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Agenda Item 4

CX/FICS 10/18/3 Add 1  
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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**  
**CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION**  
**AND CERTIFICATION SYSTEMS**

**Eighteenth Session**

**Surfers Paradise, Australia 1-5 March 2010**

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

**(N07-2008)**

**(Comments at Step 3)**

**(Brazil, Canada, Costa Rica, European Community, France, Indonesia, Mexico, New Zealand,  
Panama, Philippines, South Africa, United States of America and OIE)**

## Brazil

### **General Comments**

Brazil would like to congratulate Australia for the excellent work done and is pleased to forward its comments on the Paragraphs 7, 30 and 48 of the Proposed Draft Principles and Guidelines for the Conduct of Foreign Audits and Inspections.

### **Specific Comments**

#### **SECTION 3 – PRINCIPLES**

##### **Paragraph 7**

Where there are multiple competent authorities in an importing and/or exporting country, these authorities should coordinate their ~~assessment in order to avoid any duplication~~ efforts in order to accomplish the assessment successfully.

**Rationale:** Some countries, both importing and exporting, have more than one Competent Authority dealing with food safety issues and, in some cases, they share competence over one very single product. Therefore, in order to guarantee the correct assessment in each case, it is essential to coordinate efforts between the involved authorities.

##### **Paragraph 30**

b) ....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.

**Comment:** Brazil would like to have some clarification on the meaning of this proposal.

##### **Paragraph 48**

Once an assessment report has been finalized the competent authorities of the importing and exporting countries should discuss and ~~if possible~~ agree how and when any or all of the report will be published respecting confidentiality of information where appropriate.

**Rationale:** Brazil considers that the publication of the report should be object of agreement between both parties.

**Canada****General comments**

Canada thanks Australia for chairing the working group. Canada was a participant at the working group meeting held in Miami in July 2009, and believes the outcomes of that discussion led to a significantly improved text.

We are generally supportive of the construct of the revised document. We are of the view that it sets the appropriate framework/context around the assessment of official inspection and certification systems, provides a set of comprehensive high-level principles and describes/clarifies the approach/tools that may be deployed to carry out such assessments.

Canada is appreciative of the progress made, and supports advancement of this text with a view that it should be made available to member countries at the earliest convenience.

We have a few editorial comments as follows.

**Specific comments****Section 3 – Principles / Paragraph 5**

Regarding the sub-title immediately following Paragraph 5. We suggest to modify it so it more accurately reflects what Principles A – C apply to. Hence we suggest to add the underlined text as follows :

Principles A – C apply to the conduct **of the assessment and the understanding between** the competent authorities of the importing and exporting countries throughout the assessment process.

**Section 3 – Principle E.**

Immediately following this principle, the following sub-title should be inserted to precede Principles F and G, to indicate what these principles cover. Hence we suggest the insertion of the following:

**Principles F and G cover assessment reporting****Paragraph 18**

We suggest the following edit at the end of the paragraph as follows:

“... should be considered in selecting ~~an~~ **the most appropriate** assessment tool”. We believe that experience, knowledge and confidence should result in selecting not only “an” assessment tool, but the most appropriate tool.

**Costa Rica****General comments**

The idea that “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” would appear good in principle; however, Costa Rica considers that this could slow down audits or inspections.

**Specific comments****RECOMMENDATION**

19. The Committee is invited to consider the attached proposed draft Annex to the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997)* (Appendix I) with a view towards its further progression in the Codex Step Procedure. In providing comments members are reminded that the Annex will replace the current Annex to *CAC/GL 26-1997, Guidelines on Procedures for Conducting an Assessment and Verification by an Importing Country of Inspection and Certification Systems of an Exporting Country*.

[Correction to the Spanish as ‘Exporting Country’ appears twice and should be ‘Importing Country’ in the second instance. No change to the English]

19 Se invita al Comité a considerar el anteproyecto de Anexo a las Directrices para el Diseño, Funcionamiento, Evaluación y Acreditación de los Sistemas de Inspección y Certificación de Importaciones y Exportaciones de Alimentos (CAC/GL 26-1997) (Apéndice I) con miras a su avance en el Procedimiento de Trámites del Codex. Se recuerda a los miembros que proporcionen observaciones que el Anexo

reemplazará al actual Anexo a CAC/GL 26-1997, Directrices sobre los Procedimientos para Evaluar y Verificar los Sistemas de Inspección y Certificación de un País Exportador por parte de un País ~~Exportador~~ **importador**.

**Reason for change:** typing error.

## SECTION 1 – INTRODUCTION

2. These assessment activities should concentrate primarily on evaluating the effectiveness of the official inspection and certification systems in order to determine the ability of the exporting country's competent authority(s) to have and maintain control and deliver the required assurances to the importing country. A number of tools are available for the conduct of an assessment of an exporting country's official inspection and certification system these include, but are not limited to, audits, inspections and visits. The level of experience, knowledge and confidence the importing country has in the exporting country's official inspection and certification system is important in determining the appropriate tool to undertake the assessment.

[Correction to the Spanish as 'Exporting Country' appears twice and should be 'Importing Country' in the second instance. No change to the English]

2. Las actividades de evaluación deberían centrarse principalmente en evaluar la eficacia de los sistemas oficiales de inspección y certificación a fin de determinar la capacidad de la autoridad o autoridades competentes del país exportador de establecer y mantener control y proporcionar las garantías requeridas al país importador. Hay una serie de instrumentos disponibles para emprender la evaluación del sistema oficial de inspección y certificación de un país exportador. Ello incluye, pero no se limita a las auditorías, inspecciones y visitas. 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**.

**Reason for change:** typing error.

## In Appendix 1 SECTION 3 – PRINCIPLES

### Sub-paragraph G, Costa Rica proposes the following wording:

The final assessment report should be accurate and transparent and may be published, **within a time frame to be agreed by both parties**, respecting confidentiality of information, where appropriate

**Reason for change:** If a timeframe is not provided for the submission of the report, a country may delay the report unjustifiably.

