

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 4

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION
AND CERTIFICATION SYSTEMS

Seventeenth Session

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PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT
OF FOREIGN ON-SITE AUDITS AND INSPECTIONS

(NO7 – 2008)

(At Step 3)

(prepared by a physical working group led by Australia with the assistance of Austria, Belgium, Brazil, Canada, Denmark, European Community, France, Germany, Indonesia, Iran, Italy, Japan, Kenya, Malaysia, Mexico, Morocco, New Zealand, Norway, Philippines, South Africa, Spain, Sweden, Thailand, United States of America, Zambia, and IACFO)

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments on the following subject matter are invited to do so **no later than 15 October 2008** to: Codex Australia, Australian Government Department of Agriculture Fisheries and Forestry GPO Box 858, Canberra ACT, 2601 (fax: 61.2.6272.3103; E-mail: codex.contact@daff.gov.au - *preferably*), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Via delle Terme di Caracalla, 00153 Rome, Italy (Fax No + 39.06.5705.4593; E-mail: codex@fao.org - *preferably*).

BACKGROUND

1. The 15th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (Mar del Plata, Argentina, November 2006) during its consideration of possible new work, considered the Project Document¹ prepared by Australia, proposing that the committee consider the need to undertake new work on the development of Guidelines for the Conduct of Foreign On-Site Audits and Inspections.

2. During its discussion of new work proposals the Committee expressed general support for the proposal in view of the increasing use of foreign on-site audits and inspections and considered it would be very useful to collect in a single document the relevant provisions contained in various CCFICS texts and to develop principles and guidance with respect to the conduct of foreign audits including the purposes of such foreign on-site audits and inspections. It was observed that “audit” and “inspection” are not equally understood by countries and that the guidelines should also aim at clarifying their meaning and scope.

¹ CRD 11

3. Therefore, the Committee agreed to establish an electronic Working Group, led by Australia, to prepare a comprehensive discussion paper on the scope, justification and rationale for new work. It was also agreed that the discussion paper should include an outline of the Guidelines and a project document, for consideration at its next session.

4. The 16th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (Surfers Paradise, Australia, November 2007) considered a discussion paper prepared by an electronic working group led by Australia² which outlined 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. The Committee unanimously expressed support for this new work.

5. During the comments expressed at 16CCFICS on the proposed outline of the document³ delegations noted that:

- a) “system-based approach” should be explained;
- b) 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;
- c) The responsibility for costs should be clarified attention should be given to find mechanisms to minimise the numbers of visits;
- d) 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; and
- e) 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).

6. The Committee agreed to forward the project document to the 61st Session of the Executive Committee for critical review and to the 31st Session of the Commission for approval as new work.

7. It further agreed to establish a physical working group, 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.

8. The 31st Session of the Codex Alimentarius Commission approved new work on the proposed draft Principles and Guidelines for the Conduct of Foreign On-site Audits and Inspections (N07–2008).

9. At the kind invitation of the European Community, the working group met in Brussels, Belgium from 10-11 July 2008. The working group was chaired by Mr Greg Read, in his capacity as the Chair of CCFICS. A list of working group participants is given in Attachment 2.

10. The working group considered a redrafted working document which took into account the comments submitted to the electronic working group⁴. This working draft contained 7 Sections; Introduction, Objective, Definitions, Principles, Scope/Objective and Rationale for Undertaking On-Site Audits Procedures Associated with Undertaking an On-Site Audit and Costs.

² With the assistance of Argentina, Brazil, Canada, China, Czech Republic, European Community, Germany, Kenya, Japan, Malaysia, New Zealand, Norway, Philippines, Spain, Sweden, Switzerland, Thailand and the United States of America

³ CX/FICS 07/16/6 Attachment 1

⁴ Comments were received from Canada, the European Community, Iran, Japan, Malaysia, Mexico, New Zealand, Norway, Thailand and the United States of America, (late comments from IACFO and the Philippines were considered at the physical working group)

11. The working group discussed how the proposed draft principles and guidelines would relate to the existing Annex to CAC/GL 26-1997 *Guidelines on Procedures for Conducting an Assessment and Verification by an Importing Country of Inspection and Certification Systems of an Exporting Country* to the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems*. The working group agreed to recommend to the Committee that the proposed principles and guidelines should replace the existing Annex to CAC/GL 26-1997.

