should be reached on the language that will be utilised during the assessment including, translation, availability of impartial and knowledgeable interpretation and resources.

38. To the extent possible documentary information required for planning, conducting and completing the assessment should be requested and provided in advance of the assessment, utilizing electronic means wherever possible.

- a) The assessment preparation request should be focused and related to the stated scope and objectives.
- b) If this is a follow-up assessment, then the exporting country should only need to provide any information that has changed since the previous assessment or that has not been requested during a previous assessment;
- c) In case the purpose of an information-request is not clear to the exporting country and it has some issues related to the requested information, it may seek clarification from the importing country as to the purpose and use of such information.
- d) When an on-site visit is the assessment tool proposed a review of documents describing the system including legislative support should be conducted prior to commencement of the assessment visit. This is to allow the most efficient and effective use of time spent on-site i.e. to reduce the burden of assessments on the competent authorities of both countries.

39. In some cases the assessment may be suspended or concluded prior to an on-site visit depending on the nature of information provided by the competent authority of the exporting country and in which case the reason should be communicated clearly to the competent authority of the exporting country by the competent authority of the importing country. The competent authority of the exporting country should have the opportunity to clarify the information provided should they consider this necessary.

40. Agreement should be reached in advance concerning the use of information sharing from assessments and the parties with whom information can be shared.

#### ***Assessment Logistics***

41. When an assessment includes an on-site visit the competent authority of the exporting country should have primary responsibility for the logistical aspects of the assessment including advising on internal travel and accommodation arrangements. It is the responsibility of the competent authority of the exporting country to communicate with the responsible parties of the site(s) to be assessed.

#### ***Assessment Opening / Entry Meeting***

42. In the case of an assessment involving a visit an opening or entry meeting should be held.

- a) The meeting should be held at a place designated by the competent authority of the exporting country.
- b) The meeting should review all aspects of the assessment plan including any final adjustments and is intended to provide an overview of the official inspection and certification system of the exporting country and to confirm the parameters and logistics of the assessment.
- c) Agreement should be reached on the methods to ensure continuous liaison and communications between the parties during the assessment.

***Assessment Closing / Exit Meeting***

43. In the case of an assessment involving a visit a closing or exit meeting should be held.
- a) The meeting should be held at a place designated by the competent authority of the exporting country.
  - b) The assessment team should summarize main findings and preliminary conclusions. Any non-conformities should be identified and outline the objective evidence to support the conclusions. Correction of non-conformities should be left to the competent authority of the exporting country and verified by the competent authority of the importing country including a follow-up assessment if required.
  - c) This meeting provides an opportunity for the competent authority of the exporting country to raise questions or seek clarification of the findings and observations provided at the meeting.

**SECTION 6 - ASSESSMENT REPORTING****Principles F and G cover assessment reporting.****Principle F**

**Agreed corrective actions, timeframes and follow-up verification procedures should be clearly established and documented.**

**Principle G**

**The final assessment report should be accurate and transparent and may be published respecting confidentiality of information, where appropriate.**

44. A collaborative approach to report preparation and a process for distribution and presentation should be agreed in advance.
45. The assessed party should have the opportunity to review the draft report in an agreed timeframe, provide comments and correct factual errors before its finalization. The final report should incorporate, or be accompanied by, the comments provided by the competent authority of the exporting country.
46. The report of assessment should provide a balanced picture of the findings and include conclusions and recommendations that accurately reflect those findings. It should:
- a) Describe the purpose, scope, and outcome;
  - b) Describe the criteria and assessment process;
  - c) Include assessment findings with supporting evidence for each conclusion, along with any details of significance discussed during the closing meeting;
  - d) Be made available as agreed to between the importing and exporting country's competent authorities, including and addressing the comments made by the competent authority of the exporting country to enhance the accuracy of the report;
  - e) Take into account the timeframe for the finalisation of the report and response procedures agreed upon between importing and exporting countries' competent authorities;
  - f) Include how corrective actions will be communicated and agreed to, including how follow-up verification will be completed;
  - g) Include any checklists of elements evaluated, where required to support the findings;
  - h) Include a summary of the assessment outcome;
  - i) Include outstanding matters and issues arising during the assessment in the report if there is no agreement on the conclusions and the corresponding corrective actions;
  - j) Include uncertainties and/or any obstacles encountered that could affect the reliability of the assessment conclusion; and

- k) Indicate any areas not covered in the assessment process, though within the scope, and the reasons for such deviation from the agreed scope.
47. The timeframe and protocol for any follow-up verification should be clearly stated. Verification of corrective actions may include:
- a) Review of assurances provided by the competent authority of the exporting country;
  - b) Review of documentation provided by the competent authority of the exporting country; or
  - c) Review of stated corrective action in a subsequent assessment.
48. Confidential information must be respected in the preparation and subsequent distribution of the assessment report.
49. Once an assessment report has been finalised the competent authorities of the importing and exporting countries should discuss and if possible agree if and how any or all of the report will be published respecting confidentiality of information where appropriate.