

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 6

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Tenth Session

Brisbane, Australia, 25 February – 1 March 2002

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

COMMENTS AT STEP 3

ARGENTINA

Argentina believes that further development of the Guidelines could be accepted only in the light of their use on a voluntary basis.

From reading this document it is noted that it contains a considerable extent of material that is intended to industry and this is not appropriate within an intergovernmental forum. We do not consider the proposals included in the Draft Guidelines to be appropriate in the employment of industry experts to carry out official audits.

In CAC/GL 26-1997: “Guidelines for Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems” there is a section on Quality Assurance which makes specific mention of the voluntary application of quality assurance in industry¹.

The document places too much emphasis on the HACCP system despite the fact that it is only one amongst various other systems associated with food safety which may be used as set out by the General Principles of the Codex Committee on Food Hygiene.

It is the fundamental responsibility of governments to ensure that food complies with the requirements that have been established in relation to the protection of public health, the protection of consumers and conditions for fair trade practices. Anything else over and beyond this must be of a voluntary nature.

¹ CAC/GL 26-1997 - SECTION 4 – QUALITY ASSURANCE

The *Voluntary utilization* of quality assurance by food businesses should also be encouraged in order to achieve greater confidence in the quality of the products obtained. 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.

Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems have been adopted by the Codex Alimentarius Commission at its 22nd Meeting in 1997. These Guidelines have been sent to all Member Countries and Associated Members of the FAO and the WHO as a text of a guiding nature and it befalls to each government to decide on the use of said Guidelines.

Argentina proposes, therefore, not to continue with the present document.

CANADA

GENERAL COMMENTS

The document makes several references to “required elements of the QA system” without clearly describing what these elements are and how, or by whom, it is determined that they are required. The document also refers to “specific criteria” that a QA system must meet and links these criteria to the elements of a QA system but again, it is not clear who establishes the criteria nor how these two aspects are interrelated.

Canada proposes the following revisions to paragraphs 9 and 12 of the text which we believe provides the necessary clarification. [NOTE: New text is in italics.]

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.

9bis In general, QA systems should have the same elements regardless of the scope and objective determined by the food business for its QA system. Annex I lists elements commonly included in QA systems. If certification is sought to a recognized international quality system standard, the necessary elements of the system will be defined by that standard. In a similar manner, for official recognition, the government agency having jurisdiction will define the required elements of a QA system.

12. Official recognition of a QA system is achieved when an assessment of the QA system by an official or officially recognized assessment body⁴ objectively demonstrates that the QA system meets specific criteria *through the effective operation of the required elements*. Annex I lists suggested elements of a QA system that may be considered *by the government agency having jurisdiction* when developing these criteria.

With these suggested revisions, paragraph 21 is placed more into context; i.e., the assessment program verifies that the required elements are in place and meet the specified criteria.

SPECIFIC COMMENTS

Section 1 - Scope

Paragraph 1: In the 2nd sentence, we suggest to delete the phrase “including voluntary certification QA systems”. It is unclear what is meant by this phrase; as well, the concept is not raised or developed elsewhere in the document.

Paragraph 3: In the 2nd sentence, we suggest to delete the words, nor HACCP, as this issue is already covered in paragraph 4. The sentence would read as follows: *“However these guidelines do not mandate the use of QA systems and do not promote the use of a particular system”*.

Paragraph 4: Further to our comments on paragraph 3, we suggest to add the underlined text in the last sentence: *“The aim is to demonstrate the relationship between QA and food safety programs, using a defined, documented and internationally recognized food safety system; there is no implication that the use of HACCP or any other methodology is preferable or should be a mandatory component of a QA system”*.

Section 3 - Definitions

Definition of Quality assurance system

Add a coma between the words “structure” and “procedures”. The text would read: *“Organisational structure, procedures, ...”*

Section 4 - Nature and Purpose of QA Systems

Paragraph 7: In the 2nd bullet, to improve clarity we suggest to reorder the words as follows: *“improve product quality³ and consistency;”*.

In the 7th bullet, we suggest to delete the phrase “including food safety” since the footnote to the 2nd bullet makes it clear that, for the purpose of this guideline, quality includes food safety.

Section 5 - Official Recognition of Quality Assurance Systems

Paragraph 12, Footnote 4: Suggest to add “QA” before “system assessment functions”. The text would read as follows: *“..... as capable of performing QA system assessment functions.”*

Section 6 - Benefits of officially recognized QA systems

Paragraph 17: In the last sentence, we suggest to add the word “regulatory” since the competent authority’s responsibility is limited to regulatory requirements. The text would read: *“This modification can be made without compromise to the competent authority’s fundamental responsibility to ensure the conformity of foodstuffs to regulatory requirements”*.

Section 7 - Characteristics of an Official Assessment Program

Paragraph 22: We suggest to delete the word “system” after “official assessment program”.

Regarding the last bullet, Canada believes that a communication strategy is given effect through a communication process. Suggest to replace the words “a communications strategy” with “a communication process”.

