

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 4

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ORIGINAL LANGUAGE ONLY

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION
AND CERTIFICATION SYSTEMS**

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**PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT
OF FOREIGN ON-SITE AUDITS AND INSPECTIONS**

(NO7 – 2008)

(Comments at Step 3)

(Colombia, Ecuador, Japan, Kenya, Mali)

OBSERVACIONES COLOMBIA

Colombia respalda el anteproyecto de principios y directrices para conducir auditorías e inspecciones en el extranjero, así mismo considera, teniendo en cuenta lo señalado en el párrafo 21, que:

- a) El Apéndice I aborda los puntos enunciados en el párrafo 5 apartados a) a e) del documento en cuestión.
- b) Los principios y directrices del Apéndice I podrían sustituir el ANEXO DIRECTRICES SOBRE LOS PROCEDIMIENTOS PARA EVALUAR Y VERIFICAR LOS SISTEMAS DE INSPECCIÓN Y CERTIFICACIÓN DE UN PAÍS EXPORTADOR POR PARTE DE UN PAÍS IMPORTADOR al CAC/GL 26-1997.
- c) Se podría hacer referencia dentro del documento a la capacidad de los sistemas oficiales de inspección y certificación del país exportador, objeto de la auditoría, para satisfacer el nivel de protección adecuado NADP del importador. Sin embargo, se considera que no es conveniente hacer esta referencia en el objetivo, por cuanto el texto del apéndice está centrado a ofrecer orientación a los gobiernos para la realización de auditorías, y no necesariamente, a través de éstas se pueda evaluar si el sistema oficial del país exportador satisface el NADP del importador.

OBSERVACIONES ECUADOR

En la sección 2: Objetivo: En el documento se especifican 2 párrafos, el primer párrafo (identificado como 3) indica el objetivo y el enfoque del documento con mayor claridad que el segundo párrafo (que está tachado); es importante definir la inclusión de la referencia NADP, ya que muchos países importadores tienen niveles más altos de NADP que otros y en este caso los exportadores deben mejorar sistemas, incrementar infraestructura para alcanzar el NADP del importador.

Además se cree necesario dejar claro aunque se pensaría que está implícito, la realización de una auditoría y/o inspección por parte de los funcionarios del/los país/es o bloque importador de alimentos, como es el

caso de (Unión Europea), siempre deberán estar debidamente asistidos y acompañados por funcionarios del país auditado, en este caso el país exportador.

Para lograr el objetivo previsto de una auditoría, deberá plantearse el cumplimiento de una serie de etapas, recalcando que es imprescindible llegar en un total entendimiento entre las partes, esto es la auditora (País importador) y la auditada (País exportador).

Se debe considerar la formulación de las definiciones de términos especialmente en los términos “inspección”, “auditoría”.

Estamos de acuerdo en lo realizado durante el debate con respecto al tema de “in situ” ya que se sustenta en el hecho de que las auditorías se pueden llevar a cabo tanto en una visita a un país exportador o a través de una auditoría documental, en todo caso de iniciarse como primer paso una auditoría documental y de requerir alguna confirmación o revisión adicional se podría realizar la inspección in situ.

Queda claro además que los importadores corren con los gastos que implican realizar las inspecciones in situ en los países exportadores.

Dentro de este anteproyecto es importante especificar la frecuencia de las inspecciones, aclarar el punto sobre resolución de controversias con las indicaciones y puntos que deben cumplirse para cubrir este aspecto en caso de que existiera.

Las demás secciones se han venido aplicando dentro de las inspecciones que se realizan en el extranjero, pero es importante que esta directriz se concluya para tener normalizado los procedimientos para realizar estas inspecciones.

JAPAN

Japan would like to express its appreciations for Australia’s leading the electronic working group for developing guidelines for the Conduct of Foreign Audits and Inspections and the European Community’s hosting the physical working group in July 2008. Japan is pleased to respond to CX/FICS 08/17/4.

1. General Comments

Japan is in favor of progression of the text in Appendix 1 of CX/FICS 08/17/4 in the Codex Step Procedure and replacing the existing Annex to CAC/GL 26-1997, provided that further changes contained as below are reflected; and the essential components of the Annex are incorporated in the Proposed Draft. The comparative table between the proposed text and the existing Annex to CAC/GL 26-1997 is attached as an appendix for reference.