## CONDUCT OF ASSESSMENTS

### Principle A

For the paragraphs 10, 13 and 14 Costa Rica proposes the following wording:

10. The importing country's competent authority auditors, inspectors or auditing organizations should have a ~~professional status which ensures their impartiality. They should have~~ the appropriate qualifications, experience and training both in the relevant area of technical expertise and in audit techniques, **and also demonstrate their impartiality when performing audits, inspections and checks**

**Reason for change:** Professional status is not a guarantee of impartiality.

13. **The countries should establish a mechanism to finance** 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, **such that said costs be covered** ~~should normally be borne~~ by the competent authority of the importing country ~~except as may otherwise be agreed~~.

**Reason for change:** In this way, the objectivity of the technical experts and auditors or inspectors is assured so guaranteeing a higher level of protection of public health.

14. The costs incurred by the competent authority of the exporting country, in supporting the assessment, for support staff 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

**Reason for change:** This word is not necessary given that at the end it is said that a different procedure may be adopted if the parties agree.

### Assessment preparation

32. A plan for undertaking the assessments, including timeframes and exchange of required information should be prepared and communicated to the exporting country's competent authority well in advance. The plan should include the following:

c) The anticipated timeframe within which the assessment will be conducted and reported, **and the exporting country advised accordingly.**

### European Community

#### General comments

The European Community and its Member States (ECMS) wish to congratulate Australia for the excellent leadership in the elaboration of the proposed draft principles and guidelines for audits and inspections.

The document has been thoroughly prepared and is now at an advanced state of development. The ECMS are largely satisfied with the text as it currently stands and would like to make only some minor technical and editorial comments.

#### Specific comments

Principle 5 – Reword the principle as follows: "The plan incorporating rationale, objective, scope, assessment tools and, requirements against which the exporting country's official inspection and certification system is assessed, should be clearly identified by the importing country and notified to **and agreed by** the exporting country's ~~competent authority(s)~~ well in advance of undertaking the assessment

*Rationale: It would be useful to note at the level of principles that there should be an agreement by the exporting country for the assessment plan. Only the terms "exporting country" and "importing country" are used in other principles and for the sake of coherency the term "competent authority" should be deleted also in principle E.*

Paragraph 6 – Reword the paragraph as follows: **The An importing country's competent authority** should be able to demonstrate that its assessment findings, conclusions and recommendations are primarily focused on whether the required outcomes are likely to be achieved by the system and that they are supported by objective evidence or data which can be verified as accurate and reliable.

*Rationale: This is also about coherency: in paragraphs giving guidance on how to put the principles into practice the term "competent authority" is constantly used.*

Paragraph 14 Bis – Add the following paragraph: **In the case of an assessment undertaken by third parties, the costs for that third party should be borne by the party requesting the assessment.**

*Rationale: The issue of costs should be clarified in cases where assessments are carried out by third parties, i.e. recognized and accredited agencies or enterprises which carry out the assessment on behalf of the competent authority of the importing country.*

Paragraph 26 – Reword the first sentence as follows: "The transparency and consistency of the assessment process may be facilitated by good documentation ~~and communication.~~"

*Rationale: Paragraph 26 gives guidance on documentation and paragraph 27 covers communication.*

Paragraph 30, indent c - Reword the indent as follows: "The scope of the assessment, that is, whether the assessment is to cover a whole system or its sub-components, measures, technical requirements, or products ~~should be defined prior to the commencement of the assessment.~~"

*Rationale: The deletion is suggested only for editorial reasons as the indents in paragraph 30 give a list of information that should be exchanged during the initial request to undertake an assessment.*

Paragraph 30, indent d - Reword the indent as follows: The assessment tool intended to be used including the requirements against which the official inspection and certification system of the exporting country will be assessed ~~should be identified.~~

*Rationale: See the previous point.*

Paragraph 32, indent a – Reword the indent as follows: "Purpose and scope of the assessment including whether it is a stand alone assessment or related to another assessment (e.g. follow-up of previous assessment) or series of assessments **and the participation of a third party, if relevant;**"

*Rationale: There are cases when third parties carry out or participate in assessments on behalf of the competent authority of the importing country. The issue should be clarified in the plan.*

### **France**

**The following comments only refer to translation issues noted in the French version of the working document CX/FICS 10/18/3**

#### ***Paragraph 2 and paragraph 16:***

"... établir la capacité de la / des autorité(s) compétente(s) du pays exportateur à mettre en place et maintenir une maîtrise **du contrôle** et fournir les assurances..."

"... to determine the ability of the exporting country's competent authority(s) to have and maintain **control** and deliver the required assurances ..."

*Justification:* Translation issue.

Add "*du contrôle*". The word "maîtrise" by itself is not sufficient here to define the scope.

#### ***Paragraph 4:***

"La présente annexe fournit des orientations à l'intention des autorités compétentes des pays importateur et exportateur pour assurer une approche efficace, efficiente, transparente et ~~concordante~~ **cohérente**"

"This annex provides guidance for use by competent authorities of both importing and exporting countries to ensure an effective, efficient, transparent, and **consistent** approach..."

*Justification:* Translation issue.

#### ***Paragraph 5 – 2nd sentence:***

"Les principes ~~supplémentaires~~ **complémentaires** suivants s'appliquent à la réalisation d'évaluations de systèmes officiels d'inspection et de certification d'un pays exportateur, qu'il s'agisse d'audits ou d'inspections."

"In conducting assessments, whether audits or inspections, of an exporting country's official inspection and certification systems, the following **additional** principles apply."

*Justification:* Inappropriate word.

#### ***Paragraph 5 – A:***

"A. Les évaluations devraient **se concentrer sur** ~~être orientées vers~~ les résultats, ~~transparentes~~, reposer sur des **preuves** ~~bases factuelles~~ et être réalisées de manière concertée, éthique et professionnelle, et s'il y a lieu, respecter les informations confidentielles."