12. The working group discussed the objectives of the proposed draft principles and guidelines (Section 2) and agreed that the objective of the document would be to provide guidance to governments on a standardized approach to undertaking audits of official inspection and certification systems, or component parts thereof. During this discussion it was also agreed to remove references to ‘on-site’ as audits could be carried out either during a visit to the exporting country or by undertaking a ‘desk’ audit of the official inspection and certification systems. It was also agreed for consistency with other existing CCFICS texts that the term ‘official inspection and certification system’ would be used rather than the term food control or food safety system which had been used interchangeably throughout the working document.

13. The working group had a brief discussion on whether there was a need to include a reference in the objective, to the conduct of foreign systems-based audits of an exporting country’s official inspection and certification systems and their ability to achieve the importing country’s appropriate level of protection (ALOP), due to lack of time this issue was not resolved.

14. Discussion on the principles proposed in Section 4 of the working paper included amendments to cover the following issues:

- the right of an importing country to conduct audits;
- the need for audits to be independent, evidence-based, and conducted in a professional manner;
- the need for an agreed dispute resolution process;
- that audits should be systems-based unless otherwise agreed;
- the rationale, objective, scope and timeframe of the audit needs to be clearly defined;
- there needs to be a plan for undertaking the audit;
- need to establish agreed corrective actions, timeframes for follow-up and verification; and
- need to consider confidentiality in respect of the audit report and its findings.

15. The proposed principles were reorganised starting from more general (“high level”) principles that covered the conduct of audits, followed by principles that covered the audit process and reporting (“lower level” principles).

16. The working group then proceeded to re-order the text of the working document to closer align it with the revised set of principles. The working group considered that the inclusion of sub-headings to reflect the manner in which audits should be planned, conducted and concluded was an important aspect which would assist countries in their preparations and conduct of audits and would ensure consistency in the application of the proposed principles and guidelines.

17. The working group had a brief discussion regarding Definitions (Section 3). During its discussion the working group noted, the last session of the Codex Alimentarius Commission had recognised that the definitions for risk analysis, assessment and management are contained in the Codex Procedural Manual and apply to all Codex texts, thus there was no need to include them in Codex documents. With respect to the other definitions, since they are already included in the parent document, they have been left in the draft in order to facilitate the discussion at the Committee but will be removed when the text is submitted to the Commission for adoption.

18. The delegate from IACFO expressed the view that the definition for *certification* should be modified, as that in order to avoid conflicts of interest and other potential difficulties, certification should be undertaken by government agencies or bodies, and not by third-party auditors. The range of inspection activities currently outlined by the definition includes, for example, continuous on-line inspection, which in IACFO’s view is a process that is more properly overseen by governments and not third-parties. The working group recalled that the definition of *certification* had been agreed several years ago and that to amend the definition would mean re-examining it in the context of all CCFICS texts which was outside the mandate of this working group.

19. The working group also discussed the inclusion of proposed definitions for ‘*systems based*’ and ‘*competent authority*’ but did not consider that these needed to be included at this time.
20. Due to time constraints the working group did not fully consider the text contained in Section 1 Introduction however it agreed to recommend that the committee consider the development of a new introduction which better reflects the content of the draft document.

RECOMMENDATION

21. In light of the mandate given to the working group by 16CCFICS the members are invited to comment on Appendix 1 and to consider whether:
- a) the proposed draft *Principles and Guidelines for the Conduct of Foreign On-Site Audits and Inspections* (Attachment 1) address the points in paragraph 5 a) to e) above;
 - b) the proposed principles and guidelines should replace the existing Annex to CAC/GL 26-1997;
 - c) there is a need to include a reference in the objective, to the conduct of foreign systems-based audits of an exporting country’s official inspection and certification systems and their ability to achieve the importing country’s appropriate level of protection (ALOP).
22. The Committee at its 17th Session in November 2008 will consider the text in Appendix 1 with a view toward its further progression in the Codex Step Procedure.

PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF FOREIGN AUDITS AND INSPECTIONS¹

(NO7 – 2008)

(At Step 3)

SECTION 1 - INTRODUCTION

1. [Countries that certify exports of food and those importing countries which rely on export certificates should take measures to assure the validity of certification. Validation measures by exporting countries may include achieving confidence that official or officially recognised inspection systems have verified that the product or process referred to in the certificate conforms to requirements. Measures by importing countries may include point of entry inspection systems, audit of exporting inspection systems, and ensuring that certificates themselves are authentic and accurate. [CAC/GL 20-1995]

2. Assurance of the safety of exported foods may be achieved through the application of a country's domestic food safety system. Although the official food inspection and certification systems of importing and exporting countries may utilize different approaches to their food safety controls, an importing country may recognize the exporting country's food safety system, accept the differences as equivalent provided the same level of public health protection is achieved and maintained, or require an exporting country to apply certain of the importing country's measures for those food products exported to the importing country.] [*The Committee may wish to consider the content of this paragraph in line with the final text of the document.*]

SECTION 2 OBJECTIVE

3. These principles and guidelines provide guidance for use by national governments to ensure a standardized and consistent approach to the conduct of audits of an exporting country's official food inspection and certification system(s), or component parts thereof.

~~[4. The objective of this paper is to develop principles and guidelines for the conduct of foreign systems-based audits of an exporting country's food safety control systems and their ability [to achieve the importing country's appropriate level of protection (ALOP).] [*The working group considered the question of whether or not to retain the reference to ALOP but due to time constraints was unable to reach a conclusion. This will need to be reconsidered in light of final text in the document.*]~~

SECTION 3 DEFINITIONS²

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

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

Legislation** includes acts, regulations, requirements or procedures, issued by public authorities, related to foods and covering the protection of public health, the protection of consumers and conditions of fair trading.

Official accreditation** is the procedure by which a government agency having jurisdiction formally recognizes the competence of an inspection and /or certification body to provide inspection and certification services.

¹ These Principles and Guidelines should be read in conjunction with other Codex texts related to food import and export inspection and certification systems

² Definitions marked * are drawn from the *Principles for Food Import and Export Inspection and Certification Systems* (CAC/GL 20-1995). Definitions marked ** are drawn from the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997)

Official inspection systems and official certification systems** are systems administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function or both. **Officially recognized inspection systems and officially recognized certification systems**** are systems which have been formally approved or recognized by a government having jurisdiction.

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

Risk assessment³ is a scientifically based process consisting of the following steps (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment, and (iv) risk characterisation.

Risk analysis³ is a process consisting of three components: risk assessment, risk management and risk communication.

Risk management³ the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

SECTION 4 PRINCIPLES

4. In conducting audits of an exporting country's official inspection and certification systems the following principles apply.

- a) An importing country may conduct audits of an exporting country's official inspection and certification systems.
- b) Audits should be independent, evidence-based and conducted in a cooperative, ethical and professional manner.
- c) The parties involved should have in place an agreed dispute resolution process. [*working group felt that this is a high level principle and the Committee may consider it needs to develop further supporting text*]
- d) The audit should be systems-based, unless an alternative approach is agreed to by both importing and exporting country.
- e) The audit process should be transparent, consistent and fully documented.
- f) The rationale, objective, scope, and timeframe of the audit should be clearly identified in advance of undertaking the audit.
- g) A plan for undertaking the audit, including criteria for assessment of the exporting country's official inspection and certification system should be prepared in advance.
- h) Agreed corrective actions, timeframes and follow-up verification procedures should be clearly established and documented.
- i) The final audit report should incorporate the comments by the appropriate authorities of the exporting country and may be published.

CONDUCT OF AUDITS

Principles A to D cover the conduct of audits.

Principle A

An importing country may conduct audits of an exporting country's official inspection and certification systems.

5. Audits are one tool that an importing country may use before or after commencement of trade to assess an exporting country's food inspection and certification system.
6. An importing or exporting country may initiate a written request for an audit.

