

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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Agenda Item 5

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

**Ninth Session
Perth, Australia, 11 – 15 December 2000**

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

CANADA

GENERAL COMMENTS

Terminology

Canada notes an inconsistent use of terms throughout the document which may lead to a certain degree of confusion.

Defined terms are being assigned different meanings:

The term “officially recognized” is used in relation to those systems which have been formally approved or recognized by a government agency having jurisdiction. This currently includes “officially recognized inspection systems” and “officially recognized certification systems” but could be expanded to include “officially recognized assessment systems”. The term “officially recognized” generally applies to those bodies which “substitute” for the official body. Accordingly, a QA system developed and implemented by a company would be assessed (by either an official or officially recognized assessment body) through the stipulated assessment system (including audits).

The question that remains to be answered is how to designate, in these guidelines, a QA system that has been found to be operating to the prescribed standard. For the reasons noted above, Canada is concerned with the use of “officially recognized QA systems” (e.g., paragraphs 1, 2, 6). “Certified” may be more appropriate since the definition of certification recognizes audits of quality assurance systems. In fact, “certification” is used in paragraphs 2, 5, 8, 43 - 46.

Terms are often used interchangeably:

Different terms are used in the document, often with the same apparent meaning. Some of these terms are: food control objectives, quality objectives, quality attributes, commercial objectives, commercial requirements, performance outcomes, compliance outcomes, food safety outcomes, food safety aspects, food safety attributes and regulatory requirements.

Consistent use of terms/expressions is encouraged to enhance common understanding. Canada recommends that the above terms, and their application in the guidelines, be scrutinized with the intent to identify those which will be used consistently in the document.

Role of HACCP in QA Systems

Canada supports the demonstration, within the document, of the linkage between HACCP principles and QA systems. However, Canada believes that Section 4 and the Annexes are sufficient to demonstrate this linkage. Canada is concerned that the continuous references to HACCP tend to overly emphasize the application of QA systems in manufacturing food businesses and detract from the valuable role of QA Systems in importing food businesses.

SPECIFIC COMMENTS

Section 3 - Uses and Benefits of QA Systems

Paragraph 4

In order to make a clear link with the concept of “compliance outcomes” (Ref. paras. 15 and 41), Canada suggests rewriting that last sentence as: *These guidelines are applicable for those QA systems that include compliance with regulatory requirements as one of the outcomes.* This also removes the inference that the guidelines are most applicable for those QA Systems that include both regulatory and commercial requirements.

Section 5 - Elements of a QA System

Paragraph 12

Canada suggests to rewrite the 1st sentence as: “A QA system should be documented and aim to include, *as applicable to the food business, the elements listed below.*” This would allow flexibility on the part of the food business, whether manufacturer or importer, to design and implement a QA system that achieves its chosen objectives.

Paragraph 18 - 1st bullet

Canada suggests to replace “safety” with “quality” since many of the characteristics listed in the bullet impact on more than just the safety of the product.

Paragraph 23

Canada suggests deleting the last sentence since the interdependency between HACCP and prerequisite programs is well addressed in paragraph 38.

Paragraph 27

In the 1st sentence, Canada suggests to delete “...or appropriate actions to deal with in process and final product that fails to meet specification”. We believe this is not part of Recall procedures. As well, this concept is already addressed in paragraph 26.

Paragraph 55

Canada is concerned that a formal system for auditor registration or certification may be excessive. The concept should be reviewed in detail to determine what exactly is proposed and what costs it might entail.

INDIA

As HACCP is one of the food safety system presently available, apart from this, every member country has right to develop an equivalent system to achieve the food safety. In view of this, it would be more appropriate if the term HACCP is replaced by “HACCP or an equivalent food safety system” all over the Document.

Initially this document was developed with an objective to integrate the concept the quality assurance system along with food safety system therefore the word “in relation to food” may be deleted.

Section 1

Under this section, a reference may be given to ISO/DIS 15161 - Guidance on the application of ISO 9001 and ISO 9002 in the food and drink industry which also covers the possible interactions of ISO 9000 standards and HACCP.