"A. Assessments should be **outcome focused**, ~~transparent~~, evidence-based and conducted in a cooperative, ethical and professional manner, respecting confidential information where appropriate.

*Justification:* More appropriate words in French. Moreover the notion of transparency is included in Principle D (redundancy).

#### ***Paragraph 5 – B and C:***

"C. Les pays importateur et exportateur devraient convenir d'une **méthode** ~~instrument~~ adéquat pour la réalisation de l'évaluation avant sa mise en route, basé sur le champ d'application et les objectifs recherchés. Dans la plupart des cas, l'approche d'évaluation à privilégier ~~serait~~ ~~pourrait être~~ un audit portant sur le système officiel d'inspection et de certification dans **sa globalité** ~~son entièreté~~ ou sur une partie de celui-ci."

"C. 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."

*Justification:* Translation issues.

**Paragraph 5 – D, E and F:**

“D. Le processus d'évaluation devrait être planifié, **méthodique** ~~systematique~~, transparent, cohérent, parfaitement documenté et bien communiqué.”

“D. The assessment process should be planned, **systematic**, transparent, consistent, fully documented and well communicated.”

“E. Le **projet (ou programme ?)** ~~plan~~ comprenant la raison, l'objectif, la portée, l'instrument **la méthode** d'évaluation et les exigences **selon lesquelles** ~~par rapport auxquelles~~ le système officiel d'inspection et de certification du pays exportateur est évalué, devrait être clairement identifié par le pays importateur et notifié à/aux autorité(s) compétente(s) du pays exportateur avec un préavis suffisant avant d'entreprendre l'évaluation.”

“E. The **plan** incorporating rationale, objective, scope, assessment **tools** and, requirements **against which** the exporting country's official inspection and certification system is assessed, should be clearly identified by the importing country and notified to the exporting country's competent authority(s) well in advance of undertaking the assessment.”

“F. ~~Toutes les dispositions convenues~~, **Les** mesures correctives, calendriers d'exécution et procédures de suivi et de vérification **convenues** devraient être clairement définies et documentées.”

“ F. **Agreed** corrective actions, timeframes and follow-up verification procedures should be clearly established and documented.”

[The above changes are applicable to the French only].

Similarly in paragraphs 16, 17, 18, 19, 20, 24, 29 and 30: replace “instrument d'évaluation” (**assessment tool**) with “**méthode** d'évaluation”.

Similarly, in paragraph 39: replace “systematique” (**systematic**) with “**méthodique**”.

Similarly, in paragraphs 27, 32, 32<sup>e</sup>, 33, 34, 41b: replace “plan” (**plan**) with « **projet (ou programme ?)** ».

*Justification:* Translation issues.

**Paragraph 26:**

« La transparence et la **cohérence** ~~concordance~~... »

« The transparency and **consistency**... »

*Justification:* Translation issue.

**Paragraph 32 – b) c) and d):**

“b) Les points/éléments à examiner/exécuter ~~et~~ susceptibles de comprendre les archives et les listes de contrôle d'évaluation ;

“b) Items/ elements to be reviewed/ undertaken **which may** include records and assessment checklists;”

c) Le calendrier d'exécution prévu **pour** ~~de~~ l'évaluation, y compris la préparation des rapports y afférents,

“The anticipated timeframe **within which** the assessment will be conducted and reported”

d) Les critères **d'évaluation du** ~~par rapport auxquels le~~ système officiel d'inspection et de certification du pays exportateur sera évalué,”

“d) Criteria against which **the assessment** of the exporting country's official inspection and certification system **will be carried out**”

*Justification:* Translation issues.

**Paragraph 43:**

“Une approche collaborative durant la préparation du rapport ainsi que la procédure de diffusion et de **présentation** ~~publication~~ devraient être convenues à l'avance.”

“A collaborative approach to report preparation and a process for distribution and **presentation** should be agreed in advance”.

*Justification:* Translation issue.

**Paragraph 44:**

“e) tenir compte du calendrier d’exécution du rapport et des procédures **de réponse** correctives convenues entre les autorités compétentes des pays importateur et exportateur.”

“Take into account the timeframe for the finalisation of the report and **response** procedures agreed upon between importing and exporting countries’ competent authorities”

*Justification:* Translation issue.

**Indonesia****General Comments**

Indonesia would like to refer to general discussion and introduction of the working group as stated in paragraph 8 of the CF/FICS 10/18/3. The term assessment was agreed to be used throughout the documents after working group had a general discussion on the use of the terms ‘audit’, ‘inspection’, ‘evaluation’ and ‘assessment’.

Since the title of Section 9 of the parent documents also contains the term ‘verification’ and it was not considered by the working group, Indonesia would like to ask clarification on this. We are of the opinion that ‘verification’ should be used after ‘assessment’ throughout the documents included in the title as appropriate to enhance compatibility with the parent document. The title should be changed to be *Proposed*

*Draft Principles and Guidelines for the Conduct of Assessments **and Verification** of Foreign Official Inspection and Certification Systems*, and in order to reflect the use of term ‘verification’, some other section and paragraph throughout the document, which stated the assessment activities, might also be added with ‘verification’.

**Specific Comments****SECTION 1. INTRODUCTION**

Paragraph. 2. To delete the explanation of footnote 6 and replace it with the explanation of footnote 8. So that footnote 8 will be deleted and to add footnote 6 on paragraph 2, 18 and 29 as the explanation of experience, knowledge and confidence.

Rationale: in order to avoid redundancy between footnote 6 and 8 which are explain the same words.

