codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/FICS 02/6**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS
Tenth Session
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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 30 November 2001** to: Codex Australia, Agriculture, Fisheries and Forestry - Australia GPO Box 858, Canberra ACT, 2601 (telefax: +61.2.62723103; 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. The 9th Session (December 2000) of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) discussed[1] the proposed draft Guidelines for the Utilization and Promotion of Quality Assurance Systems to Meet Requirements in Relation to Food, and noted that the objective of the guidelines was to provide advice to governments and their official and officially recognized inspection and certification bodies in the case that an enterprise had established a quality assurance system.

2. The Committee returned the proposed draft Guidelines to Step 2 for revision and requested the drafting group (Australia, with the assistance of Canada, Denmark, France, India, Japan, Morocco, the Netherlands, New Zealand, South Africa, Switzerland, the United States and the European Commission) to revise the document based on the Committee's discussions and written comments submitted for circulation, additonal comment and further consideration at the 10th CCFICS.

RECOMMENDATION

3. It is recommended that the Committee review the attached proposed draft guidelines and consider appropriate amendments.

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1 ALINORM 01/30A, paras 57 – 69.

PROPOSED DRAFT GUIDELINES FOR THE UTILIZATION AND PROMOTION OF QUALITY ASSURANCE SYSTEMS TO MEET REQUIREMENTS IN RELATION TO FOOD (At Step 3)

SECTION 1 - SCOPE

1. This document provides guidance on how quality assurance (QA) systems implemented by food businesses may be officially recognised, through a process of assessment by official or officially recognised assessment bodies. These Guidelines are applicable where governments choose to recognise that QA systems, including voluntary certification QA systems, may assist in ensuring food regulatory requirements are met for official food inspection and certification purposes.

2. The Guidelines should be read as an elaboration of the Quality Assurance section of the "*Guidelines for Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems"* (CAC/GL 26-1997).

3. Businesses may choose to implement QA systems for meeting commercial and/or regulatory requirements including safety. However these guidelines do not mandate the use of QA systems, nor HACCP[1], and they do not promote the use of a particular system.

4. The guidelines provide advisory information on the content of QA systems and explain how HACCP steps and principles may be incorporated into a QA system as a means of achieving compliance with food safety requirements. The aim is to demonstrate the relationship between QA and food safety programs, using a defined, documented and internationally recognised food safety system; there is no implication that the use of HACCP or any other methodology is preferable.

SECTION 2 - ORGANISATION OF THIS DOCUMENT

5. Information relating to the official recognition of QA systems is given in the main body of the document. General elements of a QA system and its implementation and maintenance requirements are given in Annex I. Information relating to HACCP principles and steps is given in Annex II. The correlation of HACCP and elements of a QA system is described in Annex III.

SECTION 3 - DEFINITIONS[2]

*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.

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1 Hazard Analysis and Critical Control Point System and Guidelines for its Application, Annex to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1 – 1969, Rev. 3 (1997).

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

Official recognition is the formal approval or recognition by a government agency having jurisdiction.

Quality assurance system Organisational structure procedures, processes and resources needed to implement quality assurance.

*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.

SECTION 4 - NATURE AND PURPOSE OF QA SYSTEMS

6. A QA system is a business management technique, which operates through implementation of documented procedures and practices. It includes processes for monitoring the system's performance against its stated aims, through internal and, as appropriate, external auditing.

7. QA systems are employed by businesses to

- help ensure that requirements are met
- improve quality[3] and product consistency;
- reduce costs of production and wastage;
- meet customer demands;
- 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.

8. QA systems differ from traditional end point or continuous inspection systems by having a defined structure, documented procedures and processes for all activities in respect of the pre-harvest, harvest, processing, transport, storage etc, that can affect the final product. Final product testing is only part of the system, and is commonly used to verify the performance of system.

9. QA systems are implemented and maintained by businesses. The scope of the system will be defined by the purposes for which the system is set up. For example a business may wish to implement a QA system whose objective is limited to meeting defined regulatory requirements. Some businesses may choose to cover quality aspects beyond regulatory requirements within their QA system. If certification is sought to a recognised international quality system standard, the necessary elements of the system will be defined by that standard. Annex I lists elements commonly included in QA systems.

