

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
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WORLD HEALTH
ORGANIZATION

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Agenda Item 7

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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION
AND CERTIFICATION SYSTEMS
Seventh Session
Melbourne, Australia, 22 - 26 February 1999**

**Discussion Paper on the Development of Guidelines for the Utilisation and Promotion of
Quality Assurance Systems**

Paper prepared by Australia

Background

Following considerable discussion in regard to a discussion paper¹ on this issue, the Committee at its Sixth Session in Melbourne agreed that it would be appropriate to keep the topic of quality assurance systems on its agenda and that a further discussion paper would be prepared for consideration at the next Session. The government of Australia offered to coordinate the preparation of such a paper².

2. The terms of reference of CCFICS include: “to develop guidelines for the utilisation, 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 by countries”.³

3. The *Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems*⁴ state that the voluntary utilisation of quality assurance by food businesses should be encouraged, and that if safety and/or quality assurance tools are used by food businesses, the official inspection and certification systems should take them into account, in particular through the adaptation of their control methodologies. They go on to say that governments do, however, retain the fundamental responsibility to ensure through official inspection and certification the conformity of foodstuffs to requirements; although the degree to which industry utilises quality assurance procedures can influence the methods and procedures by which government services verify that requirements have been met.

¹ CX/FICS 98/9

² ALINORM 99/30, PARAS 59-61

³ Codex Alimentarius Commission Procedural Manual, tenth edition.

⁴ CAC/GL 26-1997, Section 4

4. The committee's consideration of quality assurance systems to date may be characterised as one of divided opinion as to the need for the elaboration of information and/or guidelines on this subject (while avoiding endorsement of any specific proprietary or commercial system of quality assurance).

5. Previously, the Delegation of France did much valuable work on the application of ISO 9000 series quality assurance systems to the food industry and, at the direction of the Committee, issued an information letter concerning these applications.⁵

6. The Committee's previous consideration of this subject, particularly at its Fourth and Fifth Sessions, has noted that clarification was needed of the relationship between quality assurance systems, the Hazard Analysis and critical Control Point (HACCP) system, and other food safety management systems.

7. This discussion paper re-examines the issues and suggests means which CCFICS may wish to utilise in order to fulfil its terms of reference in respect of quality assurance systems.

Role of Quality Systems in the Food Industry

8. There are several different models for quality systems⁶ available for adoption by food businesses and for potential recognition by government services. In Australia alone there are at least twelve different models for quality systems, most of which are based on the ISO 9000 series of quality system models. Some employ HACCP and some are targeted at specific sectors of the food and/or agricultural industries. Several of the models are commercial products, the copyright in some cases belonging to industry associations, third party certification/registration bodies⁷ or government bodies.

9. The extent to which they are being used by the food industry is difficult to estimate, the only commonly published statistics being for the ISO 9000 series, and figures for sales and implementation of many of the other standards being unavailable for commercial reasons.

10. Quality systems have long been employed by food businesses to improve quality, reduce costs of production and wastage and to meet customer demands. Customers of the food industry are increasingly demanding higher food safety standards and this has resulted in recognition of food safety as a key quality attribute, and as one able to be covered by quality systems.

11. Regulatory authorities are, likewise, aware of increasing societal pressures to assure the highest levels of food safety. At the same time, regulators recognise the need for both an affordable and safe food supply and that food inspection and certification systems must be both effective and efficient in their operation. These pressures have seen increasing emphasis given to the creation of quality systems that are amenable to audit at intervals and allow less than a full-time, and therefore less costly, regulatory presence. The challenge for regulators is to devise systems which ensure hazards to food safety inherent in a particular food production operation are identified, are actively controlled and can demonstrate that potential hazards remain under control.

⁵ ALINORM 97/30A, para 21

⁶ The term "quality system" used in the paper includes "quality assurance systems".

⁷ In some countries, the bodies which verify conformity of quality systems to specified standards are called "certification bodies" in others "registration bodies", in others "assessment and registration bodies" or "certification/registration" bodies, and in still others "registrars". For ease of understanding, the ISO convention of referring to such bodies as "certification/registration bodies", is used in this paper.

12. Companies which can effectively respond to these food safety regulatory challenges through the adoption of their quality systems can rightly expect a diminished level of regulatory intervention, commensurate with their demonstrated level of performance. This can result in direct cost savings to industry parties especially under official food inspection and certification systems which operate on a cost recovery basis. However, the general production efficiency savings inherent to effectively operating quality systems offer significant industry cost savings, including under circumstances where regulatory services are not charged to industry.

Role of HACCP in a Quality System

13. Codex has elaborated HACCP principles and encouraged their adoption at the level of individual food production processes in order to best assure food safety. It is the individual process basis of HACCP plans which lends them to integration into quality systems, the latter also addressing individual processes or facilities.