Paragraph 3. At the first sentence after the title of Section 9 “Assessment and verification of inspection and certification systems“, add the words “and other related sections”, then delete the sentence “and the appropriate sections of the OIE Performance of Veterinary Service Tool for Evaluation of Veterinary Services, Chapter 3.2 of the OIE Terrestrial Animal Health Code” and replace it with “and those adopted by OIE where appropriate”. So paragraph 3 would read

“This annex is to be read in conjunction with section 9 - Assessment and verification of inspection and certification systems **and other related sections** of Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997) ~~and the appropriate sections of the OIE Performance of Veterinary Service Tool for Evaluation of Veterinary Services, Chapter 3.2 of the OIE Terrestrial Animal Health Code.~~ **and those adopted by OIE where appropriate.**”

Rationale: to accommodate others section of CAC/GL 26-1997 e.g. Section 6 as mentioned in paragraph 23 of this proposed draft and to avoid a mending regulation of OIE which might has some effect to this proposed draft.

**SECTION 3 PRINCIPLES**

**Principles A - C apply to the conduct of the competent authorities of the importing and exporting countries throughout the assessment process.**

Principle B. To add the words “in place” before the words “an agreed process”. So the sentence would read “B. The importing and exporting countries should have **in place** an agreed process to address any issues that may arise throughout the assessment process.”

Rationale: in order to maintain the consistency with sentence of Principle B in CONDUCT OF ASSESSMENT.

### **ASSESSMENT PROCESS - Assessment Preparation**

Paragraph 32 point (e). At the last sentence delete the word “specialist” and add the words “expert, translator” so it would read “A contact for the assessment team who can negotiate the details of the assessment plan and where possible, assessment team members including foreign auditors/inspectors, the lead auditor/inspector, ~~specialists,~~ **technical expert, translator;**

Rationale: the term *technical expert* is more appropriate and it has been used in paragraph 13 and 14 and translator should be included in this team.

Paragraph 32 point (f ). At the last sentence, replace the word “audit” with “assessment” so it would be read “An indication of the type or where possible the identity of the offices, establishments, laboratories and other facilities and locations to be visited and the timing for the notification to the sites where necessary (although this task may be completed at the ~~audit~~ **assessment** opening/entry meeting);”

Rationale: in order to maintain the consistency of the document.

Paragraph 35 “to delete whole paragraph and move the words “language that will be utilised during the assessment including, translation, availability of impartial and knowledgeable interpretation and resources.” into paragraph 32. It could be placed between point (d) and point (e). Therefore, since paragraph 35 is deleted so the paragraph order should conform into up date consecutive number and so do with consecutive number in point a to k paragraph 32.

### **ASSESSMENT PROCESS - Assessment Exit Meeting**

Add the word “Closing” so it read “Assessment **Closing**/ Exit Meeting”

Rationale: to in order to maintain the consistency with the subtitle “Assessment Opening/Entry Meeting” and sentence on paragraph 42.

### **SECTION 3. PRINCIPLE- ASSESSMENT REPORTING**

To replace the letter “I” with “G” so it would read “Principles F and **I G** cover assessment reporting.”

Rationale: There is no principle I.

### **Mexico**

Mexico is grateful for the opportunity to make the following comments about the document:

**Para. 5, sub-paragraph E.-** It is suggested changing “the plan” with “a plan”; as well as using an expression of time that implies the timeliness of implementing the plan: “...**and notified to the exporting country’s competent authority(s) within a timeframe that allows for its consideration and to proceed with its timely implementation well in advance of undertaking the assessment.**”

### **CONDUCT OF ASSESSMENTS**

**Principle A.-** In the Spanish, it is suggested changing the word “pruebas” with “**evidencias**” [No change to the English].

Para. 6.- In the Spanish, it is suggested changing the word “pruebas” with “**evidencias**” [No change to the English].

Para. 10.- It is suggested using the words “**professional character**” or “**professional conduct**” rather than “professional status”. This is because the word “status” seems to refer to the academic qualifications, which does not necessarily imply impartiality; whereas character or conduct, being a personality trait, does allow for this possibility.

Para. 16.- In the Spanish, add the adjective “eficaz”, as it appears in the English version (“effective”): Reword the Spanish to read “Se debería seleccionar el instrumento más eficiente **y eficaz** para evaluar la eficacia...” (The most efficient and effective tool that can assess the effectiveness...)

Para. 20.- Remove the letter “p” from “**descripto**” [No change to the English.]

Para. 21.- Change the Spanish wording to make the sentence clearer: “las auditorias basadas en sistemas ~~evalúan con~~ **consisten en** el examen de una muestra de los procedimientos...” (“Systems-based audits rely on the examination of a sample of system procedures...”) [No change to the English.].

Para. 25, sub-paragraph a.- Change the Spanish wording to make the sentence clearer: “~~examen de~~ la manera en que el establecimiento cumple los requisitos, así como **la evaluación** ~~el examen de un trabajo~~ **actividades específicas** y la especificación de productos...” (“How establishments meet requirements, including review of specific work and product specifications...”) [No change to the English.]

Para. 25, sub-paragraph c.- The assessment of inspectors is considered rather to be an activity specific to the inspection authority. It is suggested deleting this sub-paragraph.

## ASSESSMENT PROCESS

Para. 28.- Pluralize the Spanish: “...procedimientos y protocolos para abordar ~~el~~ **los** resultados y las recomendaciones...” (“Processes and protocols for addressing assessment **findings** and recommendations...”) [No change to the English.]

**Principle E.-** Refer to the comments regarding Paragraph 5.

Para. 29.- It is suggested indicating that previous assessments may in turn come from the assessing country, other countries, or recognised international organisations: “...the importing country’s competent authority should take into account the established level of experience, knowledge and confidence together with the history of **its** previous assessments, **as well as those by other countries or recognised international organisations...**”

Para. 32.- It is suggested consideration be given to an expression of time that implies sufficient timeframes to consider and implement the plan: “A plan for undertaking the assessments, including timeframes and exchange of required information should be prepared and communicated **within a timeframe that allows for its consideration and to proceed with its timely implementation** to the exporting country’s competent authority ~~well in advance...~~”

Para. 32, sub-paragraph f) Clarify to what the expression “identity of offices” refers. If it refers to territorial scope of jurisdiction (national, state or provincial and local), perhaps it would be worthwhile giving examples to make the text clearer.