2. Specific Comments on the Proposed Draft

PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF FOREIGN AUDITS AND INSPECTIONS

SECTION 1 INTRODUCTION

Para. 2. Japan proposes to make the following changes:

2. Assurance of the safety of exported foods may be achieved through the application of a country’s domestic ~~food safety system~~ **official inspection and certification system**. Although the official food inspection and certification systems of importing and exporting countries may utilize different approaches to their food safety controls, an importing country may recognize the exporting country’s ~~food safety system~~ **official inspection and certification system**, accept the differences as equivalent provided the same level of public health protection is achieved and maintained, or require an exporting country to apply certain of the importing country’s measures for those food products exported to the importing country.

Rationale: It was agreed to use the term “official inspection and certification system” rather than “food safety system” at the physical working group as written in para. 12, CX/FICS 08/17/4.

Conduct of Audit

Principle A

Para. 6 a) Japan recommends that the term “later” be deleted.

6. An importing or exporting country may initiate a written request for an audit.
- a) The request for and planning of an audit should follow the guidance laid out ~~later~~ in this document.

Rationale: The guidance is or will be laid out in the document. Therefore, the term “later” should not be necessarily included.

Para. 6 b) Japan would like to add the following paragraph.

- b) The receiver of the request should acknowledge and confirm their acceptance or otherwise of the proposal for audit **in a timely manner. If the request for an audit is rejected or suspended, the receiver should also state due reasons and provide an alternative upon request for clarification.**

Rationale: Audits should be conducted in a timely manner. Rejecting or suspending of the request without due reasons should be avoided.

Principle B

Paras. 10 and 11 Japan proposes to include the essential component of para. 11 in para. 10.

10. The principle of confidentiality of information relating to the audit, **including photographic information** should be adhered to.

~~11. If there is a request for photographic information, there should be agreement from the exporting country with regards to the question of confidentiality.~~

Rationale: Japan fully agrees with para. 11. Both paragraphs should be combined only for simplicity.

Paras. 12, 13 and 14 We propose to make changes as follows:

12. The costs incurred by an importing country to undertake an audit, including all travel costs, costs of technical experts and auditors, and costs of support staff should normally be borne by the importing country except as **may** otherwise **be** agreed by the parties.

13. The costs for staff and technical experts in the exporting country should normally be borne by the exporting country except as may otherwise be agreed by the parties.

14. In the case of audits undertaken by **approved** third parties, the costs should be borne by the party requesting the audit **except as may otherwise be agreed by the parties.**

Rationale: Consistency among the following three paragraphs should be ensured. Regarding para. 14, the inclusion of “approved” before “third parties” is necessary to describe what kind of third parties should be.

Principle G

Notification

Para. 23 b) Japan proposes to replace the sentence in the square bracket with a new sentence as follows.

23. The following information should be exchanged during the initial request to undertake an audit of a country’s official inspection and certification system.

...

- b) The objective of the audit, (e.g. to verify the effective application/implementation of specific measures and technical requirements of the exporting country’s inspection and certification system; to verify

compliance with measures of the importing country that the exporting country is implementing; to assess compliance with equivalency agreements.) ~~{The risk assessment component of an exporting country's food control system may be audited where it is necessary to support a risk management approach.}~~ **Verification of information on food control practice in the exporting country may be found to be necessary in the course of risk assessment to support a risk management approach.**

Rationale: The intention of including the sentence should be clearly stated.

Para. 23 d) Japan proposes to modify as follows:

d) The **anticipated** timeframe within which the audit will be conducted ~~and reported~~ should be agreed prior to the commencement of the audit.

Rationale: The rationale for the addition is to allow some flexibility. The rationale for the deletion is that the timeframe for reporting is normally available after the audit is completed, in other words, the timeframe depends on the result of the audit.

