

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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**Agenda Item 5**

**CX/FICS 00/5 Add 1**

**February 2000**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS**

**Eighth Session**

**Adelaide, Australia, 21 – 25 February 2000**

#### **PROPOSED DRAFT GUIDELINES FOR THE UTILIZATION AND PROMOTION OF QUALITY ASSURANCE SYSTEMS**

##### **GOVERNMENT COMMENTS AT STEP 3**

##### **Canada**

Canada is pleased to offer the following comments on the *Proposed Draft Guidelines for the Utilization and Promotion of Quality Assurance Systems for Food Safety, CX/FICS 00/5*

##### **Section 2 - Definitions**

*Quality system* is defined; however, the guidelines refer exclusively to a “quality assurance (QA) system”. As well, the definition of *Quality system* utilizes the term “quality management” which is not used in the guidelines. We suggest to modify the definition as follows:

*Quality assurance system:* Organizational structure procedures, processes and resources needed to implement quality assurance.

##### **Section 3 - Elements of QA System**

##### **Paragraph 5**

We are concerned about the potential for confusion to result from the use of the words “risk factors” and “risk” in bullets 6 and 7 respectively. The concepts in these two bullets have been imported from the HACCP guidelines with the substitution of the word “hazards” by “risk factors” and “risk”. Codex has always clearly differentiated between “hazards” and “risk”; these bullets, as currently written, would appear to blur this distinction.

It would appear that the drafting group intends the expression “risk factors” to include problems that could compromise food safety, quality and other attributes. Although a QA system should address these problems, we recommend, for the reasons noted in the previous paragraph and our comments to paragraph 14, that another term be selected and defined which does not utilize the word “risk”.

### **Paragraph 8**

In addition to specifically identifying those elements that address regulatory requirements, the Purpose and Scope of the QA system should also specifically identify food safety aspects from quality aspects.

### **Paragraph 10**

This paragraph more appropriately belongs under **Section 4 - Implementation and Maintenance of Quality System**. [See additional comments under Section 4]

We agree that this is a role of management, but we think there are other important roles as well. We suggest to add: “Management should routinely review all deviation records (as a minimum) to maintain current knowledge of the status of their manufacturing operations. This includes a sign off to ensure accountability.”

Further, we suggest that the word “policy” be deleted from the sentence. Elsewhere in the document (e.g., paragraph 12), reference is made only to “objectives”.

### **Paragraph 11**

We suggest to modify the second bullet to read: “inputs, ingredients or additives added to the product, including levels/amounts”. As well, we suggest to add an additional bullet: “anticipated shelf life”.

### **Paragraph 13**

We suggest to add, after the first sentence: “This should include a description of each equipment used and the specifications for its operation.” For any one product, the HACCP system implemented is specific to each manufacturing plant and each production line within that plant. The effect of a change in equipment performance on the finished product should be identified and noted if a food safety hazard would result.

### **Paragraph 14**

“Risk” is specifically defined in Codex in relation to adverse health effects consequential to a hazard in food. As such, “risk factors” cannot include issues other than food safety. We suggest (as previously noted in our comments to paragraph 5) that another term be selected in place of “risk

factors”. The new term should be defined to clearly indicate that it includes all problems that could compromise food safety, quality and other attributes.

### **Paragraph 15**

We suggest to add “or prerequisite programs” after “manufacturing practice” in the first sentence.

### **Paragraph 18**

In the second sentence, we suggest to add “incoming ingredients” prior to “in-process product”; i.e., “The system should be able to identify incoming ingredients, in-process product or final product that does not meet specified quality.”

### **Paragraph 19**

Requiring recall procedures is not enough. We suggest to add after the second sentence: “The system should also include specifications for when, or under what conditions to initiate a recall”. We also believe that there should be a distinction between the recalls that are necessary because of food safety concerns versus the withdrawals that are made because of quality problems.

In the second sentence (as per paragraph 18), we suggest to add “incoming ingredients” prior to “in-process product”.

### **Paragraph 20**

We suggest to add the following bullet: “to investigate food safety issues which are often identified weeks or months after the date of production”. From a regulatory perspective, records provide a history of the conditions that existed on any particular processing day.