Para. 33.- The Spanish text does not correspond to the English. Reword as follows: “...Toda enmienda o enmiendas de importancia propuestas al plan de evaluación por la parte proponente deberían **realizarse** solamente **en circunstancias justificadas** y comunicarse a la otra parte sin demora ~~en circunstancias atenuantes~~.” (“Proposed significant amendment(s) to the assessment plan should only be made in extenuating circumstances and should be communicated by the proposing party to the other party as soon as possible.”) [No change to the English]

Para. 35.- Reword the Spanish as follows: “...la disponibilidad de interpretación y **expertos imparciales** y de recursos ~~imparciales y expertos~~.” (“...availability of impartial and knowledgeable interpretation and resources.”) [No change to the English]

Para. 35 (number repeated).- Reword the Spanish as follows: “En la medida de lo posible, se solicitaría y proporcionaría por adelantado, por medios electrónicos ~~allá donde~~ **sea factible se pueda**, la información documental necesaria para planificar, llevar a cabo y completar la evaluación.” (“To the extent possible documentary information required for planning, conducting and completing the assessment should be requested and provided in advance of the assessment, utilizing electronic means **wherever possible**.”) [No change to the English]

Para. 35 sub-paragraph d.- Change the Spanish word “~~un examen~~” by “**la revisión**” (“In general a **review** of documents...”) [No change to the English]

Para. 40.- Change the Spanish words “condiciones de alojamiento” to **gestiones** de alojamiento”. [No change to the English]

Para. 41, sub-paragraph b.- Reword the Spanish as follows: “En la reunión se deberían ~~examinar~~ **revisar** todos los aspectos del plan de evaluación; **lo anterior** tiene como finalidad...” (The meeting should review all aspects of the assessment plan and is intended to provide...) [No change to the English]

Para. 42 sub-paragraph b.- In the Spanish, change the word “pruebas” with “**evidencias**”. [No change to the English]

## ASSESSMENT REPORTING

### Principle F

It is suggested moving the current paragraph 45 to this section, given it refers to corrective actions, timeframes and follow-up, and include the following change: “The timeframe and protocol for any follow-up verification, **if applicable**, should be clearly stated. Verification of corrective actions may include:...” given that a follow-up verification will not always be required.

Para. 44, sub-paragraph c.- In the Spanish, change the word “pruebas” with “**evidencias**” . [No change to the English]

Para. 44, sub-paragraph f.- Add at the end of this paragraph the words, “**if appropriate**”, given that a follow-up verification will not always be required.

Para. 44, sub-paragraph i.- In the Spanish delete from the start of the sub-paragraph the words “~~el informe~~ ~~pedra...~~”, as this is already stated in the paragraph’s introductory sentence. [No change to the English]

Para. 45. Move to Section F.

### **New Zealand**

New Zealand was a member of the working group that developed this draft. We would like to thank the United States of America for hosting the working group meeting held in Miami, Florida and also acknowledge the leadership of Australia and the Chair of CCFICS in facilitating the work undertaken.

### **General Comment**

New Zealand supports the progress of this work and considers that the completion of principles and guidelines relating to the conduct of foreign audits will be of significant assistance to all Codex members.

The draft document that CCFICS now has before it has, in our opinion, been much improved by the extensive and detailed discussion and revision undertaken by the working group. New Zealand suggests that with some editorial amendments this draft can be significantly progressed in the Codex step process.

### **Specific Comment**

New Zealand offers the following specific comments on Appendix 1 to CX/FICS 10/18/3:

**Paragraph 2:** New Zealand proposes an additional sentence at the end of this paragraph to indicate the importance that the rational for, and objectives of, any assessment also has in identifying the appropriate tool for undertaking an assessment.

New Zealand considers identifying the purpose or rational for an assessment to be a critical first step in the initiation of any proposal for an assessment visit and these also provide a context for applying the principles and guidance set out in this document. .

2. ... The level of experience, knowledge and confidence<sup>6</sup> the importing country has in the exporting country’s official inspection and certification system is important in determining the appropriate tool to undertake the assessment, as is the reason or rational for the assessment and the objective the assessment is intended to achieve.

**Paragraph 6:** The last part of this paragraph is unclear as to what ‘and that they are supported by...’ is referring to. This needs to be clarified. On the assumption that ‘they’ refers to ‘the required outcomes from the system’ New Zealand suggests that the text be amended to:

6. An importing country should be able to demonstrate that its assessment findings, conclusions and recommendations are primarily focused on whether the required outcomes are likely to be achieved by the system and that they such outcomes are supported by objective evidence or data which can be verified as accurate and reliable.

**Paragraph 12:** New Zealand suggests that reference should also be made to the potential costs that can be incurred by the businesses or facilities that may be involved in an assessment, such costs are a real component even though they are not meet by either the importing or exporting country’s competent authorities.

12. The anticipated costs for undertaking the assessment should be understood by both competent authorities in advance of undertaking the assessment-, this includes noting the costs that may be incurred by any business or facility visited during an assessment.

**Paragraph 14:** New Zealand proposes the following amendments to improve the flow and clarity of the paragraph and to remove duplication of language:

14. The costs incurred by the competent authority of the exporting country, ~~in supporting relating to~~ the assessment, including for support staff 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.

**Paragraph 17:** New Zealand proposes a minor amendment to the first sentences of this paragraph to ensure the tense is correct:

17. In selecting the assessment tool, it is important to consider the reason the assessment is being undertaken. ....

**Paragraph 22:** New Zealand considers that an important aspect when considering the ‘context of the over-all system’ is that there is the ability to make appropriate decisions and take corrective actions. We therefore suggest the text be amended to read as follows:

22. A system-based approach focuses on the control system(s) and recognizes that any compliances/non-compliances found must be viewed in the context of the over-all system, including the country’s approach to maintaining / resolving such issues.