Paragraph 23: In the 1st sentence, we suggest to replace the word “systems” with “programs”; “verification” with “evaluation and audit”; and “evaluate” with “assess” to maintain consistency with the rest of the document. Also suggest to delete the word “fully” since there is no indication given elsewhere in the document that an assessment would be partial. The sentence would read as follows: *“Official assessment programs must have adequate resources to operate evaluation and audit procedures designed to assess QA systems implemented by businesses.”*

Paragraph 24: In the first sentence, we suggest to add the word “competent” to qualify the authorities to which reference is made. The text would read: *“For the purpose of this section legislative authority includes laws, regulations, requirements and procedures issued by competent authorities related ...”*

In the 4th bullet, we suggest deleting the word “varying” since official recognition is either granted by the assessment body or it is not. If, however, this is intended to mean that certain parts of the QA system may have official recognition withdrawn (reference paragraph 17 which recognizes partial recognition of QA systems), the text should be clarified.

Paragraph 25: Canada notes that the information listed in the bullets relates to the specifications or requirements and not the required elements. As previously noted, the effective operation of the required elements ensures the QA system meets the specified criteria. Suggest to rewrite the opening sentence and modify the bullets as follows: (Note the addition of the word “official” in the opening and the 1st bullet)

Specifications or requirements for QA systems should be documented and available to those who seek official recognition under the assessment program. The information should cover:

- *the process for gaining official recognition;*
- *the required elements of the QA system and the specific criteria against which the QA system will be assessed;*
- [continue with the remaining 5 bullets]

Paragraph 27: To maintain consistency with paragraph 13, Canada suggests that the word “assessment” in the 2nd bullet and the word “audit” in the 3rd bullet be replaced with “evaluation”.

In addition, we suggest that the order of paragraphs 26 and 27 be switched since paragraph 27 appears to address the steps leading to the granting of official recognition and paragraph 26 appears to address the on-going audits to verify that requirements for recognition are being maintained.

Paragraph 28: This paragraph addresses the factors to consider when appointing auditors. Since industry experts included in audit teams are actually technical experts and not auditors, the 4th bullet is not appropriate for this section. Canada suggests making it a separate paragraph after paragraph 28.

Paragraph 29: As Canada has commented on earlier versions, the phrase “or by auditors” implies that sanctions will be levied against the business for the deficiencies of the audits yet it is the official body that provides the audits or accredits the officially recognized assessment body. This is not appropriate. We suggest that this concept (i.e., what action to take when auditors do not appropriately fulfil their responsibilities) would more appropriately be addressed under the previous section; **Documented audit management program**.

Communications strategy: As per comments for paragraph 22, we suggest to change the title of this section from “Communications strategy” to “Communications process”.

Paragraph 33: Consistent with the proposed title change to this section, we suggest to rewrite the start of the sentence as follows: *“An official assessment program should have in place a process of communication so that trading partners,”*

We suggest to replace the word “certified” with “officially recognized”. The text would read as follows: *“...and the potential benefits derived from an officially recognized QA system.”*

Paragraph 34: We suggest to replace the phrase “officially recognized certification body” with “officially recognized assessment body” and the phrase “stipulated requirements” with “specific criteria” to ensure consistency throughout the document.

Annex I

Paragraph 2: We suggest to rewrite the sentence as follows: “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 a QA system which achieves its chosen objectives.

COLOMBIA

Please find following our comment on the document ‘DRAFT GUIDELINES FOR THE UTILIZATION AND PROMOTION OF QUALITY ASSURANCE SYSTEMS TO MEET REQUIREMENTS IN RELATION TO FOOD’

Section 1 - Scope – para. 1 replace in the Spanish version the preposition ‘o’ with ‘u’ as in ‘oficiales u oficialmente’.

Section 1 - Scope – para. 4 delete in Spanish ‘de’ to now read: ‘no hay sugerencia alguna que’.

Section 3 - Definitions – include the definition of CERTIFICATE as a document in writing that is obtained following the certification process.

Section 4 – Nature and purpose of quality assurance systems – para. 9 include the following text: Quality assurance systems are implemented and maintained (see Annex – Definition)

Section 5 – Official recognition of quality assurance systems – para. 4 line 6 we propose to retain in the Spanish version the term ‘somete’ in lieu of ‘someterán’.

Footnotes 5 and 6 on line 2: replace in the Spanish version the word ‘registración’ with ‘registros’.

Footnote 6 replace in the Spanish version ‘dessen’ with ‘deseen’.

Section 6 – Benefits of officially recognised quality assurance systems – para. 20 - line 6, replace in the Spanish version ‘ente with ‘entre’.

Section 7 – Characteristics of an official assessment program – para. 21 - line 4 – replace in the Spanish version ‘vigor’ with ‘vigencia’ and ‘encuentran’ with ‘encuentren’.