10. An important characteristic of a QA system (which may incorporate Good Manufacturing Practices, and HACCP) is the inclusion of a clear documented commitment from management covering training, provision of adequate resources to perform defined functions etc. This aspect provides greater confidence to regulatory authorities that the business management is aware of its responsibilities and committed to ensuring food safety controls are in place and are working correctly.

11. The nature of QA systems is such that the program, through which official recognition is achieved, must be capable of examining and assessing all the activities relevant to ensuring regulatory requirements are met. Section 7 deals with assessment programs in more detail.

[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 "quality" in this guideline is intended to include food safety.

SECTION 5 - OFFICIAL RECOGNITION OF QUALITY ASSURANCE SYSTEMS

Assessment process

12. Official recognition of a QA system is achieved when an assessment of the QA system by an official or officially recognised assessment body[4] objectively demonstrates that the QA system meets specific criteria. Annex I lists suggested elements of a QA system that may be considered when developing these criteria.

13. The process of official recognition of a QA system may involve the following steps:

- submission of a request for recognition by the food business to the official assessment body or officially recognised assessment body. The request should contain sufficient information to permit the assessment body to evaluate, on a preliminary basis, whether the business's QA system meets the criteria for recognition;
- initial on-site evaluation of the business's QA system by the assessment body;
- corrective actions by the food business as may be necessary to meet the criteria for recognition;
- follow-up evaluation of the business's QA system by the assessment body to verify that corrective action has been taken and that criteria for recognition have been met;
- recognition of the QA system by the assessment body;
- periodic audits by the assessment body to verify that the food business continues to maintain the requirements for recognition of its QA system.

Assessment bodies

14. Government agency having jurisdiction can directly assess QA systems and/or accredit other parties to carry out assessment of QA systems implemented by businesses for purposes of official recognition. Officially recognised bodies may include regional authorities, and commercial (third party) quality system assessment bodies. For accreditation to be granted initially, the government agency with jurisdiction should ensure that the proposed assessment body meets accepted criteria and is made subject to official verification measures[5.] The government agency with jurisdiction should implement procedures for assessing the ongoing capability of bodies accredited to assess QA systems implemented by businesses for purposes of official recognition.[6.]

15. In order that the impartiality and independence of official assessments of QA systems is not compromised the assessment body, whether government agency with jurisdiction or officially accredited, should maintain clear separation of auditing functions and any advisory services in relation to development and implementation of QA systems.

SECTION 6 - BENEFITS OF OFFICIALLY RECOGNISED QA SYSTEMS

16. QA systems that are officially recognised are a means of assuring that food produced under such a system meet specified food safety and other regulatory requirements.

17. Official recognition of QA systems, or relevant parts of those systems, allows competent authorities to modify inspection methods used to ensure that official food import and export control objectives are achieved, so that regulatory resources can be employed more efficiently and effectively.

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[4] An officially recognised assessment body is an individual or company that has been accredited/formally approved by the government agency having jurisdiction, as capable of performing system assessment functions.

[5] Governments may choose to refer to ISO/IEC 61:1996 *General requirements for assessment and accreditation of certification/registration bodies* which provides criteria for bodies operating accreditation systems for recognition at national or international level.

[6] Governments may choose to refer to ISO/IEC Guide 62:1996 *General requirements for bodies operating assessment and certification/registration of quality systems* which provides criteria that should be met for recognition as a competent, reliable certification/registration body.

This modification can be made without compromise to the competent authority's fundamental responsibility to ensure the conformity of foodstuffs to requirements.

18. Official recognition of QA systems should therefore result in a reduced frequency of official inspections and audits where the system as implemented and operated by a business consistently complies with regulatory requirements.

19. Official recognition of QA systems may facilitate the issuance of official certification for food produced within the scope of such QA systems.

20. Officially recognised QA systems should facilitate international trade through recognition of such systems by trading partners. One mechanism to achieve this is through the use of equivalence or other agreements. Recognition by official or officially recognised food import and export inspection and certification bodies should occur if:

- there is a demonstrated and consistent relationship between the objectives and performance outcomes of the QA system and the identified regulatory requirements; and,
- the elements and implementation of the QA system are consistent with this guideline.

