

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 4

CX/FICS 02/11/4
September 2002

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Eleventh Session

Adelaide, Australia, 2 – 6 December 2002

PROPOSED DRAFT GUIDELINES FOR THE UTILIZATION AND PROMOTION OF QUALITY ASSURANCE SYSTEMS TO MEET REQUIREMENTS IN RELATION TO FOOD

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 15 November 2002** to: Codex Australia, Agriculture Fisheries and Forestry - Australia GPO Box 858, Canberra ACT, 2601 (fax: 61.2.6272.3103; E-mail: codex.contact@affa.gov.au), with a copy to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy (Fax No + 39.06.5705.4593; E-mail: codex@fao.org).

BACKGROUND

1. At its 10th Session (February 2002) the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS)¹ discussed the proposed draft Guidelines for the Utilization and Promotion of Quality Assurance Systems to Meet Requirements in Relation to Food. The terms of reference for CCFICS include: *“to develop guidelines for the utilization, as and when appropriate, of quality assurance systems to ensure that foodstuffs conform with requirements and to promote the recognition of these systems in facilitating trade in food products under bilateral/multilateral arrangements between countries”*. Members noted broad support for the continuation of this work, and comments regarding how to achieve progress, particularly the possibility of developing a set of principles on which to base further work.

2. The Committee returned the Proposed Draft Guidelines to Step 2 for revision by a drafting group led by Australia, with the assistance of Canada, Denmark, France, India, Japan, the Netherlands, New Zealand, Papua New Guinea, South Africa, Switzerland, the United States and the European Commission. The Committee agreed that the revised document would reflect appropriate principles. The revised document would then be submitted for circulation, additional comment and further consideration at the 11th CCFICS.

¹ Alinorm 03/30 paragraphs 76 – 84.

3. The drafting group in examining the revised version of the document that was presented at 10th CCFICS agreed that in order to progress the revision within the guidance given by the committee² that it should focus the work initially on developing a set of principles. The drafting group accordingly has elaborated a stand-alone principles document, while noting that the principles may be incorporated into a detailed guideline document at a later stage.

4. The principles document (Annex 1) addresses QA systems that are voluntarily implemented by businesses. The document does not address the possibility that the competent authority of an exporting or importing country may make the use by business of QA systems mandatory.

RECOMMENDATIONS

5. The 11th Session of CCFICS is invited to consider the proposed draft principles and consider options for advancing this work, in particular:

- advance the Proposed Draft Principles for the Assessment and Recognition of Quality Assurance Systems to Meet Requirements in Relation to Food within the Codex step procedure
- resume work on a detailed guideline document
- if the Committee agrees to resumption of work on a detailed document, what elements should be included in a detailed guideline, noting the contents of the detailed document revised following the 10th CCFICS covered:
 - Preamble
 - Principles
 - Scope
 - Definitions
 - Responsibilities
 - Specification for a QA system
 - Official recognition of QA systems
 - Characteristics of an official assessment program
 - Assessment of officially accredited bodies.

² Alinorm 03/30 paragraph 84.

PRINCIPLES FOR THE ASSESSMENT AND RECOGNITION¹ OF QUALITY ASSURANCE SYSTEMS TO MEET REQUIREMENTS IN RELATION TO FOOD

PREAMBLE

1. A food quality assurance (QA) system is a management system implemented by a business. It has a defined structure with documented procedures and processes for activities in respect of pre-harvest, harvest, processing, transport and/or, storage that can affect the final product. It includes processes for monitoring the system's performance against its stated aims, through detailed record keeping, internal and, as appropriate, external auditing. A QA system may incorporate Good Manufacturing Practices (GMP), and Hazard Analysis and Critical Control Points², (HACCP) or other food safety elements and systems.
2. It is increasingly part of business practice to use QA systems to:
 - help ensure that customer demands are met
 - improve quality³ and product consistency;
 - reduce wastage and costs of production;
 - increase consumer and / or government confidence;
 - increase market access;
 - improve staff and management commitment to quality including food safety; and,
 - decrease business risk such as legal and insurance costs.
3. In appropriate circumstances, official assessment of QA systems may be a cost effective means of assuring food conforms to requirements. Competent authorities are able to employ inspection options that include audit techniques to ensure regulatory requirements are achieved. One benefit may be that official inspection resources can be more efficiently and effectively applied.
4. The following principles do not suggest or imply that competent authorities of exporting or importing countries should require food businesses to utilise QA systems to ensure food produced meets regulatory requirements, nor that these authorities should necessarily accept that a commercial QA system instituted by a food business is an adequate means of ensuring food produced meets requirements. Additionally these principles do not mandate the use of any particular QA system.