**Paragraph 29 Bis:** New Zealand suggests that the current paragraph 39 should be moved to follow paragraph 29. This text is a general statement that relates to whatever particular tool is chosen to undertake an assessment. Currently the paragraph is under the sub-heading ‘Assessment Logistics’, which implies it related only to an on-site visit, which is only one of the assessment tools that may be appropriate. An amended opening to the discussion of Principle E would read:

29. When establishing the rationale, objective, scope, frequency of assessment and assessment tools, the importing country’s competent authority should take into account the established level of experience, knowledge and confidence together with the history of previous assessments, the period since the last assessment and any other relevant factors.

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

**Paragraph 30:** There is a disconnect between the current sub-paragraphs in that a) and b) relate to information that should be provided in the initial request to undertake an assessment, while c) and d) relate to information that should be exchanged prior to commencement of an assessment but need not be in the initial request. The examples in a) and b) should also be separated from the key point. An amended paragraph to resolve these editorial issues would read:

30. The following information should be exchanged during the initiating stage and prior to commencing ~~initial request to undertake~~ an assessment of a country’s official inspection and certification system:

a) The rationale or need to conduct an assessment, This may arise from a number of reasons including, an importing country’s legal obligations or the need to understand the respective roles of the competent authorities in both importing and exporting countries or the need to verify the adequacy of an exporting country’s system or food production/processing facilities.

b) The objective of the assessment, This may be for example ~~is~~ to verify the effective application/implementation of specific measures or 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 or other types of mutual acceptance of systems, conduct an investigation of outbreaks of foodborne diseases related to imported/exported food and to follow up corrective action resulting from previous assessments or of situations derived from food safety issues. 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.

c) The scope of the assessment, that is, whether the assessment is to cover a whole system or its sub-components, measures, technical requirements, or products ~~should be defined prior to the commencement of the assessment.~~

d) The assessment tool intended to be used including the requirements against which the official inspection and certification system of the exporting country will be assessed ~~should be identified~~.

**Paragraph 32 f):** New Zealand suggests that the words ‘as relevant’ are added to this sub-paragraph. It may not be necessary that all of locations mentioned will need to be visited in all instances, they are in effect examples and also only apply when an on-site visit is the assessment tool being used.

f) An indication of the type or where possible the identity of, as relevant, the offices, establishments, laboratories and other facilities and locations to be visited and the timing for the notification to the sites where necessary (although this task may be completed at the audit opening/entry meeting);

**Paragraph 32 h):** New Zealand suggests that the addition of words at the end of this sub-paragraph. Travel arrangements will only apply in the case of an assessment visit, which is only one tool for undertaking an assessment.

h) Travel schedules and other logistics, as necessary for an assessment visit; and

**Paragraph 36 c)** (currently numbered as the second paragraph 35): This sub-paragraph contains redundant terms ‘auditee’ and ‘auditor’, they are not used anywhere else in the document and do not added value. New Zealand suggests they are deleted:

c) In case the purpose of an information-request is not clear to the exporting country (~~auditee~~) and it has some issues related to the requested information, it may seek clarification from the importing country (~~auditor~~) as to the purpose and use of such information.

**Paragraph 36 d):** This sub-paragraph implies that a visit to the exporting country is the only form of assessment. In fact a review of documents may be the assessment tool that is used. Also any assessment may impose a burden on the competent authorities of the exporting country – this is not limited to visits. New Zealand suggests rewording as follows:

d) ~~In general~~ When an on-site visit is the assessment tool proposed a review of documents describing the system including legislative support should be conducted prior to commencement of the assessment visit. This is to allow the most efficient and effective use of time spent on-site i.e. to reduce the burden of assessments on the competent authorities of the exporting countries.

**Paragraph 37:** As drafted this paragraph implies that an on-site visit is always necessary as part of an assessment. The paragraph also concludes that the implication that an early conclusion is a bad thing and means the information provided needs clarifying. New Zealand proposes amendments as follows to clarify these points:

37. In some cases the assessment may be suspended or concluded prior to ~~the~~ an on-site visit depending on the nature of information provided by the competent authority of the exporting country and in which case the reason should be communicated clearly to the competent authority of the exporting country by the competent authority of the importing country. The competent authority of the exporting country should have the opportunity to clarify the information provided, should they consider this necessary.

**Paragraph 40:** This relates only to an assessment that includes visiting the exporting country. New Zealand suggests that this point should be more clearly stated:

40. When an assessment includes a visit to the exporting country ~~The~~ competent authority of the exporting country should have primary responsibility for the logistical aspects of the assessment including advising on internal travel and accommodation arrangements. It is the responsibility of the competent authority of the exporting country to communicate with the responsible parties of the site(s) to be assessed.

**Paragraph 41 a):** This sub-paragraph implies that a visit to the exporting country is the only form of assessment. It is possible, in the case of an assessment that involves only a documentary review that the opening discussion may be conducted long distance by electronic means, e.g video conference. In such cases the place of the meeting is not critical. New Zealand suggests that sub-paragraph be amended to read:

a) In the case of an assessment involving a visit to the exporting country, ~~The~~ meeting should be held at a place designated by the competent authority of the exporting country.

**Paragraph 42 a):** This sub-paragraph also implies that a visit to the exporting country is the only form of assessment. New Zealand suggests that sub-paragraph be amended to read:

a) In the case of an assessment involving a visit to the exporting country, the meeting should be held at a place designated by the competent authority of the exporting country.

**Paragraph 42 b):** New Zealand proposed the following text changes to improve clarity and grammar. Any non-conformities are part of the ‘findings’:

b) The meeting should summarize all findings and observations. Any identify non-conformities, should be identified and an outline of the objective evidence to support the non-conformities included. Correction of non-conformities should be left to the competent authority of the exporting country and verified by the competent authority of the importing country.

## **Panama**

### **General comments**

We have no general comments.

### **Specific comments**

The specific comments are set out below:

Paragraph 2. Correct the last word in the Spanish sentence as follows:

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**.