Section 7 – Characteristics of an official assessment program – para. 22 - line 4 - replace in the Spanish version ‘autoridad legislativa’ (legislative authority) with ‘soporte legal’ (legal support)

Section 7 – Characteristics of an official assessment program – replace the heading in the Spanish version ‘Autoridad legislativa’ (legislative authority) with ‘Soporte legal’ (legal support)

Section 7 – Characteristics of an official assessment program – para. 24 - line 1 - replace in the Spanish version ‘autoridad legislativa’ (legislative authority) with ‘soporte legal’ (legal support)

Section 7 – Characteristics of an official assessment program – para. 24 - line 3 - replace in the Spanish version ‘autoridad (authority) with ‘soporte legal’ (legal support)

Section 7 – Characteristics of an official assessment program – para. 24 - line 8 - add ‘and the application of any applicable sanctions’.

Section 7 – Characteristics of an official assessment program - para. 25 - line 8 - replace in the Spanish version ‘aranceles’ (fees) with ‘tarifas’ (fees)

Section 7 – Characteristics of an official assessment program - para. 26 – change the definition as follows: Management of an official assessment system is a set of procedures which must include a documented system of audit management

Section 7 – Characteristics of an official assessment program - para. 26 - line 5 – replace in the Spanish version ‘pogramación’ with ‘programación’ and delete ‘esto’.

Section 7 – Characteristics of an official assessment program - para. 26 - line 12 - in the Spanish version delete ‘propietaria’.

Section 7 – Characteristics of an official assessment program - para. 27 - line 8 - in the Spanish version replace ‘del tipo’ with ‘por tipo’ and line 9 replace ‘del producto’ with ‘de producto’.

Section 7 – Characteristics of an official assessment program - para. 30 - line 2 - in the Spanish version replace ‘controversias’ (disputes) with ‘reclamos’ (claims).

Annex I - para. 7 - line 2 -in the Spanish version replace ‘de garantizar que’ with ‘que garantice’.

Annex I - para. 8 - line 6 - in the Spanish version replace ‘microbios’ (microbes) with ‘microorganismos’ (microorganisms).

Annex I - para. 11 - in the Spanish version replace ‘consumición’ with ‘consumo’, replace ‘deberá cocinar’ with ‘someter a un proceso de cocción’ and ‘antes de poder servirse’ with ‘antes de servirse’.

Annex I - para. 15 - line 1 - in the Spanish version replace ‘desde’ with ‘incluyendo’, line 2 replace ‘hasta’ with ‘y’ and line 3 delete ‘de’ in ‘la inspección y ensayos’.

Annex I - para. 22 – delete this paragraph as it is not clear.

Annex I - para. 24 - line 2 - in the Spanish version replace ‘la ejecución y al mantenimiento’ with ‘la ejecución y mantenimiento’.

Annex I - para. 25 - line 2 in the Spanish version replace ‘una estrategia’ with ‘la estrategia’.

Annex II - Principle 7 in the Spanish version replace ‘establecer’ with ‘establecer’ and ‘aplicción’ with ‘aplicación’.

The information contained in this Annex is neither complete nor consistent with the provisions of the Recommended International Code of Practice – Codex General Principles of Food Hygiene (CAC/RCP 1 - 1969, rev. 3 (1997)). We propose, therefore, that this document be revised.

Annex III – Table – in para. 2 – in EXPRESSED IN QA SYSTEM ELEMENT delete ‘política de capacitación’ (training policy) as this is repeated.

Annex III – Table – in para. 3 – in EXPRESSED IN QA SYSTEM ELEMENT delete ‘política de capacitación’ (training policy) as this is repeated. In the ISO 8402 standard, the terms ‘ASEGURAMIENTO’ (Assurance) and ‘GARANTÍA’ (Guarantee) have already been defined as two different terms. What is the scope of CODEX in relation to this terminology?, as this document deals with ‘ASEGURAMIENTO’ (Assurance) yet the title in the Spanish language is ‘GARANTÍA’ (Guarantee).

NEW ZEALAND

The New Zealand Government would like to make the following comments:

Section 1 – Scope

Paragraph 2 should precede the current paragraph 1 as it is essential to understanding the scope of the document. The current paragraph 1 then provides the scope of the “elaboration”. Both paragraph 3 and 4 make reference to the fact that HACCP and QA systems are not being promoted or considered preferable to other systems. This point does not need to be repeated, therefore suggest deleting the second sentence in paragraph 3 and combining the remaining [first] sentence in paragraph 3 with paragraph 4, e.g. “Businesses may choose to implement QA systems for meeting commercial and/or regulatory requirements including safety. The guidelines provide advisory information etc etc..”

Section 3 – Definitions

Requirements - If the “competent authority” mentioned in this definition is the same as the “government agency having jurisdiction”, then one term should be selected and used throughout the text, rather than both.

Section 4 – Nature and Purpose of QA Systems

Paragraph 6 - suggest replace “monitoring the system’s performance” with “verifying the system’s performance”.

Paragraph 8 – last sentence. Suggest rewording as “Final product testing may only be part of the system used as a verification tool.

