

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 6

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

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**DISCUSSION PAPER ON THE DEVELOPMENT OF PRINCIPLES AND
GUIDELINES FOR THE CONDUCT
OF FOREIGN ON-SITE AUDITS AND INSPECTIONS**

(prepared by an electronic working group led by Australia 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)

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.
3. Therefore, the Committee agreed to establish an electronic Working Group, led by Australia², 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.

1 CRD 11

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.

Rationale for development of Guidance and Principles in respect of the conduct of audit inspections by importing countries

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

5. While the concepts of on-site audits and inspections are touched upon in the documents there may be benefit in developing a consolidated set of principles and guidelines for use by Codex members to assist in the conduct of foreign on-site audits and inspections.

6. While the terms ‘audit’ and ‘inspection’ are defined by Codex, the Committee recognised that they are not equally understood and that the proposed draft guidelines should clarify their meaning and scope. The following are Codex definitions:

Audit is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives. (CAC/GL 26-1997).

Inspection is the examination of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify they conform to requirements. (CAC/GL 26-1997).

The term **examination** is used in CAC/GL 26-1997 and includes both documentary material and on-site verification.

7. A Codex definition for “**review**” does not exist and, as the term is used regularly in discussions, should be properly defined.

8. The approach of foreign on-site audits and inspections to this task is often inconsistently applied. There are often differences between audits conducted domestically and those conducted in a foreign country.

9. The terms evaluation, audit team inspection, on-the-spot audit and on-site visit can be ambiguous. For the purpose of this paper the terms evaluation, audit team inspection, on-the-spot audit and on-site visit will encompass the concepts of audit, visit and inspection. These terms need further discussion and agreement.

10. There is recognition between Codex members that increasing resources are required to complete foreign on-site audits and inspections. By developing a consistent approach Codex members will have confidence that decisions in relation to the trade in food are consistent with member’s rights and obligations under the World Trade Organization (WTO) Agreements (Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) in respect of being accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country. A consistent approach to reviews of exporting country food inspection and certification systems will ensure fair practices in the food trade and contribute to the objective of protecting consumer’s health.

11. Consideration should also be given to Article 8 of the WTO/SPS Agreement and to Annex C in relation to confidentiality of information arising from the operation of control, inspection and approval procedures to protect legitimate commercial interests.

12. In developing principles and guidelines the Committee should outline a standard method for how importing countries conduct on-site audits and inspections of exporting country food inspection and certification systems by promoting a systems-based approach. A systems-based approach can more easily be applied consistently regardless of the objective and scope of the evaluation that takes place.

13. The principles and guidelines should provide a transparent framework in which risk assessment and risk management of the exporting country's food control systems are assessed. This in turn provides the importing country with confidence in the safety of imported food. The guidelines assist with the consistent application and implementation of Codex principles, guidelines and standards and could be used to support implementation of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003).

14. In undertaking this work the Committee should take into consideration existing international standards which relate to audit procedures developed by other internationally recognised organisations, in particular the International Standards Organization (ISO).

Scope of the proposed new work

15. In scoping the content of proposed principles and guidelines the Committee will need to identify the rationale (or objective) for conducting on-site audits and/or inspections of foreign food inspection and certification systems which may be:

- to verify exporting country compliance with importing country requirements for new or existing trade in specific commodities between two countries;
- to verify the effectiveness of the exporting country's measures in delivering food safety objectives;
- to verify changes or improvements to existing measures following repeated non-compliance with importing country measures; and
- to complement the documentary review carried out in the process of determination of equivalence.

16. Other areas that should be covered by the proposed principles and guidelines include:

- Definitions;
- General Principles for conducting foreign on-site audits and inspections;
- Defining the Objective/Scope and Rationale for undertaking foreign on-site audits and inspections;
- Defining the Procedures associated with undertaking foreign on-site audits and inspections; and
- Reporting the findings and conclusions of foreign on-site audits and inspections.