Section 2

Definition of food safety may also be added as this terminology is used at several places in the Document.

Section 5, Point No. 12

(i) The element of “review” may also be covered in the bullet point “verification activities including internal audit” to read as follows:

“Verification activities including review and internal audit”

(ii) An element to deal with “control of inspection, measuring and test equipment” to also be included as a separate bullet point.

Section 5, Point No. 13

It may be added at the end of the para
“In case of developing countries the implementation of Quality Assurance System with all elements may be carried out in a phased manner.”

Box after Point No. 17

After resources, the following words be added:

“In terms of infrastructure, work environment and trained staff” and the words “including trained staff” be deleted.

Point No. 18

The following words to be included in the last bullet point:

“Expiry date” so that the bullet point reads as follows:

“Necessary labeling where there are special instructions required for storage or preparation (eg keep frozen, expiry date etc).”

Point No. 19

The factors given in first bullet may be separated as sometimes the legislative requirements mandates more than food safety attributes i.e.

- Food safety
- Legislative requirements

Heading of Clause No. 28

The element of review may also be added in the heading to read as follows

“Verification activities including internal auditing and review”

Point No. 30

The following additional bullet point to be added at the end:

“to provide for transparency of the system?”.

Point No. 32

The following additional bullet points to be included:

- manual
- quality policy
- vendor ratings
- job description
- work instructions
- record of customer complaints
- calibration records

In addition, “specification of final product” to be modified as follows

“Specification of final product/regulations of country of destination.”

In addition, “training and qualification records” to be modified as follows:

“Training and qualification records with job descriptions”

Point No. 33

The following to be added in the box at the end:

“This aspect of training is given in the Codex HACCP standard after the 7 principles”.

Point No. 34

The following to be added at the end in the box:

- and if so, then step 8, 9, 10, 11 and 12 will also be applicable.

Point No. 39

Fifth bullet point to be amended as follows:

“Findings of internal audits, customer complaints and management review”

ANNEX 2**Column 2, against Point No. 11**

The third element to be modified as follows:

“Verification activities including review and internal audit”

The following new element to be added:

“Documentation and record keeping”

Column 2, under Point No. 12

All elements is given under **Section 5, Point No. 12** of the document would be applicable.

Benefits of Quality Assurance Systems

As the exercise of implementation of quality assurance systems will not result into the expected objective until and unless it is supported by an exercise of quality building. Therefore, the following para under the Title of “Need for Quality Building Mechanism” should be included.

Need for Quality Building Mechanism

Creation of awareness for quality and food safety among the food industry assumes great significance and it is an important prerequisite for the introduction of quality assurance mechanism. The introduction of quality assurance systems in terms of guidelines as mentioned above, by itself will not ensure large scale introduction in food industry unless there is a simultaneous exercise for creating awareness about the need for and the importance of quality assurance system. Such an exercise of awareness creation and technical guidance should be of continuous and dynamic nature addressing to the changing requirements that will continuously keep emerging even after the quality assurance system is established.

NEW ZEALAND

New Zealand has been involved in the drafting of this paper and supports the recognition of QA systems as having a role in assuring the production of food products that meet the requirements of regulators and purchasers (both foreign and domestic). This concept also fits well with the move for industry to accept more responsibility for producing 'fit for purpose' products and for regulators to focus on system audit/verification rather than prescriptive production requirements.

New Zealand supports the continued development of these guidelines and recommends their progress to step 5.

UNITED STATES

The United States is pleased that significant progress has been made in the development of these guidelines. We believe they will be beneficial to both countries and food manufacturers.

General Comments

The United States believes that greater clarity is needed in the document with respect to the food safety nature of HACCP. It is important to indicate that HACCP is a food safety-focused program. While HACCP can and, as appropriate, should be a component of a quality assurance program, it is important to both separate the function of HACCP from the control of non-safety quality attributes, and to not confuse HACCP with non-safety quality elements. We would recommend the introduction of two sentences in paragraph 3 of Section 1- Scope, to address this need. The sentences would follow the first sentence of paragraph 3 and might read as follows: "HACCP is a system that is science-based and systematic, which identifies specific hazards that must be controlled to ensure the safety of a food product. HACCP relates specifically to food safety but may be a component of a comprehensive quality management system."