SECTION 7 - CHARACTERISTICS OF AN OFFICIAL ASSESSMENT PROGRAM

21. An assessment program, whether operated by an official body or officially recognised body, has the purpose of evaluating compliance with required elements of a QA system. Assessment should verify that the required elements are in place, are operating to the prescribed standard and are effective in meeting the specified criteria. The confidence delivered by any QA system depends on the comprehensiveness and appropriateness of the QA system implemented by the business in addressing regulatory requirements and adequate rigour in external assessment.

22. The official assessment program system, regardless of whether operated directly by government or an officially recognised third party body, should include:

- adequate resources for operation;
- legislative authority;
- documented specifications or requirements;
- a documented audit management program;
- a sanctions policy and procedures;
- reporting and record keeping policy and procedures; and,
- a communications strategy.

Adequate resources for operation

23. Official assessment systems must have adequate resources to operate verification procedures designed to fully evaluate QA systems implemented by businesses. This includes competent personnel sufficiently trained in the elements of the QA systems and the relevant regulatory authority.

Legislative authority

24. For the purpose of this section legislative authority includes laws, regulations, requirements and procedures issued by authorities related to officially recognized quality assurance systems. Such authority must, at a minimum, provide for:

- officially recognized quality assurance systems;
- official assessment program;
- granting and maintaining official recognition of quality assurance systems;
- varying, suspending and withdrawing official recognition from quality assurance systems.

Documented specifications or requirements

25. Required elements for QA systems should be documented and available to those who seek recognition under the assessment program. The information should cover:

- the process for gaining recognition, including the criteria against which the QA system will be assessed;
- the specific areas for which recognition is offered and its limitations;
- process for complaints/appeals;
- applicable fees;
- rights and responsibilities of applicants; and,
- sanctions that may apply in the event of failure to meet required elements of the QA system.

Documented audit management program

26. Management of an official assessment system for a QA system needs to ensure procedures are followed and defined objectives can be consistently met, regardless of personnel changes. Procedures should include a documented system of audit management, that is periodically reviewed and/or updated, to cover:

- audit programming and scheduling (this may take into account the hazards presented by the particular food products and the performance of businesses under audit);
- audit reporting (including format, recipients and maximum time for reporting);
- follow-up of corrective actions issued and or sanctions that were applied at audit; and,
- protection of proprietary information.

27. The official assessment program is dependent upon an objective audit approach that includes the following steps and/or elements:

- defining the qualifications for auditors of QA systems and the powers for appointing (and withdrawing appointment) of auditors;
- an initial assessment of the documented QA system;
- an initial audit covering the entire QA system as implemented;
- a stipulated audit frequency which should take into account the risk classification of the product type and seasonal factors;
- a policy for variation of audit frequency and scope in response to the compliance performance of the business; and,
- specification of action, including sanctions that may be applied where non-conformities are identified.

28. The audit management program must include food safety qualifications of prospective auditors as well as other elements, particularly auditing methodology. It must include procedures for appointing auditors and withdrawing those appointments. In appointing auditors, the following should be taken into consideration:

- auditors understanding of regulatory requirements
- the formal training and experience of personnel in auditing, food safety, technology and other areas relevant to the auditor's task and status. A classification ranking auditors may be implemented.
- an evaluation of auditor skills including effective communication.
- procedures to consider industry experts onto audit teams, providing that requirements, as appropriate, relating to prevention of conflict of interest are met.
- continuation of auditor status, specifically maintaining skill levels through continuing education and peer review findings.

Sanctions policy and procedures

29. An official assessment program should include a sanctions policy that addresses specific actions and procedures when violations or non-conformities occur by either businesses implementing the QA system or by auditors. These may include the withdrawal of recognition if non-conformities are not addressed or are sufficiently serious to compromise the objectives of the QA system, particularly in relation to food safety.

30. The program should also include an appeals process for the resolution of complaints and disputes.

Reporting and record keeping policy and procedures

31. The assessment of QA systems should accurately record what action has been taken in respect of audit findings, including sanctions as appropriate. Reporting should follow an established format and should be retained for a specified duration.

32. Records should be maintained with due regard for confidentiality. Any legal requirements for keeping reports and other records and maintaining confidentiality/privacy should be incorporated into the assessment program.

Communications strategy

33. An official assessment program should develop a communications strategy so that trading partners, industry and consumers understand how an official assessment program is utilized and the potential benefits derived from a certified QA system.