*Reason for the change: The importing country will perform the assessment based on the experience, knowledge and confidence that it has in the exporting country's official assessment and certification system. [No change to the English]*

Paragraph 3. Delete from the sentence the reference to the chapter in the OIE Terrestrial Animal Health Code to read as follows:

This annex is to be read in conjunction with section 9 - Assessment and verification of inspection and certification systems of *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997) and the appropriate sections of the *OIE Performance of Veterinary Service Tool for Evaluation of Veterinary Services*; ~~Chapter 3.2~~ of the *OIE Terrestrial Animal Health Code*.

Reason for the change: It is not recommended any reference be made to the chapter in the Code that contains the information. Given the rate at which this OIE document is revised and updated, the chapter number could very easily change.

Paragraph 13. Change part of the text with the following suggestion:

*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** ... [Change to Spanish only]*

*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~~, **however, they may be borne, after prior agreement, by other interested parties based on the applicable rules governing this matter.***

Reason for the change: We consider that the decision by the party bearing them should be the result of an agreement between the parties, especially given that in some countries there are regulations governing the expenditure of state monies.

Paragraph 14. Change part of the text with the following suggestion:

*Los gastos en los que 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** ...*  
 [Change to Spanish only]

*The costs incurred by the competent authority of the exporting country, in supporting the assessment, for support staff 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~~, **however, they may be borne, after prior agreement, by other interested parties based on the applicable rules governing this matter.***

Reason for the change: We consider that the decision by the party bearing them should be the result of an agreement between the parties, especially given that in some countries there are regulations governing the expenditure of state monies.

Paragraphs 16 to 25. Replace the word “tool” with “method”.

Reason for the change: We consider that the word “method” is broader and more explanatory regarding the manner adopted to perform the assessment.

Paragraph 44. Include a sentence to clarify the meaning of the word “recommendations”, for which purpose we suggest adding a sub-paragraph stating the following:

**l) The results of the assessment should take into account the recommendations of the auditors of the importing country’s relevant authorities, inspectors or audit organisations, regarding the ability of the official import and export inspection and certification system to instil confidence in the importing country.**

Reason for the change: Under the current wording, it is possible to understand that the auditors must make recommendations providing some indication of how to correct an identified non-compliance. It is the auditor’s responsibility to report a non-compliance based on objective evidence of the non-fulfilment or partial fulfilment of a requirement established by the importing country or the exporting country, such that the auditor is able to determine the corrective action, timeframes and procedures that will be the subject of discussion and agreement between the parties.

## **Philippines**

### **General Comments**

The Philippines congratulates the members of the Physical Working Group that met in Florida, USA for a well revised draft of the Guidelines. We concur with the recommendation of using the term ‘assessment’ throughout the text as this is more encompassing. Audits and inspections, whether documentary or on-site are just but tools that can be used to determine whether the official inspection and certification system of an exporting country is working to achieve its objectives.

On the sections on Assessment Process, Assessment Process should have sub-heading for Pre-Assessment and Actual Assessment (e.g. compliance of the questionnaire of the exporting country, exchange of communications, etc.) prior to onset of inspection and audit.

### **Specific Comments**

Section 1 – Introduction

Paragraph 1

In the context of a ~~relationship~~ **trade** between two countries, an importing country may determine that it is necessary to assess or verify an exporting country’s official inspection and certification systems. This annex is not intended to mandate such assessments or verifications **for trade to commence** but to provide guidance in the case that they are used.

*Rationale: There are many relationships that exist between two countries (i.e. diplomatic, etc). The document should only be focused on relationship pertaining to trade. Moreover, we propose to insert the phrase ‘for trade to commence’. We are of the position that assessments and its tools (i.e. audits, inspection) may be used if the importing country determines that there is a need for it. An importing country, through knowledge, experience and confidence, may also decide that a trade relationship can commence through its prior experience, knowledge and confidence with the exporting country.*

## Principle B and Principle C

## Move to Assessment Process (D to G)

*Rationale: We are of the impression that Principle B and C are part of the assessment process, thus, this should be placed under the heading of Assessment Process together with principles D to G*

## Conduct of Assessments

## Principle A – Paragraph 10

The importing country's competent authority auditors, inspectors or auditing organizations ~~should have a professional status which ensures their impartiality.~~ They should have the appropriate qualifications, experience and training both in the relevant area of technical expertise and in audit techniques.

*Rationale: The phrase is very vague and its deletion will make the paragraph clearer and not open to interpretations. We also believe that once both the importing and exporting countries have determined that there will be an assessment exercise, both parties should ensure that the experts that will be tapped or involved are impartial.*

## Principle D

## Paragraph 28

Processes and protocol for addressing assessment findings and recommendations should be documented and agreed **by both parties** prior to the assessment

*Rationale: Both the importing and exporting countries should agree on the processes and protocols.*

## Principle E – Notification

## Paragraph 30, (b)

The objective of the assessment, for example is: ~~...conduct an investigation of outbreaks of foodborne diseases related to imported/exported food~~ and to follow up corrective action resulting from...

*Rationale: We propose to delete the phrase as this should be the role or under the jurisdiction of the national competent authority and this activity should not be the objective of a foreign assessment.*

## Principle E – Notification

## Paragraph 30, (c)

The scope of the assessment, that is, whether the assessment is to cover a whole system or its sub-components, measures, technical requirements, **establishments** or products should be defined prior to the commencements of the assessment.

*Rationale: Determining if there will be establishments that will be used as sample should also be determined in the initial steps.*

## Assessment Preparation

## Paragraph 32 (e)

A contact **point** for assessment team who can negotiate the details of the assessment plan ~~and where possible, assessment team members including foreign auditor/inspectors, the lead auditor/inspector, specialist;~~ **and assessment team composed of foreign inspectors and auditors should be responsible for the pre-assessment of communications and requested documents or data prior to its onsite inspection and audit.**

*Rationale: There is a need to emphasize the role of the contact point for the whole assessment process as there may be cases that there are several authorities that have a shared jurisdiction on a specific product.*

**South Africa**

The National Regulator for Compulsory Specifications (NRCS) has the following comments to offer on draft documents to be discussed at the Eighteenth Session of CCFICS to be held in Australia from 1 March to 5 March 2010.

