

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
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HEALTH  
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Agenda Item 6

CONFERENCE ROOM DOCUMENT

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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

#### MEXICO COMMENTS AT STEP 3

##### Secretariat Note:

These comments replace those produced in CX/FICS 02/6-Add 1.

##### 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 **Párcticas 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 compenente, 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 tambien 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’).

### Paragraph 23

**Third bullet:** replace the word “**títulos**” (‘qualifications’) with “**evaluación**” (‘assessment’).

**Fourth bullet:** replace ‘**en funcionamiento**’ with ‘**de operación**’ (‘operational’/‘in operation’).

**Seventh bullet:** after essays, add ‘**pruebas**’ (‘tests’/‘testing’) in parenthesis.

#### Paragraph 24

We suggest an amendment to the text ‘**...personal afectado a la ejecución...**’ (‘staff involved in the implementation’) to ‘**...personal involucrado en la ejecución..**’ (‘staff involved in the implementation’).

**We suggest to change the word ‘títulos’ (qualifications) with ‘nivel de competencia’ (‘level of competence’).**

#### Heading II (including paragraphs 25 to 28)

We suggest to replace the term ‘**ejecución**’ (implementation) with ‘**implantación**’ (‘implantation’/‘introduction’).

#### Paragraph 26

**Second bullet:** replace the (Spanish) word ‘**plaza**’ with ‘**mercado**’.

**Third bullet:** replace ‘**... personal afectado a la ejecución...**’ (‘staff involved in the implementation’) with ‘**...personal involucrado en...**’ (‘staff involved in...’).

#### Paragraph 28

We suggest to replace the (Spanish) wording ‘**programas esenciales como condición previa**’ (‘prerequisite programs’) with ‘**prerrequisitos**’ (‘prerequisites’).

Leave ‘**buena práctica**’ (‘good practice’) in the plural form.

#### Paragraph 29

**We suggest to amend ‘pertinencia continua’ (‘continuous relevance’) to ‘vigencia’ (‘in force’).**

Reword the second bullet as follows: ‘**cambios en el procesamiento o formulación del producto**’ (‘changes in the processing or formulation of the product’).

Fourth bullet: replace the term ‘**exigencias legislativas**’ (‘legislative requirements’) with ‘**requerimientos legislativos**’ (‘legislative requirements’).

#### Paragraph 30

We suggest changing the end of the paragraph as follows: ‘**...documentación y distribuirla al personal y a otras instancias, incluyendo las autoridades regulatorias**’ (‘...documentation and for distribution of the same to staff and other parties, including regulatory authorities’).

### ANNEX III

#### Paragraph 1

We suggest an amendment to the text: ‘**...aplicación de principios y etapas HACCP en la ejecución de sistemas de ...**’ (‘...application of HACCP principles and steps in the implementation of ... systems...’) as follows: ‘**...aplicación de los principios y etapas del HACCP implantando sistemas de ...**’ (‘application of HACCP principles and steps with the implementation of ... systems...’).

At the end of the paragraph, replace the term ‘**de pertinencia**’ (‘pertinent’) with ‘**relevantes**’ (‘relevant’).

## Paragraph 2

We suggest an amendment to the wording: **”The relevant prerequisite HACCP plans should be operating...”** to **“The prerequisite HACCP programmes should be operating...”**

We suggest an amendment to the wording: **“The HACCP steps correlate in this annex with elements...”** to **“The HACCP steps relate here to the elements...”**

## Title in the table:

We suggest this be amended to read: **“The following table presents a summary of elements of a quality assurance system described in the present document, within which the HACCP steps of Codex may be documented”**.

## Table:

**Training Policy is repeated in bullets 2 and 3.**

**Point 7** – add the following elements: identification and analysis of factors to be monitored and monitoring measures for the minimisation or elimination of factors that may compromise quality.

**Point 10** – and the following element: monitoring measures for the minimisation or elimination of factors that may compromise quality. Replace the term **“plaza”** with **“mercado” (market)**.

**Consider that the elements:** Structure of defined management with specification of responsibilities and a training policy which are mentioned in each HACCP step, consider a more specific relationship between these two steps and the elements of a quality assurance system.