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Agenda Item 4

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION
AND CERTIFICATION SYSTEMS
Eighteenth Session
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PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT
OF FOREIGN ON-SITE AUDITS AND INSPECTIONS
(N07-2008)
(Comments at Step 3)
(Japan, Norway and Panama)

Japan

General Comments

Japan, while generally supporting the proposed draft document, is of the view that it is still necessary to look at scope of this document as the current text does not reflect the result of the July physical working group precisely. And the draft document also needs to clarify how audit, inspection and other activities are interrelated and selected for use in the assessment of system.

Audit, inspection and other activities are all very important tools for assessing the system of exporting countries, depending on their purpose and objectives and an appropriate and the most suitable tool should be selected on case by case basis. In this sense, Japan does not think it is appropriate to designate audit as the most preferred approach and proposes some amendments on Principle C as provided later.

Japan identifies that some important points presented in the existing document, i.e. the Annex of *Guidelines on Procedures for Conducting an Assessment and Verification by an Importing Country of Inspection and Certification Systems of an Exporting Country* (CAC/GL 26-1997), which are supposed to be replaced with this document, are still missing. Specific comments on this point are also presented below.

Specific comments

SECTION 2 SCOPE

Last sentence of **paragraph 4** should be amended to align with the context of the last sentence of paragraph 19 which states that other activities should also be subject to these guidelines if they are conducted by a competent authority as part of an assessment:

4.This annex should also apply to any other **activities (e.g. visit, or requests for information) conducted by competent authorities as** ~~that may be part of an assessment which has the ability to impact on the exporting country.~~

SECTION 3 PRINCIPLES

Principle A

Paragraphs 13 and 14

13. The costs incurred in undertaking an assessment, including all travel costs, costs of technical experts and auditors or inspectors, and costs of support staff ~~including translators~~ should normally be borne by the competent authority of the importing country except as may otherwise be agreed.

14. The costs incurred by the competent authority of the exporting country, in supporting the assessment, for support staff **including interpreters** and technical experts in the exporting country should normally be borne by the competent authority of the exporting country except as may otherwise be agreed.

Rationale: In the current common practice for assessment and/or inspections, interpreters are provided by exporting countries at their expense. Documents for assessment are usually submitted by an exporting country in a language which the importing country can understand. Interpretation during audits or inspections should be provided, in principle, at the expense of an exporting country similarly.

Principle C, Paragraphs 19

Audits, inspections and other activities are equally important in assessing the system of exporting countries. The most relevant tool is not always audits. In this sense, it is preferable to focus on ways of selecting tools (audits, inspection and other activities) in this section. Japan proposes some amendments on Principle C as follows:

Principle C, second sentence of chapeau text

The importing and exporting countries should agree on an appropriate tool for the conduct of the assessment prior to its initiation based on the scope and objectives desired. ~~In most cases the preferred assessment approach would be an audit that considers the official inspection and certification system as a whole or part.~~

19. In ~~most cases general, the preferred assessment tools would be~~ **audit can be used to assess** all or part of an exporting country's official inspection and certification system including the ability of the competent authority ~~whento, for instance, minimize the burdens incurred by both importing and exporting countries related to assessment.~~ **whento, for instance, minimize the burdens incurred by both importing and exporting countries related to assessment.** Inspections can also be an appropriate assessment tool. ~~In some instances, where competent authorities use other terms to describe assessment activities, e.g. vitits, information exchanges, such activities should also be subject to these guidelines.~~

19bis. Inspection can also be an appropriate assessment tool, especially in situations where there is a need to verify whether one or more specific elements of an inspection or certification system meet the requirements.

Audit tools

The term "systems-based audits" should be replaced with "audits" throughout this part as audit is defined to be systematic in the parent document and thus redundant.

Paragraph 20

Insertion of a new paragraph 20bis

20bis. Generally document audits precede on-site audits. In proceeding with an on-site audit, the process should not be automatic but should follow a transparent and open manner to consider necessary various factors such as risk assessment results of the concerned food commodity(ies), histories of conformity with official requirements, volume of production, import or export, results of the document audits etc.

Rationale: Various factors that need to be considered in making decision on the commencement of an on-site audit, followed by a document audit, should be described in this document. This proposed insertion is also intended to include the context of Section 4 of the existing Annex.