14. There are diverse approaches on the part of regulatory bodies to requiring the application of HACCP principles as either a mandatory or voluntary system. However, in recent years a number of countries have mandated HACCP, including in respect of the meat and dairy processing industries. It can be expected this trend will continue. At the same time the food industry are moving to incorporate HACCP into their quality systems in order to satisfy both regulatory demands and customer expectations. In this regard, a number of major European supermarket chains are specifying companies operate HACCP-based quality assurance systems in order to satisfy their quality, including food safety, expectations. These demands are, in part, driven by the need to be seen to have exercised “due diligence” in ensuring the safety of the food (and other products) offered for sale.

15. The ISO 9000 series, in particular, has been the subject of criticism in the past because some food companies have been certified/registered by third party certification/ registration bodies although their system documentation either lacks any references to food safety or does not adequately address all the relevant food safety issues. Since the publication of ISO/IEC Guides 61 and 62 relating to the competence of accreditation and certification/registration bodies and their staff, and because of the influence of the International Accreditation Forum⁸ the likelihood of such systems being certified/registered, at least by accredited certification/registration bodies, is now much less.

16. At least one national standards making body has developed guidance texts to assist food companies to apply the ISO 9000 series and HACCP. These include Guidelines⁹ that, to quote the publishers, “address the issue of food safety and indicate where HACCP systems are used, showing how they are complementary and fit in with ISO 9000 requirements”. The same organisation has also produced a Handbook¹⁰ which maps the ISO 9000 clauses to the HACCP Principles.

⁸ The International Accreditation Forum (IAF) is an association of accreditation bodies that accredit certification/registration bodies as complying with the relevant international guidance documents relating to competence, impartiality and integrity of process. Under the auspices of ISO the IAF is developing a multilateral mutual recognition agreement that will lead to acceptance of the concept of “one audit, accepted globally” for certifications/registrations to the ISO 9000 series. Thirty five countries are currently participating in the IAF.

⁹ *Guide to AS/NZS ISO 9001:1994 for the food processing industry.* AS/NZA 3905, 13:1998, QR/2, ISBN 0 7337 1940 6

¹⁰ *Correlation between AS/NZS/ISO 9002:1994 and the HACCP Principles.* QR/2, ISBN 0 7337 1752 7

Implications for the International Food Trade

17. Against the background of expanding adoption of quality systems (including systems which incorporate HACCP) for food moving in international trade, it is evident that official food inspection and certification systems need to be sufficiently flexible to accommodate these approaches. CCFICS has previously stated¹¹ that the introduction or use of such a system was voluntary but could, as required, be taken into account by competent authorities.

18. In order to assist the work of competent authorities in respect of quality systems and to facilitate international trade, it would appear desirable that Codex elaborate guidance on key aspects, including:

- compatibility of quality systems and HACCP;
- features of a good quality system model;
- the advantages and disadvantages of integrated systems;
- the use of HACCP as a certification/registration standard;
- relationship with regulatory requirements;
- typical auditing procedures;
- typical audit scopes and frequencies;
- typical auditor competencies;
- surveillance frequencies;
- the difference between validation and verification;
- scope for using third party certification/registration bodies;
- training; and
- the capability of systems to provide equivalent outcomes.

19. A suggested outline for proposal guidelines for the utilisation of quality systems by food import and export inspection and certification systems is at Attachment 1.

RECOMMENDATION

20. It is recommended that CCFICS considers the elaboration of appropriate guidelines in this area as a new work item.

¹¹ ALINORM 97/30A, para 85

SUGGESTED OUTLINE FOR PROPOSED GUIDELINES FOR THE UTILISATION AND PROMOTION OF QUALITY SYSTEMS BY FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

SECTION 1 - SCOPE

SECTION 2 - BACKGROUND

- reasons why food businesses implement quality systems
- possible scope for increased assurance to be recognised and acknowledged by government services
- scope for inclusion in bilateral/multilateral arrangements

SECTION 3 - DEFINITIONS

SECTION 4 - QUALITY SYSTEM STANDARDS/MODELS

- wide range of available models
- generic/food specific/sector specific/commercial/regulatory models
- relationship with HACCP
- integrated systems - advantages/disadvantages
- suitability/unsuitability of HACCP as a certification standard
- elements of quality systems that are typically relevant to HACCP and conformance to regulatory requirements
- options for incorporating regulatory requirements
- partial or phased implementation of quality systems
- relationship between quality systems and product inspection
- relationship with environmental and other management systems

SECTION 5 - ASSESSMENT OF QUALITY SYSTEMS

- validation and verification
- typical assessment procedure
- typical auditor competencies
- relevant ISO/IEC Guides
- government control of the process
- use of existing accreditation infrastructures
- dealing with changes to quality systems and new products/processes
- ongoing surveillance audits/testing

SECTION 6 - RECOGNITION OF QUALITY SYSTEMS

- conditions for recognition
- options for redirecting inspection resources
- importance of retaining government control
- consultation with importing countries
- scope for bilateral/multilateral agreements
- capability versus performance
- dealing with non conformance