Paragraph 11 – suggest that this paragraph is reworded to read “The nature of QA systems should be such, that the official assessment program, through which official recognition is achieved, must be able to examine and assess all the activities relevant to ensuring regulatory requirements are met. Section 7 deals with Official Assessment Programs in detail.”

Section 5 – Official Recognition of Quality Assurance Systems

Paragraph 12 – suggest reword first sentence as “...when an assessment of the system by a government agency having jurisdiction, or an officially recognised assessment body objectively demonstrates that the system meets specific criteria.” The assessment is either by the government agency or an officially recognised assessment body, therefore remove the extra terminology “official assessment body”. “QA system” is already mentioned at the beginning of the sentence therefore there is no need to mention “QA” every time “the system” is used in the sentence.

Paragraph 12 - Superscript 4 – this gives a definition of ‘officially recognised assessment body’ and should be in the Definitions Section rather than a footnote.

Paragraph 13 – replace “official assessment body” with “government agency having jurisdiction”. Suggest change next sentence to read “ The request should contain sufficient information to permit the evaluation on a preliminary basis, as to whether the business’s QA system...”

Next bullet point and subsequent bullet points substitute “ assessment body” with “ government agency or officially recognised assessment body”

Paragraph 14 – To improve clarity and remove superfluous words we suggest rewording to:

“The government agency having jurisdiction can directly assess QA systems implemented by businesses, for the purpose of official recognition, and /or can recognise other bodies to carry out such assessments. Officially recognised assessment bodies may include regional authorities, and commercial (third party) quality system assessment bodies. For recognition to be granted, the government agency should ensure that the proposed assessment body meets accepted criteria and is made subject to official verification measures⁵. The government agency should implement procedures for assessing the ongoing capability of bodies recognised as being able to assess QA systems, implemented by businesses, for the purposes of official recognition⁶.”

Paragraph 15 – suggest shorten sentence by changing as follows “....is not compromised, the government agency or officially recognised assessment body should maintain clear separation.....”

Section 6 – Benefits of Officially Recognised QA Systems

Paragraph 16 – suggest change to “Officially recognised QA systems are a means of...”

Paragraph 17 – suggest change to “Officially recognised QA systems, or relevant parts of those systems, allows competent authorities to modify inspection methods to ensure...”

Paragraphs 18 and 19 - suggest change to “Officially recognised QA systems” at start of these paragraphs.

Section 7 – Characteristics of an Official Assessment Program

Paragraph 21 – suggest change “assessment program” to “official assessment program”, and in the last sentence – “...in addressing regulatory requirements and adequate rigour in external assessment” to “in addressing regulatory requirements, and adequate rigour in the external assessment of that system.”

Paragraph 22 – suggest delete “system” after “official assessment program” as the program should be the system and add “the government agency or an officially recognised assessment body” to be consistent.

Paragraph 23 – suggest change first sentence to read “ The official assessment program must have adequate resources to operate procedures designed to fully evaluate and verify QA systems implemented by businesses.” Suggest change in last sentence to “ This includes competent personnel sufficiently trained in the elements of QA systems, evaluation, verification and the relevant regulatory requirements.”

Paragraph 24– suggest change “issued by authorities” to “issued by the national government or the government agency having jurisdiction”

Suggest rework bulleted points as follows:

- official recognition of QA systems as implemented by businesses;
- official recognition of assessment bodies other than the government agency having jurisdiction;
- maintenance of official recognition status, for QA systems and assessment bodies other than the government agency having jurisdiction;
- varying, suspending and withdrawing official recognition of QA systems and assessment bodies other than the government agency having jurisdiction.

Paragraph 25 – suggest that the second sentence starts with “Other” rather than “The”. The QA system elements are quite different to the information listed in the bulleted points.

Paragraph 26 – suggest rewording to read “ The audit management program should have documented procedures and should ensure that these are followed and defined objectives are consistently met, regardless of personnel changes. Procedures should be periodically reviewed and/or updated, and should cover:....”

Paragraph 27 – suggest reworded second and third bullet point as follows:

- requirements for evaluation of the QA system, including initial assessment of the documentation and initial audit of the entire system as implemented;
- requirements for verification audits;”

Paragraph 29 – suggest add the word “documented” to read “should include a documented sanctions policy that addresses....”. Add to the last sentence, the following words “ or the objectives of the official assessment program” seeing as the intent is to cover auditors as well as the QA system.

Paragraph 33 – suggest that the following words be added “....so that government officials, trading partners, industry and consumers understand what the program is, how it is utilised, and the potential benefits associated with officially recognised QA systems.”

Paragraph 34 – suggest that the language remain consistent therefore change beginning of first sentence to “The government agency having jurisdiction and/or the officially recognised assessment body may choose to publish.....”

Annex 1

Paragraph 2 - suggest change to fourth bullet point using “ outcomes” rather than “quality objectives” Similarly in text and title before paragraph 9, change “objectives” to “outcomes”.

Annex 1 - Control measures for minimising or eliminating factors that can compromise quality

Control measures within this section also should cover process and other operational controls.