Pre-Audit

Para. 24 b) Japan proposes to make the following change:

24. The importing country, in consultation with the exporting country, should prepare the audit plan and program which should include the following:

...

b) items/ elements to be reviewed/ undertaken **which may include previous** records and inspection checklists;

Rationale: Japan believes that the "records" should be identified. Regarding checklists, Japan recalls that provision of checklists was discussed at the physical working group in July. It was our understanding that provision of checklists in advance was not a common practice among the Member countries, which should be reflected here.

Para. 24 f) Japan would like to make an addition as follows:

f) offices, establishments, laboratories and other facilities and locations to be visited, **if applicable, with clarification whether the audit plant should not be notified;**

Rationale: An unannounced or surprise visit is important for an importing country to appropriately evaluate the official control system of an exporting country. The possibility of conducting an unannounced or surprise visit is ensured with consent of the exporting country.

Para. 24 g) Japan would like to modify as follows:

g) audit dates, opening/closing meeting dates, ~~reporting element dates;~~ and

Rationale: Same as para. 23 d) above.

Para. 26 Japan would like to delete the second sentence of para. 26.

26. In advance of the audit the importing country should clearly identify the standards against which the audited party is to be assessed. ~~If there is equivalency between the two parties, then auditing standards should be those of the audited party.~~

Rationale: If there is equivalency between two parties, the auditing standards could be those of the auditing country. There is no need to identify which should be applied.

Para. 41 Japan agrees to remove the square brackets and retain the text as it is, with a comma in between.

41. Once an audit report has been finalized, ~~the importing and exporting country should discuss and if possible agree how and when any or all of the report will be published.~~ Publication of material relating to audits may be of assistance to other Codex members.

Rationale: Japan recalls that some member countries suggested efficiently utilizing the records in the past. The result of the discussion at the physical working group in July should be respected.

KENYA

APPENDIX 1

PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF FOREIGN AUDITS AND INSPECTIONS¹ (NO7 – 2008) (At Step 3)

SECTION 1 - INTRODUCTION

1. Countries that certify exports of food and those importing countries which rely on export certificates should take measures to assure the validity of certification. Validation measures by exporting countries may include achieving confidence that official or officially recognised inspection systems have verified that the product or process referred to in the certificate conforms to requirements. Measures by importing countries may include point of entry inspection systems, audit of exporting inspection systems, and ensuring that certificates themselves are authentic and accurate. [CAC/GL 20-1995]

Comment

Kenya is in agreement with the proposal as is therefore we propose that the opening and closing brackets be opened.

2. Assurance of the safety of exported foods may be achieved through the application of a country's domestic food safety system. Although the official food inspection and certification systems of importing and exporting countries may utilize different approaches to their food safety controls, an importing country may recognize the exporting country's food safety system, accept the differences as equivalent provided the same level of public health protection is achieved and maintained, or require an exporting country to apply certain of the importing country's measures for those food products exported to the importing country.] ***[The Committee may wish to consider the content of this paragraph in line with the final text of the document.]***

Comment

We believe that the sentence in bracket is in line with the context of the entire document so we propose that the square bracket should be opened and the sentence be part of the document.

SECTION 2 OBJECTIVE

~~4. The objective of this paper is to develop principles and guidelines for the conduct of foreign systems-based audits of an exporting country's food safety control systems and their ability [to achieve the importing country's appropriate level of protection (ALOP).] [The working group considered the question of whether or not to retain the reference to ALOP but due to time constraints was unable to reach a conclusion. This will need to be reconsidered in light of final text in the document.]~~

Comment

We would like the statement to read as follows: ***These principles and guidelines provide guidance for use by national governments to ensure a standardized and consistent approach to the conduct of audits of an exporting country's official food inspection and certification system(s), or component parts thereof to achieve the importing country's appropriate level of protection (ALOP).***

SECTION 4 PRINCIPLES

4. In conducting audits of an exporting country's official inspection and certification systems the following principles apply.

- c) The parties involved should have in place an agreed dispute resolution process. *[working group felt that this is a high level principle and the Committee may consider it needs to develop further*

supporting text]

Comment

We agree that there should be a detailed procedure on how to go about disputes. The procedure to be amended and put as an annex of this document for guidance.

Comment

We would like to add another statement as (i) under this section 4 to modify and clarify the issue of the final audit.