Conclusion and Recommendation

17. Evaluation of the risk assessment and ongoing evaluation of the risk management is necessary for exporting countries. Given the increasing use of foreign on-site audits and inspections to verify inspection and certification systems and assess compliance with equivalence determinations or agreements of those systems there is a clear need for CCFICS to develop Principles and Guidelines for the Conduct of Foreign On-Site Audits and Inspections in order to provide a consistent framework that may be applied by both importing and exporting countries in the conduct of fair practices in the international trade in food. The reports of these evaluations may also be used by third countries to form their own assessments of exporting countries' systems, particularly for developing countries that

may not have the resources to conduct their own evaluations. The development of clear principles and guidelines for such evaluations would have wide reaching benefits to both importing and exporting countries.

18. The Committee is invited to consider the proposed framework provided at Attachment 1 and to forward the proposal for new work, as outlined in the Project Document at Attachment 2 for approval by the 31st Session of the Codex Alimentarius Commission in 2008.

ATTACHMENT 1**Proposed outline for Development of Principles and Guidelines for the Conduct of Foreign On-Site Audits and Inspections****Objective**

1. To develop principles and guidelines for the conduct of foreign on-site audits and inspections of food safety control systems that would ensure a consistent systems-based approach to the evaluation of food safety systems in order to objectively evaluate whether the measures of an exporting country achieve the importing country's appropriate level of protection (ALOP³).

Definitions

2. This section should incorporate existing CCFICS definitions for terms such as audit, inspection, legislation, competent authority, requirements, official accreditation, official inspection systems and official certification systems etc.

General Principles for conducting on-site audits and inspections

3. This section will provide a short and concise set of principles relating to the conduct of foreign on-site audits and inspections.

Objective/Scope and Rationale for undertaking an on-site audit or inspection

4. This section would include the type of information to be exchanged during the initial request by the importing country to undertake an on-site audit and/or inspection and agreement on the scope/objective/rationale. The type of information that may be needed is:

- a) The scope of the on-site audit and/or inspection, that is, if the audit is to cover components, measures or technical requirements⁴ within a system or a whole system; the audit scope should be defined prior to the commencement of the on-site audit and/or inspection;
- b) Selection of the number and type of establishments, regulatory sites, etc, that are to be visited;
- c) Purpose of the on-site audit and/or inspection, for example, to verify specific measures, to assess compliance with equivalency agreements. In defining the purpose it would be useful to state which components of a food safety system – the initial risk assessment and/or the ongoing risk management - are to be evaluated;
- d) The legitimacy and legal basis for the on-site audit and/or inspection;
- e) Guidance on audit planning procedures;
- f) Supporting data to be submitted by the exporting country during or prior to the on-site audit and/or inspection; and
- g) Information relating to the selection of the number and type of establishments, regulatory offices, laboratories etc that are to be visited.

3 Guidelines for Food Import Control Systems CAC/GL 47-2003 – ALOP is the level of protection deemed appropriate by the country establishing a sanitary measure to protect human life or health within its territory. (This concept may otherwise be referred to as the 'acceptable level of risk').

4. Technical requirements in the sense of the TBT Agreement are also the subject of foreign audit inspections for example halal slaughtering systems and organic production systems.

Procedures associated with undertaking an on-site audit and/or inspection

5. This section would clearly outline the procedures associated with foreign on-site audits and inspections and what should be agreed between the importing and exporting country competent authorities before the on-site audit and/or inspection takes place. This may include:

- General - administrative guidelines, contacts etc. for example:
 - a) Initial request including timing of the on-site audit and/or inspection, entry and exit meetings, selection and notification of individual establishments to be visited, length of time the evaluation will take etc;
 - b) Determination on who pays for the on-site audit and/or inspection;
 - c) Who will arrange the internal travel etc in the exporting country; and
 - d) An outline of the number of importing country representatives and their competence; will they be accompanied by the competent authority of the exporting country.
- Audit Initiation (notification, agreement on scope etc)
- Preparation of the Audit Plan (Collection of necessary information, logistics, time frames etc)
- Conducting the Audit (actual audit)
 - a) Opening or Entry Meeting
 - b) Audit Execution
 - Document review
 - On-Site audits and inspections
 - c) Closing or Exit Meeting
- Initial Audit Report (Report preparation and process for distribution)
- Dispute Resolution Process (Process to resolve differences of opinion of findings)
- Final Audit Reporting Process – how and where the final report is published and circulated
- Corrective Action and Follow-Up (Understanding of expectations after the final report)

Reporting the findings and conclusions of on-site audits and inspections

6. This section should clearly outline:

- a) How the results of the evaluation will be conveyed to the exporting country – including findings, non-compliance and recommendations;
- b) Reporting – the format and the type of information to be included in the final report;
- c) Report availability – including timings for its finalisation and the timeframe for the exporting country to respond;
- d) Right of response by the exporting country to the findings, including publication of this response; and
- e) How corrective actions will be communicated and agreed to, including how follow-up verification will be completed.

ATTACHMENT 2**Project Document****Proposal for New Work – Codex Committee on Food Import and Export Inspection and Certification systems****PROPOSAL TO DEVELOP PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF FOREIGN ON-SITE AUDITS AND INSPECTIONS****Prepared by: CCFICS****Purposes and scope of the proposed standard**

The purpose of the proposed standard would be to consolidate existing work on the conduct of foreign on-site audits and inspections into a single document and to develop principles and guidelines for these activities.

Its relevance and timeliness

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

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

Given the importance and prominence of these importing country assessments in order to ensure consistency of approach Codex development of a Guideline document will ensure fair practices in the food trade and contribute to protection of consumers' health.

The main aspects to be covered

There are really two aspects to the work: 1) the examination of existing Codex texts; 2) the development of principles/guidelines. We suggest these aspects need to be made clearer and that both need to be delineated, for example.

The main aspects of the work are the following.

- 1) The examination of existing CCFICS (and Codex texts) to identify the relevant provisions contained in various CCFICS texts as to when and why a foreign on-site audits and inspections might be conducted.
- 2) The development of principles and guidelines for the conduct of foreign on-site audits and inspections. The document will provide a consistent framework for a systems-based approach to the conduct of foreign on-site audits and inspections.

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

The proposal is consistent with the criteria as follows:

Diversification of national legislations and apparent resultant or potential impediments to international trade:

Several countries or groups of countries have developed their own legislative frameworks regarding foreign on-site audits and inspections. The envisaged guidelines would provide essential guidance on the consistent conduct of foreign on-site audits and inspections to the benefit of both exporting and importing countries and international trade. Current diverse conduct of such evaluations results in suboptimal outcomes and impedes international trade.

Scope of work and establishment of priorities between the various sections of work:

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

Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body (ISO):

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

In developing these guidelines CCFICS will take into consideration international standards already set for example the International Standards Organization (ISO).

Relevance to Codex Strategic Objectives

The proposal is consistent with Goal 1 Promoting Sound Regulatory Frameworks of the Codex Strategic Plan 2008-2013 which states:

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

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

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

Information on the relation between the proposal and other existing Codex documents

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

Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003) and the Principles and Guidelines for Imported Food Based on Risk (adopted in 2006).

Identification of any requirement for and availability of expert scientific advice

None required

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

None required

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

Subject to Commission approval at its 31st session in 2008, it is expected that the work can be completed in three to four years with:

- commencement of work and consideration of a scope for the consolidated text by CCFICS 16 in 2007;
- consideration at Step 3 by CCFICS 17 in 2008;
- consideration at Step 5 by CCFICS 18 in 2009; and
- adoption of the proposed Guidelines by the Commission in 2010.