Paragraph 14 – suggest change to “Process and other operational controls that relate to food safety requirements, should be as appropriate, managed.....”

Paragraph 15 – Similarly – “Process and other operational controls should cover.....”

Paragraph 16 – Suggest change to allow expanded application to process and other controls, i.e. “Operating procedures should be specified and included in the QA system documentation.”

Annex 1 – Verification activities including internal auditing

Paragraph 19 – suggest add in validation at beginning of second sentence. “Procedures for validation, internal audit, and for sampling and testing where applicable, should be appropriately documented and applied...”

Annex 1 - Implementation

Paragraph 26 – suggest that this paragraph be reworded to assist the reader. There should be three clearly identified phases with sub-points as necessary:

Phase 1:

- develop appropriate controls over raw materials, through stipulating specifications;
- implement controls and checks to verify that specifications have been met;
- implement a training program for personnel involved in the process to ensure consistent application of procedures;
- consider developing QA systems for processing, manufacturing, storage, transport.

Phase 2:

- develop a recall system, which should lead to corrective action and controls “backwards” to raw material controls.

Phase 3: Staff

- develop and document responsibilities and training needs”

MEXICO

Preamble:

In order to maintain this document consistent with the Codex objectives and with the World Trade Organization’s Agreement on Sanitary and Phytosanitary Measures, in relation to the protection of health and fair trading practices, we believe it is of fundamental importance to maintain the voluntary nature of the quality assurance systems, noting that under no circumstance these should be established as a requirement for international food trade.

General Comments:

We suggest that the Spanish language version be adequately revised, as it is often the case that texts translated into the Spanish language differ significantly from their English language versions.

Throughout the document, the imperative form of the verb “**deber**” must be replaced with “**debiera**”, as it is more appropriate given the recommendatory nature of the draft guidelines.

Where the term “Seguridad de los Alimentos” (‘Food Safety’) is used, we seek to define whether reference is being made to safety or to a broader quality including other characteristics of food (absence of foreign matter, for example).

Section 3 – Definitions

Certification – Replace the word “**acabados**” with “**terminados**” as reference is made to food destined to the end user.

Inspection – same.

Paragraph 7

First bullet – In the Spanish language version, replace “**poder garantizar**” (‘to be able to ensure’) with “**ayuda a asegurarse**” (‘help ensure’), bearing into consideration that the use of quality assurance systems does not guarantee compliance with requirements associated with food.

Sixth bullet – In the Spanish language version, amend the word “**ingreso**” (‘access’) to “**acceso**” (‘access’).

Paragraph 10

In the Spanish language version, replace “... Se sugiere incorporar **Párcicas para una Buena Elaboración y HACCP**” (‘to incorporate Good Manufacturing Practices, and HACCP) with “**incorporar Buenas Prácticas de Manufactura y HACCP**” (‘to incorporate Good Manufacturing Practices, and HACCP).

Paragraph 12

Footnote 4 reads: “...**agencia gubernamental competente, habiendo podido desempeñar ...**” (‘... Competent government agency, as capable of performing, we suggest this be changed to “...**agencia gubernamental competente, para desempeñar...**” (‘... competent government agency, to perform...’).

Paragraph 14

Replace “**ingresar**” (‘access’) with “**evaluar**” (‘assess’) where it reads “...**podrá ingresar directamente a los sistemas...**” (‘can directly assess QA systems’) and “**ejecutados**” (‘implemented’) with “**implantados**” where it reads “**garantía de la calidad ejecutados por las empresas...**” (‘QA systems implemented by businesses’), and “**una**” (‘an’) with “**la**” (‘the’) in “**..partes para efectuar una evaluación de los sistemas...**”, (‘parties to carry out assessment of QA systems’).

Paragraph 16

Add at the end of the paragraph “**where said systems incorporate the relevant elements for such purposes**”.

Paragraph 18

In the Spanish version, amend “**cumple**” to “**cumpla**” in “... **por parte de una empresa cumple en forma constante...**” (‘operated by a business consistently complies with regulatory requirements’).

Paragraph 20

Amend the future form of **“ocurrirá”** (‘shall occur’) to **“podría ocurrir”** (‘should occur’), as per the English language version.

Paragraph 21

Amend **“seguridad”** (‘safety’) to **“confianza”** (‘confidence’) where it reads: **“La seguridad que otorgue todo sistema...”** (‘The confidence delivered by any QA system’).

Paragraph 25

Fourth bullet – in the Spanish version, amend the word **“aranceles”** (‘fees’) to **“tarifas”** (‘fees’).

Paragraph 26

Amend the wording of this paragraph as follows: **“Management of an official assessment system for a QA system needs to ensure procedures are applied and that defined objectives can be consistently met, regardless of personnel changes. Procedures should include a documented system of audit management, periodically reviewed and/or updated, to cover:”**

Fourth bullet – Amend **“información propietaria”** (‘proprietary information’) to **“información confidencial”** (‘confidential information’).