The United States believes that the use of boxed sections indicating which HACCP step applies to which element of a QA system is a useful tool that will help users of the document integrate HACCP into QA programs. Additionally, we believe the use of the Steps of HACCP in the text is more helpful than using the Principles of HACCP since the steps are more comprehensive in regard to HACCP application than are the Principles themselves.

Specific Comments

SECTION 1- SCOPE

The United States believes that the primary purpose of these guidelines is the potential recognition and use of QA systems by officially recognized bodies. The implementation of QA systems by food businesses for such purposes and the integration of HACCP into such systems are also components of the scope of this document. With this in mind, we would suggest a rewriting of the paragraph 1 of the Scope section as follows.

These Guidelines outline how quality assurance (QA) systems may be officially recognized to assist in ensuring that food regulatory requirements are met by food businesses and how HACCP may be integrated into such systems. The Guidelines also outline how QA systems may be implemented by food businesses to meet both regulatory and commercial purposes.

Section 2- DEFINITIONS

Quality. Insert the word “is” after *Quality*.

Section 5 – ELEMENTS OF A QA SYSTEM

Paragraph 12. We suggest moving the last bullet point dealing with purchasing procedures up the list, just below the current fourth bullet point, “established quality objectives...”. This would be the logical place for this bullet in the normal sequence of operations.

Purpose and Scope, Paragraph 15. With respect to the HACCP box following the paragraph, we note that Step 1 is indicated to relate to describing the scope of the HACCP plan. Step 1 actually relates to the assembling the HACCP team. While Step 1 may apply to this section, the step that is missing from this HACCP application box is Step 3, identifying the intended use of the product. The preferable steps to note here are steps 2, 3 and 4.

Defined Management Structure and Stipulated Responsibilities, Paragraph 16. First sentence. Change “their” to “its”.

Additionally, re: paragraph 17, the United States would recommend that the frequency of the management review of QA systems should be least annually.

Control Measures for Minimizing or Eliminating Factors that can Compromise Quality, Paragraph 24. Second sentence. Change “part” to “partially”.

Control Measures for Minimizing or Eliminating Factors that can Compromise Quality, Paragraph 26. In the HACCP box following the paragraph. Step 7 (Determine Critical Control Points) and Step 10 (Establish Corrective Action) need to be added. Step 7 is a mandatory prerequisite to steps 8 and 9 and thus its need for inclusion. Step 10 is an important part of the control measures process, thus its need for inclusion.

Verification Activities Including Internal Auditing, Paragraph 29. For clarity replace “their” with “a business’s”.

Purchasing Procedures, Paragraph 34. The United States believes this paragraph more logically fits in the flow of operations between “Established Quality Objectives for Each Product Covered by the System” and “Process Description” and should be moved up accordingly.

Section 6- IMPLEMENTATION AND MAINTENANCE OF QUALITY SYSTEM

Title. Insert “the” before “Quality”.

Implementation, Paragraph 36. First bullet. The word “some” is vague. We suggest replacing it with the word “appropriate.”

Section 7- OFFICIAL ASSESSEMENT AND CERTIFICATION SYSTEM

Paragraph 42. Insert “and/” before “or,” since governments can, if they wish, both directly assess QA systems and officially recognize third parties to carry out assessment activities.

Audit Personnel and Qualifications, Paragraph 53. The United States believes that it is best that audit teams be composed of individuals employed by the official body or the officially recognized body. The United States believes individuals with expertise in a particular industry may provide useful assistance to audit teams in some cases. However, it is not certain that adequate procedures can be drawn up to both prevent conflicts of interest and provide the openness necessary to ensuring that all expert NGO interested parties be considered for use on official audit teams. We believe it best to delete this paragraph.

ANNEX 2

A careful review of the HACCP steps against the Elements of a QA system is recommended to ensure that each of the appropriate HACCP steps are included for each element.