### **Paragraph 22**

We suggest to add to the list: “process deviation records; consumer complaint and investigation records; production records with corresponding lot numbers; and product distribution records”.

### **Paragraph 23**

In the second sentence, it is not clear whether the word “system” refers to the control program or the QA system. If it is the latter, we suggest to add “QA” before “system” and reverse the order of the second and third sentences.

## **Section 4 - Implementation and Maintenance of Quality System**

### **Maintenance**

As previously noted, we suggest to relocate paragraph 10 under this section. A fundamental requirement of a QA system is the need to verify, on a regular basis, that the system is achieving its objectives, regardless of whether any modifications to the process have been made.

## **Section 5 - Elements of an Official Assessment System**

In this section, the expression “Official Assessment System” is introduced. As well, in paragraph 33, reference is made to a system for assessing the capability of third parties that are operating an official assessment system. It is essential that, wherever the word “system” is used in this section, it is clearly indicated whether it is in reference to the QA system, the official assessment system or the system to assess the capability of the third parties. The section, as currently written, is confusing and should be revised.

### **Paragraph 48**

A new term “QA food safety program” is introduced here. Is this synonymous with QA system? If so, we suggest consistent use of terminology.

## **Appendix 1 - Relationship of HACCP Principles to Elements of QA System**

HACCP principle No. 6 would be more appropriately expressed in a QA system element as follows: “management reviews to verify that the objectives of the system are being achieved”. This element is found in paragraph 10 which we suggest should be moved to Section 4, under Maintenance.

## **India**

### **COVERING NOTE**

1. Background, No comments
2. Rationale for Development of Guidelines

On Terms of Reference, it was expressed that the level of inspection and observation should depend upon basic requirements related to food safety rather than on the level of implementation of quality assurance systems in the industry.

3. On para 5 to para 18, No comments.

### **MAIN DOCUMENT**

1. As indicated in the title of the document, the major objective of preparing these guidelines is to promote and utilize the quality assurance systems for maintaining the food safety. Therefore, wherever the phrase “quality assurance system” is used, it should be replaced by “quality assurance and food safety systems”. Apart from this, in the para 4 of the scope it says “this system may address the commercial elements not of regulatory interest”. Since most of the food safety objectives are generally a part of regulatory interest rather than a commercial element therefore, the Committee recommended that the 4th para may be deleted to avoid dilution of the impact of the usage of this document.

2. Under Section 2 on Definition the Committee desired that the definition of food safety may also be included in this since this terminology is used at several places in this document. The food safety definition may be taken as under :

“Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.”

The Committee recommended that the phrase fair trading which is referred to under the definition of “requirements” may also be explained in this section as a separate definition.

3. Under Section 3,

Clause 5

The Committee recommended inclusion of following elements:

- Preventive maintenance and periodic inspection of production facilities.
- Internal audit
- Responsiveness to change

In the QA system the elements suggested above are very important since preventive maintenance and periodic inspection of production facilities will help in reducing the breakdowns and entry of additional risks. The internal audit would help in reducing the possibilities of drawbacks to be noticed in external audits and improve the level of implementation of the adopted QA system. Keeping into view the dynamics of technology and introduction of new systems responsiveness to change should be an integral part of the system.

Clause 6

It may be added, “ In case of developing countries, the implementation of QA System with all component elements may be carried out in a phased manner.

4. Clause 7 to 11 - No comments

5. Under Established Quality Objectives of each product Covered by the System

The Committee recommended to split the first factor i.e. food safety and legislative requirements and list this as two separate points since sometimes the legislative requirements mandates more than food safety attributes.

6. On Processed Description and Identification and Analysis of Risk Factor - No comments.

7. On Control Measures for Minimizing or Eliminating Risks

The Committee considered that apart from HACCP System there could be other equivalent systems which would result in the food safety and recognized bilaterally or multilaterally among the trading

partners. Therefore, the phrase “or an equivalent system” should be added after “HACCP principle” in 3rd line and the word “and endorsed by Codex” should be deleted.

8. Under Clause 16, 17 & 18 - No comments.

9. The Committee recommended that the testing plays a vital role in the quality assurance systems therefore a separate Clause indicating importance of the basic in-house testing facilities along with method of sampling should be included after Clause 18.