SCOPE

5. This document sets out principles directed to governments and their competent authority(ies). The principles are intended to be applied to both exporting and importing countries.
6. The principles relate to:
 - the official assessment of QA systems that are implemented by businesses, in conformity with the specifications of the competent authority, to achieve compliance with regulatory requirements, and, as appropriate, as a basis for export certification; and,

¹ The term "recognition" is used in this document in a general sense and without any implication that recognition by a competent authority of a QA system will necessarily involve formal approval or certification of the system. As a matter of policy the competent authority of some countries may choose to accord recognition in a formal manner to QA systems operated by businesses that wholly or partly ensure that requirements are met: the competent authorities of other countries may choose not to do so.

² as described in the Annex to the Codex International Recommended Code of Practice: General Principles for Food Hygiene (CAC/RCP 1-1969, rev 3 (1997)).

³ The *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995) includes the statement "the confidence of consumers in the quality (including safety) of their food supply depends in part on their perception as to the effectiveness of food control measures". On this basis the term "quality" in this guideline includes food safety.

- recognition by the competent authority of an importing country of QA systems operated by businesses, which may include acceptance of official certification provided by the competent authority of an exporting country.

DEFINITIONS

*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.

*Equivalence** is the capability of different inspection and certification systems to meet the same objectives.

*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 that they conform to requirements.

Official assessment of a QA system is the inspection [surveillance] and evaluation activities conducted by or on behalf of a competent authority having jurisdiction, to determine whether a QA system operated by a business produces food that meets regulatory requirements.

Quality assurance system Organisational structure, procedures, processes and resources needed to assure product quality for a food business. Elements may include, as appropriate, good hygienic practices, good manufacturing practices, and food safety programs such as HACCP.

*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.

*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.

GENERAL PRINCIPLES

7. Governments retain the fundamental responsibility to provide assurance or to verify, by official inspection and, where appropriate, certification, that food or food control systems conform to requirements.

8. The competent authority should have adequate legislation and resources to operate its official inspection and certification system and ensure that the objectives of the system are met.

9. The responsibilities of all parties involved in implementing, inspecting and assessing systems for control of food quality should be clear.

10. The assessment by a competent authority of QA systems implemented by businesses may be a valid means by which a competent authority determines compliance with specific regulatory requirements. The determination of compliance should be based on objective evidence that the system has the ability to reliably ensure that regulatory requirements are met.

11. Voluntary utilization of QA systems by food businesses should be encouraged⁴ by the competent authority, as the inspection of QA systems may provide enhanced ability of the competent authority to verify and enforce specific regulatory requirements.

⁴ *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26 1997), Section 4, Quality Assurance (CAC/GL 26 1997)

PRINCIPLES IN RELATION TO OFFICIAL ASSESSMENT OF QA SYSTEMS⁵

12. The competent authority should specify the elements of QA systems that it may assess in order to determine compliance with regulatory requirements.
13. The competent authority should have a system capable and appropriate for assessing QA systems implemented voluntarily by businesses, where such systems are intended in whole or in part to meet regulatory requirements.
14. The manner in which QA systems are specified and assessed by the competent authority should be sufficiently flexible to allow a business to meet the expectations of its customers, while ensuring that regulatory requirements are met.

PRINCIPLES IN RELATION TO RECOGNITION OF QA SYSTEMS

15. The competent authority of an importing country should accept that certification provided by an exporting country may be based, partly or wholly, on the assessment by the competent authority of the exporting country of QA systems that are implemented by businesses.
16. Measures applied by an exporting country which allow for requirements to be met by officially assessed QA systems implemented by business may be the subject of a request for an equivalence determination.
17. Recognition of QA systems by the competent authority of an importing country should not result in discrimination against nations or exporters that meet requirements of the importing country in other ways.
18. Recognition should not favour or impose a specific type of QA system.
19. Where QA systems are recognized by importing country authorities, the criteria and procedures to obtain recognition should be communicated in a transparent manner to all interested parties.

⁵ This includes cases where the importing country has cause to directly assess the QA system operated by business in an exporting country.