Paragraph 21

21. ~~Systems based~~ Audits rely on the examination of a sample of **the elements as contained in Section 6, Inspection and Certification System Infrastructure or other elements** ~~system procedures, documents or records and where required sites within the scope of the system under audit, as opposed to examining all procedures.~~

Rationale: Japan suggests merging paragraph 23 to further clarify the factors to be examined. In addition, “ as opposed to examining all procedures” should be deleted as it is not necessary

Principle D

Paragraph 26 should be amended as follows for clarity:

26. The transparency and consistency of the assessment process may be facilitated by good documentation and communication. Documents supporting findings, conclusions and recommendations should be standardised **be made in systematic and consistent manners** ~~as much as possible~~ in order to make the performance of the assessment and the presentation of its outcome uniform, transparent and reliable.

In Paragraph 27, “contact person” should be deleted as it is not necessary.

Principle E

Paragraphs 33, 34, 38 and 47

Noting that various stakeholders including private sectors are involved in audits or inspection in practice, the governments’ responsibilities should be clearly distinguished, therefore Japan suggests the term “party(ies)” in these paragraphs should be replaced with “competent authority(ies)”.

Paragraphs 41 and 42, a) should be amended as follows to suggest who should participate in the meeting:

a) The meeting should be held at a place designated by the competent authority of the exporting country **with the participation of inspectors or auditors, persons from relevant competent authority(ies) of both countries.**

Paragraph 41 b) should be amended as follows to add a reference to paragraph 32 as these two paragraphs are interrelated:

b) The meeting should review all aspects of the assessment plan and is intended to provide an overview of the official inspection and certification system of the exporting country and to confirm the parameters and logistics for the assessment **(see paragraph 32) to ensure adequate assessment in advance.**

Paragraph 42, point b) should be amended as following for clarification:

b) The meeting should summarize all findings and observations, identify non-conformities, outline the objective evidence to support the non-conformities, **Identified non-conformities should be explained by the inspectors or auditors at the meeting.** Correction of non-conformities should **in principle** be left to the competent authority of the exporting country and verified by the competent authority of the importing country **through a follow-up audit, as appropriate, where required and agreed by the competent authorities of both countries.**

Principle F and G

Paragraph 44, point j) should be amended as follows for clarification:

j) Include uncertainties ~~and/or any obstacles encountered~~ **and their impact on** ~~that could affect the reliability of the assessment conclusion~~ **and/or any obstacles encountered where necessary;** and

Norway

Norway wishes to thank Australia for leading the work on *Proposed Draft Principles and Guidelines for the Conduct of Foreign On-site Audits and Inspections* and acknowledge the thorough work with preparing the draft document. Norway finds the draft well outlined and arranged and this document will provide useful and essential guidance for the conduct on foreign on site Audits.

Norway supports the development and progress of the text, however we would like to take the opportunity to forward a few specific comments.

Specific Comments

With reference to Principle E and paragraph 29, Norway suggests a new paragraph in addition to paragraph 29:

Paragraph 29 (bis) The frequency of assessments is to be kept at a sufficient level necessary to fulfil its objective and should be agreed upon between the competent authorities in the importing and exporting country.

Rationale: The added paragraph will ensure that both parties are well informed of what is to be expected of the assessment in question and possible series of assessment(s) to come. Most importantly, it ensures that the exporting country may comment on the approach from the importing country on the number/series of assessments. The new paragraph gives the exporting country a possibility to reply on whether it is capable of conducting the frequency of assessments planned by the importing country. It may also prevent the possibility of the number/series of assessment set by the importing country becoming an unnecessary burden to the exporting country being assessed.

With reference to paragraph 39, Norway sees two different interpretations of the paragraph and therefore asks for clarification on our understanding of the following:

Assessment Logistics

39. A systematic evaluation procedure should be used, based on a predetermined and structured program consistent with the purpose of the assessment.

1) Does paragraph 39 mean that the assessment process as a whole is to be evaluated? In that case, who will conduct the evaluation and, more specifically, which elements are to be evaluated? How should this process be documented?

2) Does paragraph 39 mean that the assessment as such should be carried out in consistence with the predetermined programme and follow a systematic procedure? By that we mean that the party assessing a system or establishment must conduct the assessment in a systematic manner and in accordance with the programme and purpose for the assessment.

In case interpretation number 2 is the correct understanding, we suggest new wording:

Paragraph 39. **When conducting an assessment, a** ~~An~~ systematic ~~evaluation~~ procedure should be used, based on a predetermined and structured program consistent with the purpose of the assessment.