34. The official or officially recognised certification body may choose to publish general guidance information about how businesses can develop a QA system that will meet stipulated requirements. This is distinct from providing detailed advice to a particular business, where the separation of advisory functions and assessment are critical to avoid any conflict of interest (paragraph 15).

ANNEX I

Suggested Elements of a QA System for Food Production and the Implementation and Maintenance of a QA System

I. Suggested elements of a QA system

1. In general, a QA system should have the same elements whether the system is implemented with the intent of addressing regulatory requirements or commercial objectives, or both.

2. A QA system should be documented in an appropriate manner and include at least the elements listed below.

- purpose and scope;
- defined management structure with stipulated responsibilities;
- product description and intended use;
- established quality objectives, including those required by legislation, for each product covered by the system;
- identification and analysis of factors to be controlled
- purchasing procedures
- process description;
- control measures for minimizing or eliminating factors that can compromise quality;
- recall procedures;
- verification activities including internal auditing;
- documentation and record keeping requirements;
- training policy.

3. The manner in which the elements are documented should be adapted to suit the particular business, rather than narrowly prescribed.

4. Each of these elements is expanded further in the remainder of this section.

Purpose and scope

5. Businesses should document precisely what their QA system is to cover, i.e. what products and processes, operations and outputs are involved, what premises and locations are included, and the objectives (i.e. commercial and/or regulatory) that the system aims to achieve. While the business may determine a range of quality objectives which its QA system is intended to achieve, elements that address regulatory requirements should be specifically identified when documenting the system.

Defined management structure with stipulated responsibilities

6. In order for its QA system to operate effectively, it is critical that the business has a management structure that can support and take ultimate responsibility for the system. The QA system documentation should identify those staff who have specific quality responsibilities and authority in relation to the system's management, and how those responsibilities should be discharged.

7. In order for the QA system to remain effective, management review should occur at least annually to ensure that the purpose and objectives of the system are being achieved and remain relevant.

Product description and intended use

8. A description of each product and its intended use is necessary for determining desired outcomes of their QA system, particularly in relation to food safety. Factors that should be described include:

- characteristics of the product being grown, raised, harvested or manufactured that will impact on

the safety of the final product; subsequent steps in the food chain, such as processing treatments that will reduce or arrest microbial growth; packaging and storage conditions; product composition, including water activity and pH and attributes that inhibit the growth of pathogenic bacteria;

- ingredients added to the product;
- how and where the product will be used or prepared for use, for example whether the product is for further processing, is consumer ready or will be cooked prior to serving; vulnerable consumer groups should also be identified;
- packaging material in respect of its role in product quality; and
- necessary labelling where there are special instructions required for storage or preparation (e.g., "KEEP FROZEN").

Established quality objectives for each product covered by the system

9. Some of the factors that should be considered when determining objectives include:

- food safety and legislative requirements;
- customer requirements; and
- other quality attributes such as consumer expectations.

10. Quality objectives may be described quantitatively or qualitatively in terms of specifications, such as absence of *Salmonella* in a 25g sample, or a range of tolerances, such as packaged weight acceptability between 250g and 255g.

Identification and analysis of factors to be controlled

11. Identification and analysis of factors that can compromise the quality of the foods which are the subject of a QA system is essential to a QA system and is particularly important in the application of food safety management. The range of factors covered will be determined by the scope of the QA system and may include factors other than food safety.

Purchasing procedures

12. The QA system should include a purchasing procedure in order to ensure that raw materials, ingredients and other inputs to the process, conform to the specifications of the QA system. The purchasing controls should extend not only to goods, but also to services such as water supply, transport, hygiene services, laboratory and testing services, pest control etc.

Process description

13. A description of each process is essential to development of a QA system for food production. A process flow diagram is a useful means to document details.

Control measures for minimizing or eliminating factors that can compromise quality

14. Process controls that relate to food safety requirements should be, as appropriate, managed through the application of good practices programs such as good agricultural/ hygienic/ manufacturing practices. These programs serve as prerequisites for the successful application of HACCP.

15. Process controls should cover the entire production flow from the acquisition of raw materials, each processing step and through to dispatch of final product. Inspection and testing of partially finished or in-process product and final product should be included, as appropriate to achieve quality objectives including any relevant regulatory requirements.

16. The operating procedures to be followed during the identified processing steps should be specified and included in process control documentation.