- i) The final audit report should incorporate the comments by the appropriate authorities of the exporting country. ~~and may be published.~~ *In accordance to the amendments that had been quoted in the background of agenda item 4, which states that “there is need to consider confidentiality in respect of the audit report and its findings” we fill that it should ne honoured and in case the the report is published, it should be within the consent of the auditee.*

CONDUCT OF AUDITS

Principle G

Notification

23. The following information should be exchanged during the initial request to undertake an audit of a country’s official inspection and certification system.

Comment

We proposes that the square bracket indicated in (b) below be opened as this approach will assist the audited countries get information on areas requiring improvement in order to further improve its risk management systems.

- b) The objective of the audit, (e.g. to verify the effective application/implementation of specific measures and technical requirements of the exporting country’s inspection and certification system; to verify compliance with measures of the importing country that the exporting country is implementing; to assess compliance with equivalency agreements.) **[The risk assessment component of an exporting country’s food control system may be audited where it is necessary to support a risk management approach.]**

28. To the extent possible documentary information required for planning, conducting and completing the audit should be requested and provided in advance of the audit, utilizing electronic means wherever possible.

Comment

We propose that the bracket indicated in (d) below should be deleted, there are cases where the audit conclusion “out of a desk audit “would be satisfactory for the official competent authority of the importing country to arrive at a decision or suspended carrying out on-site visit if the desk audit reveals the system is not ready for an on-ste visit.

- d) [In some cases the audit may be suspended or concluded prior to the on-site visit depending on the nature of information provided by the exporting country and in which case the reason should be communicated clearly to the exporting country by the importing country.]

Principle I

35. The report of audit findings and conclusions should:

Comment

We would like to comment on (f) by deleting the word “of” and modified (h) by adding the word “include” to make it more sensesible as indicated below:

f) may include any checklists of [for] elements evaluated.

Kenya proposes that we delete the entire square bracket and modify the statement to read “the report of audit findings and conclusion may include any check list of elements evaluated”

h) ***include*** outstanding matters and disputes ~~should be included~~ in the report if there is no agreement on the conclusions and the corresponding corrective actions.

Comment

We propose the removal of the brackets indicated in (41) below since we are in agreement with the statement as is, but, in case the report is published, it should be within the consent of the auditee.

41. Once an audit report has been finalised **[the importing and exporting country should discuss and if possible agree how and when any or all of the report will be published]**. Publication of material relating to audits may be of assistance to other Codex members.

OBSERVATIONS DU MALI

Le Mali souhaite adresser ses compliments au groupe de travail physique, présidé par l’Australie pour la préparation du document de travail.

Le Mali souhaite formuler des commentaires sur les points suivants du document de travail « Avant-projet de principes et Directives concernant la réalisation d’audits et d’inspections à l’étranger- CX/FICS08/17/4 » :

Titre de l’avant-projet :

Le Mali souhaite proposer la modification suivante au titre actuel de l’avant-projet, afin de mieux cadrer avec le contenu du document.

En lieu et place de «**AVANT-PROJET DE PRINCIPES ET DIRECTIVES CONCERNANT LA RÉALISATION D’AUDITS ET D’INSPECTIONS À L’ÉTRANGER**», retenir «**AVANT-PROJET DE PRINCIPES ET DIRECTIVES CONCERNANT LA RÉALISATION D’AUDITS DES SYSTEMES D’INSPECTION ET DE CERTIFICATION À L’ÉTRANGER**»

Section 3 définitions

Se conformer aux définitions de la version française des principes applicables à l’inspection et à la certification des importations et des exportations alimentaires afin d’assurer une cohérence des versions françaises des documents du Codex.

Section 4 Principes :

Pour être cohérent avec la terminologie utilisée en français en matière d’audit, remplacer :

- « Réunion de début d’audit » par « Réunion d’ouverture » ;
- « Réunion de fin d’audit » par « Réunion de clôture »

Le Mali soutient la poursuite des travaux, compte tenu de la nécessité d’élaborer une directive du Codex concernant la réalisation d’audits des systèmes d’inspection et de certification à l’étranger et de son importance sur l’amélioration du commerce des denrées alimentaires et de la protection de la santé des consommateurs.