Rationale: Make the paragraph more clear and ensure a common understanding of its content.

Panama

(This is a correction to the Spanish text in CX/FICS 10/18/4 Add 1)

(i) Observaciones generales

No tenemos observaciones de carácter general.

(ii) Observaciones específicas

Las observaciones específicas se señalan a continuación:

Párrafo 2. Corregir en la última oración de la siguiente forma:

La determinación del instrumento adecuado para emprender la evaluación dependerá de la experiencia, conocimiento y confianza que el país importador tenga con respecto al sistema oficial de inspección y certificación del país importador **exportador**.

Fundamento: El país importador emprenderá la evaluación basado su experiencia, conocimiento y confianza que tenga en el sistema oficial de inspección y certificación del país exportador.

Párrafo 3. Suprimir la alusión al Capítulo del Código Sanitario para los Animales Terrestres de la OIE en la frase, la cual debería quedar así:

El presente anexo deberá leerse junto con la sección 9 – Evaluación y Verificación de los sistema de inspección y Certificación de las *Directrices para la Formulación, Aplicación, Evaluación y Acreditación de los Sistemas de Inspección y Certificación de Importaciones y Exportaciones de Alimentos* (CAC/GL 26-1997) y las secciones pertinentes de la *Herramienta de la OIE para la evaluación de las prestaciones de servicios veterinarios, Capítulo 3.2 del Código Sanitario para los Animales Terrestres de la OIE*.

Fundamento: No es recomendable hacer referencia al capítulo del Código en donde aparece la información, debido al dinamismo con el cual se revisa y actualiza este documento de la OIE, por lo que en el futuro podría incluso cambiar el número del capítulo.

Párrafo 13. Reemplazar parte de la redacción por la siguiente propuesta:

Los gastos en los que incurra un país importador para llevar a cabo una evaluación, incluidos todos los gastos de viaje, los gastos de técnicos expertos y auditores o inspectores, y los gastos del personal de apoyo y traductores, estarían **deberían estar** a cargo de la autoridad competente del país importador, a menos que las partes acuerden

proceder de otro modo **sin embargo, podrían ser asumidos por otras partes interesadas, previo acuerdo y basándose en las regulaciones que rigen esta materia.**

Fundamento: Consideramos que la decisión sobre la parte que asumirá estos debe ser producto de un acuerdo entre las partes, especialmente tomando en cuenta que en ciertos países, hay regulaciones que rigen sobre el desembolso de fondos del estado.

Párrafo 14. Reemplazar parte de la redacción por la siguiente propuesta:

Los gastos en los que se incurra la autoridad competente del país exportador con respecto a los servicios y personal de apoyo y expertos técnicos en el país exportador generalmente estarían **deberían estar** a cargo de la autoridad competente del país exportador, a menos que se acuerde proceder de otro modo **sin embargo, podrían ser asumidos por otras partes interesadas, previo acuerdo y basándose en las regulaciones que rigen esta materia.**

Fundamento: Consideramos que la decisión sobre la parte que asumirá estos debe ser producto de un acuerdo entre las partes, especialmente tomando en cuenta que en ciertos países, hay regulaciones que rigen sobre el desembolso de fondos del estado.

Párrafos 16 al 25. Reemplazar la palabra “instrumento” por la palabra “metodología”.

Fundamento: Consideramos que el término “metodología” es más amplio y aclaratorio sobre la forma seleccionada para llevar a cabo la evaluación.

Párrafo 44. Incluir una frase que permita aclarar el significado del término “recomendaciones”, para lo cual proponemos añadir un literal que señale lo siguiente:

l) los resultados de la evaluación deberán tomar en cuenta las recomendaciones de los auditores de la autoridad competente del país importador, inspectores u organizaciones de auditoría, en cuanto a la habilidad del sistema oficial de inspección y certificación de importaciones y exportaciones de proporcionar confianza al país importador.

Fundamento: Mediante la redacción actual, puede prestarse para interpretar que los auditores deben hacer recomendaciones tendientes a dar una indicación sobre cómo corregir una no conformidad identificada. Es responsabilidad del auditor reportar la no conformidad basándose en evidencia objetiva de que se ha incumplido o no se ha cumplido plenamente un requisito establecido por el país importador o el país exportador, de forma que permita al auditado determinar las acciones correctivas, plazos y seguimientos que serán objeto de discusión y acuerdo por las partes.