17. The identification of deviations from specification that may compromise food safety or other quality attributes and the timely implementation of corrective action to rectify and prevent re-occurrence of the deviations, are essential elements of a QA system. The system should be able to identify in-process product or final product that does not meet specified requirements. It should also be able to identify structural and equipment faults that lead to deviations from specification. Corrective action procedures should be established to ensure that when deviations occur, process control is restored as soon as possible, affected product is dealt with appropriately, and measures to prevent recurrence of the deviation are implemented.

Recall procedures

18. Appropriate internal and external recall procedures should be defined and incorporated within the QA system to enable efficient and rapid recall or appropriate actions to deal with in process and final product that fails to meet specification. This should include recall from external customers, including parts of the distribution chain that are outside the control of the processor, such as coolstores, warehouses and distributors.

Verification activities including internal auditing

19. The QA system should include procedures for verification of the correct operation of the system. Internal audit procedures and procedures for sampling and testing, where applicable, should be appropriately documented and applied in order to ensure that the specified objectives are met. An internal auditing schedule should give appropriate emphasis to food safety aspects of the QA system. The internal auditing should be undertaken by staff that are not directly responsible for the particular aspect under scrutiny.

20. Verification activities should also ensure that the objectives of a business's QA system are being met and determine whether these remain adequate for the product. Any necessary changes to the QA system should be introduced, following validation, and be appropriately documented.

Documentation and record keeping requirements

21. Documentation of the QA system is essential:

- to set out in detail the responsibilities of those who implement and maintain the system;
- as the basis for objective auditing (internal and external); and,
- to provide evidence that due care has been taken during production and processing.

22. The extent and detail of the documentation will depend *inter alia* on the purpose and complexity of the system. Applicable legislation may specify the nature and extent of documentation required if the system includes elements of regulatory interest.

23. Documents and records typically utilized within a QA system include, but are not limited to:

- specifications for purchasing raw materials, services or other supplies;
- specifications of final product;
- training and qualification records;
- operating procedures;
- internal verification activities including reviews and audits;
- process control records;
- results of inspection and testing;
- procedures to identify and trace product including nonconforming product at all stages of production; and,
- corrective action records.

Training policy

24. The QA system should specify the nature of formal training and experience required for personnel engaged in implementing and maintaining the QA system, in particular any food safety and or regulatory compliance aspect of the control program. Training and qualification needs should be identified for each aspect of the system and may include implementation of procedures. In some circumstances there may be legislative requirements that demand minimum training and qualifications. For example, operators of some machinery such as pasteurizers and retorts; administering livestock medication; and calculating the lethality of a thermal process.

II. Implementation and Maintenance of a QA System

Implementation

25. The implementation of a QA system can be phased using a strategy that best suits the particular food business. Once the QA system is established, or defined elements are implemented, then the system or elements should be verified to ensure objectives set for the system, or part system, are being met.

26. Some possible options for phased implementation include:

- developing appropriate controls over raw materials, through stipulating specifications, then implementing controls and checks to verify that specifications are met, together with a training program for personnel involved in the process to ensure consistent application of procedures.
  - this may lead the QA development process forward, to cover processing, manufacturing, storage and transport steps; or

developing a recall system, which should lead to developing corrective action and controls "backwards" to raw material controls;
developing and documenting responsibilities and training needs for personnel involved in implementing and maintaining the QA system.

27. Phased implementation should not preclude implementation of a QA system proceeding at several discrete points in the production system.

28. The development and implementation of a QA system with a HACCP component should recognize that there exists a critical interdependency between HACCP and prerequisite programs. Good agricultural practice, good manufacturing practice, and good hygienic practice programs, as appropriate for the process, should be operating before HACCP implementation.

Maintenance

29. An established QA system must be maintained to ensure its continued relevance and that is achieves the stated objectives. Change is a normal part of food production and distribution and a QA system must respond to any modification of the relevant processes. The system may need to be amended for various reasons including:

- new product lines or raw material/ingredient sources;
- changes to processing or product formulation;
- adopting new technology, such as automated machinery;
- changes to legislation or customer requirements;
- findings of internal audits and management review;
- findings of external audits;
- new threats to food safety; and,
- new scientific findings or technological solutions related to food safety hazards.