Paragraph 27

First bullet – We suggest the use of **“nivel de competencia”** (‘level of competence’) in lieu of **“títulos”** (‘qualifications’). We further suggest the deletion of **“de los auditores”** (‘of auditors’) at the end of the bullet.

Amend the Spanish language version of the **fifth bullet** as follows: **“...variación de la frecuencia y ámbito de aplicación de las auditorías en respuesta...”** (‘variation of audit frequency and scope in response to’).

Amend the Spanish language version of the **sixth bullet to now read**: **“una especificación de acciones, incluyendo sanciones, que se pudieran aplicar cuando se identifiquen situaciones de no conformidad”** (‘specification of action, including sanctions that may be applied where non-conformities are identified’).

Paragraph 28

Amend **“...todo título en materia...”** (‘qualifications’) to **“...toda competencia en materia...”** (‘competence’).

Second bullet – We suggest a change for the last part of this bullet to now read: **“Se podrá poner en práctica una clasificación por niveles.”** (‘A classification ranking may be implemented’).

Third bullet – Amend this paragraph as follows: **“...una evaluación de las habilidades del auditor incluyendo la comunicación efectiva.”** (‘an evaluation of auditor competencies including communication efficacy’).

Fourth bullet – It would be useful to clarify whether the auditor’s condition is subject to assessment on the part of his peers or to a comparison with his peers.

Paragraph 29

Amend in the Spanish language version “**particularmente**” (‘particularly’) to “**específicamente**” (‘specifically’) at the end of the paragraph.

Paragraph 34

Amend in the Spanish language version “**...al abastecimiento de un asesoramiento...**” (‘from providing detailed advice to ...’) to “**...a proporcionar asesoramiento...**” (‘from providing detailed advice to ...’).

ANNEX 1

Paragraph 1

Ninth bullet – In the Spanish language version, replace the expression “**retiro de plaza**” (‘recall’) with “**retiro de mercado**” (‘recall’).

Paragraph 6

In the Spanish language version, amend “**y a como se deberán administrar dichas responsabilidades**” to now read as follows: “**y cómo se debieran cumplir dichas responsabilidades.**” (‘and how those responsibilities should be discharged.’)

Paragraph 7

In the Spanish language version, amend “**de manera de**” with “**con objeto de**”, and “**pertinentes**” (‘relevant’) with “**vigentes**” (‘current/in force’).

Paragraph 8

Third bullet – In the Spanish language version, amend “**consumición**” with “**consumo**” (‘consumption’), and change the final part of this paragraph to now read as follows: “**se debieran identificar también aquellos grupos de consumidores vulnerables.**” (‘those groups of vulnerable consumers should also be identified’).

Paragraph 12

In the Spanish language version, amend “**control pesticida**” (‘pest control’) to “**control de plagas**” (‘plague control’).

Paragraph 14

Plural form of “**buena práctica**” programs (‘good practice programs’).

Amend “**condiciones previas necesarias**” (‘prerequisites’) to “**prerrequisitos**” (‘prerequisites’).

Paragraph 15

In the Spanish language version, include in parenthesis “**prebas**” (**pruebas/tests**) immediately after the word **ensayos** (‘testing’).

Title between Paragraphs 17 and 18

Replace “**plaza**” (‘recall’) with “**mercado**” (‘recall’).

Paragraph 18

Replace “**plaza**” (‘recall’) with “**mercado**” (‘recall’).

In the Spanish language version, amend “Ello deberá incluir el retiro de plaza respecto de tools los clientes externos...” with “Ello debiera incluir el retiro de producto de clientes externos...” (‘This should include product recall from external customers’).

Paragraph 19

In the Spanish language version, include in parenthesis “**prebas**” (**pruebas/tests**) immediately after the word **ensayos** (‘testing’).

In the Spanish language version, add the preposition “**a**” after “...**el énfasis adecuado...**” (‘appropriate emphasis to’).

UNITED STATES

General Comments

The United States supports the development of the *Draft Guidelines for the Utilization and Promotion of Quality Assurance Systems to Meet Requirements in Relation to Food*. The United States believes this guidance document will be helpful to countries when regulatory bodies wish to recognize and utilize quality assurance systems as a component of their food control systems.

Specific Comments

The United States offers the following specific comments on the Proposed Draft Guidelines.

TITLE

The United States suggests that the title of the document be changed to “*Guidelines for the Recognition of Quality Assurance Systems to Meet Requirements In Relation to Food*”. This change more clearly articulates the purpose of the document.

SECTION 1 – SCOPE

Paragraph 1 and elsewhere. Throughout the document, the term “food regulatory requirements” is used when it should more appropriately state “food regulatory and national certification requirements. The use of the broader term permits the document to appropriately include certification to conformity with grades and standards, which may not be regulatory requirements. Within paragraph 1, add the phrase “and national certification” after “regulatory” and before “requirements. A global search should be made to determine other points in the document where this change is needed (e.g., in paragraphs 9, 16 and 21). The document should be reviewed to ensure that the wording, where appropriate, includes governmental product and grade certification programs.