10. In Recall Procedures the phrase “with human safety” should be included in place of “specification” in line 3.

11. In Clause 20 & 21 - No comments

12. Under Clause 22, sub clause 1 may be replaced by “specifications of raw materials, services or other supplies”. The Committee also recommended to include the following:

Internal audit Compliance record of observation of internal and external audit/inspection.

13. Under Clause 23 No comments

14. Under Clause 24 Implementation the Committee recommended to include "or equivalent system" after HACCP in line 3.

15. Under Clause 25-27 - No comments.

16. Under Clause 28 on Maintenance the Committee expressed that since the process of validation is not a one time activity therefore the word “periodically” should be included before “validated” in 2nd line of Clause 28.

17. In Clause 29 and 30 No comments.

18. Under Section 5 Clause 31, the Committee Expressed that the process of verification is also not a one time activity therefore the word “periodically” should be included before “verifying”.

19. In Clause 32 No comments.

20. In Clause 33 word “periodically” may be added before the word “assessing” in the last line.

21. In Clause 34, 37 - No comments.

22. In Clause 38, the Committee suggested to replace the final part of the Clause after the word compromised in line 3 as, the certification body should ensure that advisory services as well as auditing the systems set up in response to advice the two functions are not performed by the same organisation.

23. In Clause 39, 41 - No comments.

24. Under Clause 42 on Audit Personnel and Qualifications the word “or equivalent system” should be added in point 2 in the listed matter after HACCP.
25. In Clause 43, 44 - No comments
26. Under Clause 45 the word “to” in second line should be deleted.
27. In Clause 46, 48 - No comments.
28. Under section on benefits of recognised quality assurance systems under Clause 49 the Committee decided to include “recognised” before “commercial parties”.
29. The Committee felt that 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.

30. The Committee suggested that on the basis of the changes recommended in various Clauses, the necessary changes may be carried out in the Annex I.

#### **International Organization for Standardization**

ISO/TC 34 Secretariat has received the above document from ISO Central Secretariat and has the following comments on it.

#### ***General comments:***

#### **Clause 7, page 2**

It is a fact, that ISO 9000 standards contain general requirements and this is the reason for preparing specific guidelines for the food and drink industry. It was also a demand of ISO/TC 34 members to have an industry specific international standard to assist this sector in understanding the requirements of ISO 9001, being written in the language of the food and drink sector. We do hope that the publication of ISO 15161:2000 will also promote the unanimous interpretation of ISO 9001.

**Clause 9, page 2**

We agree with the facts mentioned in this clause since we have had similar experience. During development of the second ISO/DIS 15161 (see details in comment related to clause 10) we made efforts to clarify for the food businesses that safety is a basic requirement and without its assuring, certification according to ISO 9001 cannot be received.

**Clause 10, page 3**

We would like to inform you that the 2<sup>nd</sup> Draft International Standard (ISO/DIS 15161.2 “*Guidelines on the application of ISO 9001:2000 for the food and drink industry*”) has been finalized, the French version is under preparation and the document is going to be published in the first quarter of this year. The new version of ISO/DIS 15161 follows the structure of the new ISO/DIS 9001 and, in order to avoid repetition and to prepare a document which is easier manageable for the users, includes, in blocks, the relevant clauses or sub-clauses of ISO/DIS 9001.

We agree that the ISO document is prepared primarily for those food businesses which would like to achieve certification according to ISO 9001 standard, and the Codex guidelines will be useful mainly for small businesses not intending to build up the whole quality assurance system specified in ISO 9001:2000. So the ISO and the Codex guidelines will be complementary to each other.

It seems that the number of food businesses operating according to ISO 9000 standards rapidly increases worldwide.

***Technical comments:*****Clause 9, page 2 line 1**

We propose to change “members to certify ISO standards” to “members to certify according to ISO standards”, since certification bodies do not certify the standards themselves, but the quality management system.

**Annex, Section 2 — Definitions****Page 2, paragraph 1 and 2**

We would like to draw your attention to the fact, that the existing ISO 8402 is under revision and will be part of the new ISO 9000:2000. It means that the definitions taken from ISO 8402 standard should be updated, accordingly.