³ See Definitions for the purposes of the Codex Alimentarius Commission, Procedural Manual of the Codex Alimentarius Commission

- a) The request for and planning of an audit should follow the guidance laid out later in this document.
- b) The receiver of the request should acknowledge and confirm their acceptance or otherwise of the proposal for an audit.
- c) If differences arise as to the purpose, scope or other aspects (e.g. timing) the parties will work to resolve such issues.

Principle B

Audits should be independent, evidence-based and conducted in a cooperative, ethical and professional manner.

7. An importing country should be able to demonstrate that its audit findings, conclusions and recommendations are supported by objective evidence.
8. Professional conduct should be observed by both parties throughout the course of the audit.
9. Auditors should be free of conflict of interest.
10. The principle of confidentiality of information relating to the audit should be adhered to.
11. If there is a request for photographic information, there should be agreement from the exporting country with regards to the question of confidentiality.
12. The costs incurred by an importing country to undertake an audit, including all travel costs, costs of technical experts and auditors, and costs of support staff should normally be borne by the importing country except as otherwise agreed by the parties.
13. The costs for staff and technical experts in the exporting country should normally be borne by the exporting country except as may otherwise be agreed by the parties.
14. In the case of audits undertaken by third parties, the costs should be borne by the party requesting the audit.

Principle C

The parties involved should have in place an agreed dispute resolution process. [*The working group considered this to be a high level principle that may need further supporting text.*]

15. All outstanding issues should be discussed between the parties using the agreed dispute resolution process.

Principle D

The audit should be systems-based, unless an alternative approach is agreed to by both importing and exporting country.

16. Agreement should be reached between the importing and exporting countries as to the audit approach.
 - a) Normally a systems-based audit should focus on the implementation of the inspection and certification system or components thereof in operation in the exporting country.
 - b) A systems-based approach typically relies on a sample of sites to be audited as opposed to inspecting all establishments of a particular type.
17. In conducting a systems-based audit, the audit may involve examination of the following:
 - a) compliance records;
 - b) review of the control of the system by the competent authority;
 - c) review of infrastructure i.e. legislation, programs;
 - d) review of an establishment meeting requirements including reviewing establishments during operation and appropriate operating records;
 - e) review of inspectors' capability;
 - f) review of laboratory capability; and
 - g) adequacy of test results.

AUDIT PROCESS

Principles E to G cover the audit process.

Principle E

The audit process should be transparent, consistent and fully documented.

18. The transparency and consistency of the process will be facilitated by good documentation and communication.
19. In order to prepare and carry out an audit, ongoing and transparent communication will be required. Consultation should occur between importing and exporting countries at all points in the process, from developing the audit plan through to final reporting and, if needed, resolution of any disputes.
20. Processes and protocols for addressing audit recommendations should be documented and agreed prior to the audit.
21. The importing country should advise in advance of all issues that may be raised during the visit.
22. The audit should utilise clearly defined criteria for evaluation.

Principle F

The rationale, objective, scope, and timeframe of the audit should be clearly identified in advance of undertaking the audit.

Principle G

A plan for undertaking the audit, including criteria for assessment of the exporting country's official inspection and certification system should be prepared in advance.

Notification

23. The following information should be exchanged during the initial request to undertake an audit of a country's official inspection and certification system.
 - a) The rationale or need to conduct an audit, 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 to follow up on a food safety incident.
 - b) The objective of the audit, (e.g. to verify the effective application/implementation of specific measures and 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.) [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 audit, that is, whether the audit is to cover a whole system or its sub-components, measures or technical requirements should be defined prior to the commencement of the audit.
 - d) The timeframe within which the audit will be conducted and reported should be agreed prior to the commencement of the audit.