Paragraph 4. First sentence. Replace “explain” with “indicate” These guidelines do not actually explain how HACCP may be incorporated into QA systems.

SECTION 3 – DEFINITIONS

Quality Assurance: For clarity, insert a comma after “structure”.

SECTION 4 – BENEFITS OF OFFICIALLY RECOGNIZED SYSTEMS

Paragraph 11. First sentence. For clarity, rewrite the sentence to read: “When a QA system is recognized by an official body or officially recognized body, the system must be capable of assuring that all relevant regulatory requirements are met.

SECTION 5 – OFFICIAL RECOGNITION OF QUALITY ASSURANCE SYSTEMS

Paragraph 14. First sentence. For grammar, insert “The” as the first word of the paragraph. Last sentence. For clarity as to which QA systems are being referred to, insert “recognized” before “QA systems”.

SECTION 6 – BENEFITS OF OFFICIALLY RECOGNIZED QA SYSTEMS

Paragraph 16. Recognition of QA systems is only one way of assuring that foods meet regulatory requirements. Further, no system can provide complete assurance that foods meet regulatory requirements. It is suggested that the words “a means of assuring that produced under such a system” be deleted and replaced by “one means by which government agencies can help assure that foods”. The revised sentence would read:

“QA systems that are officially recognized are one means by which government agencies can help assure that foods meet specified food safety and other regulatory requirements.”

Paragraph 17. First sentence. Replace “allows” with “should allow” since official recognition of QA systems should allow, but will not necessarily always permit modification of inspection methods.

Second sentence. Replace “can” with “should” as the modification should not compromise the competent authority’s responsibility to ensure conformity of the food. Also in the second sentence, add the words “the safety and” before conformity, since both safety and quality are components of a QA system.

Paragraph 18. Delete “therefore” and, for grammar, insert “which” before “consistently”. Additionally, to reflect that reduced inspections and audits can facilitate trade, add the following sentence to the end of the paragraph “This reduction in official inspection and audits can facilitate trade.”

Paragraph 20. First sentence. For clarity, rewrite as follows: “Mutual recognition by trading partners of officially recognized QA systems could facilitate trade.”

SECTION 7 – CHARACTERISTICS OF AN OFFICIAL ASSESSMENT PROGRAM

Paragraph 25. Fourth bullet point. Rewrite as follows to insure equitable fees and clarity as to what the fees are for: “applicable and equitable fees imposed for official assessment;”.

Fifth bullet point. Rewrite as follows to include the issue of confidentiality: “rights and

responsibilities of applicants, including those related to the confidentiality of information arising from or supplied in connection with assessment procedures; and, “.

Paragraph 26. First sentence. Since this paragraph is dealing with the audit management program, to clarify that the assessing body is the body being referred to in this paragraph, insert “by the assessing body” after “consistently met”.

Bulleted list. Add an additional bullet point, to read, “a sanctions policy for violations made by an auditor who is a member of an assessing body” (see comment on paragraph 29 below).

Paragraph 28. First sentence. The phrase “must include food safety requirements,” infers that recognized QA systems would only involve food safety, when, in fact, they might involve certification with quality grades and standards. To make the types of auditors to which this section refers more inclusive, insert “as appropriate” after “include” and insert “or other” between “safety” and “qualifications”, so that the phrase would read: “...must include, as appropriate, food safety or other qualifications...”.

Fifth bullet point. For grammar, insert “including” between “consider” and “industry”.

Paragraph 29. First sentence. Delete the words “or by auditors” at the end of the sentence. The inclusion of this phrase “or by auditors” seems to be outside the scope of the this section since the section deals with procedures for an assessing body to handle non-conformance found with respect to the QA system, not the non-conformance of the auditors themselves. The issue of how to handle violations made by an auditor (who is a member of the assessing body) is better addressed in the section on “Documented audit management program” (see note under paragraph 26 above). Alternatively a separate paragraph in this section may be appropriate.

ANNEX 1

Paragraphs 26 and 27. It is not clear that the limited discussion that these paragraphs provide on the subject of “phased implementation” are of value in this guidance document. The United States suggests deleting the paragraphs.

Paragraph 28. It is suggested that a better placement for this paragraph dealing with the relationship of HACCP and QA programs would be under the section on “Identification and analysis of factors to be controlled” following current paragraph 11.

ANNEX III

While the United States is aware that there have been differences of opinion as to whether the narrative information on integration of HACCP into QA systems should appear in an Annex or be integrated into the text, we prefer the information to be in the body of the Guideline document. In this case, the two paragraphs currently in Annex III can go into a new Section 8 (see language for Section 8 below). With this change, the United States also believes that Annex II and Annex III can be combined in a single Annex II.

If this change were made, the title of Annex II would become “HACCP Principles, the Steps of HACCP and the Integration of HACCP into QA System Elements. The heading before the table currently in Annex III would become “Integration of HACCP into QA System Elements”.

Regarding the table in current Annex III, add “use” to HACCP step 3 so the step would read: “identify intended use”. Additionally a further review should be undertaken to be sure all QA

system elements listed for each HACCP are, in fact, applicable; for example, we question whether the QA system element “Defined management structure with stipulated responsibilities” applies to all HACCP steps as indicated.