30. Whenever changes are implemented, the effect on other parts of the process or QA system should be considered. The altered system should be validated as being able to achieve the objectives set to meet regulatory, customer and internal requirements, covering food safety quality and other issues. Any training that is necessary as a result of the changes should be provided. Documentation should be updated and circulated to relevant personnel or other parties, including regulatory authorities.

ANNEX II

HACCP PRINCIPLES AND THE STEPS OF HACCP[7]

I. Principles of HACCP.

Principle 1: Conduct a hazard analysis.

Principle 2: Determine the Critical Control Points (CCPs).

Principle 3: Establish critical limit(s).

Principle 4: Establish a system to monitor control of the CCP.

Principle 5: Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

Principle 6: Establish procedures for verification to confirm that the HACCP system is working effectively.

Principle 7. Establish documentation concerning all procedures and records appropriate to these principles and their application.

II. Tasks (Steps) Necessary to Apply the HACCP System .

1. Assemble a HACCP team
2. Describe product
3. Identify intended use
4. Construct a flow diagram
5. On-site confirmation of flow diagram
6. List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards (see Principle 1)
7. Determine Critical Control Points (see Principle 2)
8. Establish critical limits for each CCP (see Principle 3)
9. Establish a monitoring system for each CCP (see Principle 4)
10. Establish corrective actions (see Principle 5)
11. Establish verification procedures (see Principle 6)
12. Establish documentation and record keeping (see Principle 7)

Note: an additional unnumbered step included in the HACCP Annex to CAC/RCP 1-1969, rev. 3 (1997) is that of training.

[7] HACCP is as described in the HACCP Annex to the Codex *International Recommended Code of Practice: General Principles of Food Hygiene* (CAC/RCP 1-1969, rev. 3 (1997)).

ANNEX III

INTEGRATION OF HACCP INTO QA SYSTEMS

1. In some cases legislation may require implementation of HACCP by food businesses. Alternatively, food businesses may voluntarily elect to address food safety aspects through applying HACCP principles and steps when implementing QA systems. In such situations, the steps of the HACCP system, which relate specifically to food safety, can be effectively integrated into a QA system in a way that achieves food safety outcomes and addresses relevant regulatory requirements.

2. When integrating HACCP into QA systems, it is important to consider how the HACCP principles applicable to a particular food safety process may apply within the broader quality management programs of the QA system. Relevant HACCP pre-requisite programs should be operating prior to HACCP implementation. Annex II lists the 7 HACCP principles and the tasks necessary to apply HACCP (often referred to as the 12 HACCP steps). The HACCP steps are correlated here with the broader QA system elements outlined in Annex I.

This table summarises elements of a QA system described in this document and their correlation to the Codex HACCP steps.

HACCP STEP	**EXPRESSED IN QA SYSTEM ELEMENT**
1. Assemble HACCP team .	Purpose and scope Defined management structure with stipulated responsibilities Training policy
2. Describe product	Defined management structure with stipulated responsibilities Training policy Product description and intended use Identification and analysis of factors which can compromise quality (including food safety) Purchasing (goods and services) procedures Training policy
3. Identify intended	Defined management structure with stipulated responsibilities Training policy Product description and intended use Established quality objectives for each product covered by the system Identification and analysis of factors which can compromise quality (including food safety) Training policy

HACCP STEP	EXPRESSED IN QA SYSTEM ELEMENT
4. Construct flow diagram	Defined management structure with stipulated responsibilities Training policy Process description
5. On-site confirmation of flow diagram	Defined management structure with stipulated responsibilities Training policy Process description
6. List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards	Defined management structure with stipulated responsibilities. Training policy Identification and analysis of factors to be controlled. Control measures for minimizing or eliminating factors that can compromise quality
7. Determine Critical Control Points	Defined management structure with stipulated responsibilities. Training policy.
8. Establish critical limits for each CCP	Defined management structure with stipulated responsibilities Training policy Control measures for minimizing or eliminating factors that can compromise quality
9. Establish a monitoring system for each CCP	Defined management structure with stipulated responsibilities Training policy Control measures for minimizing or eliminating factors that can compromise quality
10. Establish corrective actions	Defined management structure with stipulated responsibilities. Training policy Recall procedures
11. Establish verification procedures	Defined management structure with stipulated responsibilities Training policy Verification activities including internal audit
12. Establish Documentation and Record Keeping	Defined management structure with stipulated responsibilities. Training policy Documentation and record keeping