Pre-Audit

24. The importing country, in consultation with the exporting country, should prepare the audit plan and program which should include the following:
 - a) purpose and scope of the audit;
 - b) items/ elements to be reviewed/ undertaken including records and inspection checklists;
 - c) previous audit outcomes, corrective actions;
 - d) criteria for assessment;
 - e) audit team members including foreign auditors, lead auditor, specialists and local responsible staff and their qualifications as relevant;
 - f) offices, establishments, laboratories and other facilities and locations to be visited;

- g) audit dates, opening/closing meeting dates, reporting element dates; and
 - h) travel schedules and other logistics.
25. As part of the audit plan, the parties should reach agreement on how the results of the evaluation will be conveyed to the exporting country, including findings, non-compliance and recommendations.
26. In advance of the audit the importing country should clearly identify the standards against which the audited party is to be assessed. If there is equivalency between the two parties, then auditing standards should be those of the audited party.
27. Advance agreement should be reached on the language that will be utilised during the audit including, translation, availability of impartial and knowledgeable interpretation and resources.
28. To the extent possible documentary information required for planning, conducting and completing the audit should be requested and provided in advance of the audit, utilizing electronic means wherever possible.
- a) The pre-audit request should be focused and related to the stated scope and objectives.
 - b) The purpose of data and information requested should be stated, including how the data will be used.
 - c) In general a review of documents describing the system including legislative support should be conducted prior to commencing the audit.
 - d) [In some cases the audit may be suspended or concluded prior to the on-site visit depending on the nature of information provided by the exporting country and in which case the reason should be communicated clearly to the exporting country by the importing country.]
29. Agreement should be reached concerning the suitability and use of information sharing from audits.

Audit Logistics

30. A systematic evaluation procedure should be used, based on a predetermined and structured program consistent with the audit's purpose. The agreed audit approach should be adhered to with the understanding that adjustments can be made if local or other extenuating conditions warrant.
31. The exporting country should have primary responsibility for the logistical aspects of the audit including advising on internal travel and accommodation arrangements.

Audit Opening/Entry Meeting

32. An opening or entry meeting should be held.
- a) The meeting should review all aspects of the audit plan 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 audit.
 - b) Agreement should be reached on the methods to ensure continuous liaison and communications between the parties during the audit.

Audit Exit Meeting

33. A closing or exit meeting should be held.
- a) The meeting should summarize all findings and observations, identify non-conformities, outline the objective evidence to support the non-conformities and reach an understanding on how non-conformities will be corrected and verified.
 - b) Questions or concerns from the exporting country's competent authorities may be raised.
 - c) During this meeting agreement should be reached on timeframes for corrective actions if applicable.
 - d) Follow-up procedures to assess corrective action should be explained if applicable.

AUDIT REPORTING

Principles H and I cover audit reporting.

Principle H

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

Principle I

The final audit report should incorporate the comments by the appropriate authorities of the exporting country and may be published.

34. A collaborative approach to report preparation and a process for distribution and presentation should be agreed in advance.
35. The report of audit findings and conclusions should:
 - a) set out the expectations, purpose, scope, criteria and auditing process.
 - b) include audit findings with supporting evidence for each conclusion, along with any details of significance discussed during the closing meeting.
 - c) be made available as agreed to between the importing and exporting country authorities.
 - d) take into account the timeframe for the finalisation of the report and response procedures agreed upon between importing and exporting countries.
 - e) take into account how corrective actions will be communicated and agreed to, including how follow-up verification will be completed.
 - f) may include any checklists of [for] elements evaluated.
 - g) include a summary of the audit outcome.
 - h) outstanding matters and disputes should be included in the report if there is no agreement on the conclusions and the corresponding corrective actions.
36. The timeframe and protocol for follow-up verification should be clearly stated.
37. Reporting audit findings and conclusions should be standardized as much as possible to make the approach to audit more uniform and transparent.
38. The frequency of subsequent audits should be established, justified and agreed. Factors to be taken into account include the findings of previous audits and the existence and effectiveness of self-audit systems or third party audit of the exporting country's control systems.
39. Should a corrective action plan be required, there should be an agreed method for approval and follow-up of the plan.
40. The audited party should have the opportunity to review the draft report, provide comments and correct factual errors before its finalization. The final report should incorporate the comments by the appropriate authorities of the exporting country.
41. Once an audit report has been finalised [the importing and exporting country should discuss and if possible agree how and when any or all of the report will be published]. Publication of material relating to audits may be of assistance to other Codex members.

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