The new Section 8 would read as follows:

SECTION 8 – INTEGRATION OF HACCP INTO QA SYSTEMS

31. 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.
32. 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 prerequisites programs should be operating prior to HACCP implementation. Annex II lists the seven HACCP principles and the tasks necessary to apply HACCP (often referred to as the 12 HACCP steps). The table given in Annex II also correlates the 12 HACCP steps with the QA system elements given in Annex I."

EUROPEAN COMMUNITY

General Comments

The European Community is seriously concerned about the direction the document has taken.

Section 1 – Scope

The scope of the document is to ‘provide guidance on how quality assurance systems implemented by food businesses may be officially recognised’ (p.1, nr.1). The position of the European Community is that QA systems of food businesses should be used, should be promoted, but should not be officially recognised, in order to keep the responsibilities clear. The European Community is very reluctant to accept private QA systems as being equivalent to official controls.

This position is in line with Section 4 (Quality Assurance) of the “*Guidelines for Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems*” where is stated:

- “*The voluntary utilization of quality assurance by food businesses should also be encouraged in order to achieve greater confidence in the quality of products obtained*”
- “*Governments do, however, retain the fundamental responsibility to ensure by official inspection and certification the conformity of foodstuffs to requirements.*”

Section 5 – Official Recognition of Quality Assurance Systems

Assessment Bodies

The document states that bodies that are assessing QA systems for official recognition, may also carry out advisory services in relation to development and implementation of QA systems (p. 3, nr. 15). Besides, they may be commercial (third party) bodies (p. 3, nr. 14) and include industry experts in audit teams (p. 5, nr. 28). For all these elements, the risk that impartiality and

independence of official assessment of QA systems is compromised is real. All these elements together create a situation that is difficult to assess.

Paragraph 15 refers to the need to have clear separation between auditing functions and advisory functions within bodies responsible for auditing QA systems for official recognition. In fact, the document allows for the co-existence of both activities (as laid down in § 15) as long as they are clearly separated, which is a rather imprecise condition. Furthermore, while a separation of functions may be sufficient to ensure independence within a government auditing body, it may need to be considered whether separation is sufficient to prevent any compromise of impartiality and independence in the case of commercial auditing bodies. To avoid potential conflict of interests, the assessment/auditing bodies should not run any advisory services at all.

Section 6 – Benefits of officially recognised QA Systems

The document states that official recognition of QA systems allows competent authorities to modify inspection methods used, and that official recognition should result in a reduced frequency of official inspections (p.3, 4, nr.17, 18). The philosophy of the European Community is that it is possible, for competent authorities, to take into account the existence of QA systems in carrying out official controls and that a QA system may lead to a change in method and frequency of official controls. However, this is not a general rule, this should be completely to the discretion of the competent authority and this should be evaluated on a case-by-case basis.

The document states that official recognition of QA systems may facilitate the issuance of official certification for food produced within the scope of such QA system (p.4, nr.19). The European Community believes that issuance of official certification can only be done by the competent authority, on the basis of official controls. It is not clear how official recognition of QA systems could facilitate certification.

The document states that officially recognised QA-systems should facilitate international trade through recognition of such systems by trading partners, for example through the use of equivalence (p.4, nr.20). The European Community will have a real difficulty to accept private QA systems as being equivalent to official controls.

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

Paragraph 30 requires operators of QA systems to send updated documentation to, inter alia, regulatory authorities. This could impose an unreasonable burden on such authorities that may be responsible for supervising many thousands of food businesses. This should perhaps be considered.

Annex III – Integration of HACCP into QA Systems

The table tries to make the correlation between the 12 HACCP steps and the suggested elements of a QA system. However, the correlation drawn between the steps for implementing HACCP and the elements of a QA system are so broad that their usefulness is diminished. For example, management responsibility and training policy are mentioned for every stem (training policy is actually mentioned twice for steps 2 and 3). While recognising that these are overarching elements of QA, their repeated inclusion in the table dilutes its effect. Conversely, for certain steps in HACCP implementation, such as “*Determine Critical Control Points*” and “*Establish Corrective Actions*” the links to QA systems offered seem rather weak and incomplete. For the former, only management responsibility and training policy are mentioned and for the latter recall procedures are also mentioned.

Considering that HACCP and QA have complimentary roles to play in an organisational structure, perhaps another type of model representation, different from a table, could be envisaged.

Editorial Remarks

Definitions

While most of the definitions are drawn from other Codex documents, the definition of ‘*quality assurance system*’ is new. The definition offered “*Organisational structure, procedures, processes and resources needed to implement quality assurance*” is rather jargonistic and not very clear, so it is difficult to understand.

Later in the document (paras. 26-28) the terms “*official assessment system*”, “*official assessment program*” and “*audit management program*” are used. It may enhance the clarity of the document if definitions for these terms were offered at the section “*Definitions*”.