**Principle G** (: "The final assessment report should be accurate and transparent and **if the scope of the assessment covered Codex requirements**, it may be published respecting confidentiality of information, where appropriate. **It is advisable to respect the requirements of the country having been assessed with the publishing of such a report, where the report is published internationally and the report to be published, reflects on requirements that are over and above the requirements in Codex Standards, Codes of Practice and Guidelines.** "

Rationale: It must be borne in mind that assessments are mostly conducted by developed countries (importing countries) on developing countries (exporting countries). Where a country comply with Codex requirements, but not with certain more specific importing country's requirements, the option of that particular importing country to publish the report internationally should be a matter of obtaining the consent of the exporting country, as such international exposure could be subject to misinterpretation and have an influence on the exporting country's trade with other countries.

## **United States of America**

### **General Comments**

The United States appreciates the efforts of the physical Working Group to further develop the *Proposed Draft Principles and Guidelines for the Conduct of Foreign On-Site Audits and Inspections*. We believe the document is well developed and will provide very useful guidance to governments in carrying out foreign audits and inspections.

The United States notes and supports that the scope of the document includes the use of both audits and inspections to verify the performance of an exporting country's food control system by an importing country. Principle C includes the statement "In most cases the preferred assessment approach would be an audit that considers the official inspection system as a whole or part." The United States supports this statement. The use of inspections in the context of this guidance is for the same purpose as audits; that is, as noted in the Introduction, paragraph 2, "to determine the ability of the exporting country's competent authority(s) to have and maintain control and deliver the required assurances to the importing country."

The United States observes that this document is to replace the current Annex to the *Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997). Since the existing Annex is an extension of Section 9 (Assessment and Verification of Inspection and Certification Systems) of the main document, the United States suggests that the Committee review Section 9 regarding consistency with the new Annex and ensure that all key provisions from the existing Annex have been incorporated into the document under development. Our review of Section 9 would suggest that the only change needed would be to insert "Principles and" before "Guidelines" in paragraph 57. We have reviewed the existing Annex and believe all key provisions are addressed.

### **Specific Comments**

#### **Title**

Add a footnote to the title noting that the document is to become an Annex to the *Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems*, replacing the existing annex.

*Rationale: for clarity that the document is an annex and not a stand-alone document.*

### **Section 1 Introduction**

Paragraph 2 - In the second sentence, add a semi-colon (;) after "system." The second sentence would read:

*A number of tools are available for the conduct of an assessment of an exporting country's official inspection and certification systems; these include, but are not limited to, audits, inspections and visits.*

Rationale: editorial change for grammar.

Paragraph 3 – Add a period after (CAC/GL 26-1997), strike through "and the," insert "In addition," in front of appropriate sections, add "can be consulted" at the end of this sentence. The new second sentence would read:

*In addition, appropriate sections of the OIE Performance of Veterinary Service Tool for Evaluation of Veterinary Services, Chapter 3.2 of the OIE Terrestrial Animal Health Code can be consulted.*

Rationale: The reference to the OIE text is intended as a valuable reference, not necessarily to be read in conjunction.

### **Section 3 Principles**

Paragraph 5 – In the second sentence, delete “, whether audits or inspections,”. The sentence will now read:

*In conducting assessments, ~~whether audits or inspections~~, of an exporting country’s official inspection and certification systems, the following additional principles apply.*

Rationale: As stated in paragraph 2, the term “assessment” includes but is not limited to audits, inspections and visits”, so it is not necessary to include only audits and inspections at this point.

Principle C - The United States observes that the second sentence of this principle is guidance rather than a principle. However, because of the importance of this concept, the United States suggests the second sentence be retained in its current position. If removal from the Principle is considered appropriate, the sentence could be placed as a new paragraph following current paragraph 16.

Principle E – Strike through “notified to” and insert “shared with”. The principle will now read:

*The plan incorporating rationale, objective, scope, assessment tools and, requirements against which the exporting country’s official inspection and certification system is assessed, should be clearly identified by the importing country and shared with ~~notified to~~ the exporting country’s competent authority(s) well in advance of undertaking the assessment.*

Rationale: editorial change.

### **Conduct of Assessments**

Section Heading - The heading sets out a section. Thus, the heading should be: **Section 4 Conduct Of Assessments**

*Rationale: proper formatting of the document.*

Principle B - Principle B as written in this Section is inconsistent with Principle B as written in the “Principles” section. Specifically, the words “in place” need to be removed from the Principle B in this section.

*Rationale: consistency of text.*

Paragraph 15 – In the second sentence, replace “from” with “throughout.” The sentence would read:

*Where they are available, the competent authorities of the importing and exporting countries should use existing processes to resolve issues arising throughout the assessment to the extent possible.*

Paragraph 17 – In line 3, the first “e.g.” should be replaced by “or”.

*Rationale: editorial change.*

Paragraph 24—In the first sentence, delete the comma after “tool” and delete the examples in parentheses “(e.g. establishments, farms, aquaculture)”. The sentence will read:

*The inspection tool assesses individual elements of the food production system ~~(e.g. establishments, farms, aquaculture)~~ to verify that they conform to requirements and can in some instances, be used to confirm the effectiveness of the controls in the exporting country.*

Rationale: Paragraph 25 addresses examples where inspections could be involved.

### **Assessment Process**

Section Heading: The heading sets out a section. Thus, the heading should be: **Section 5 Assessment Process**

*Rationale: proper formatting of the document.*

Paragraph 29 – At the end of the sentence, delete “other relevant factors” and add “progress in addressing non-conformities, and any other status changes (e.g. new technical requirements).” The sentence would then read:

*When establishing the rationale, objective, scope, frequency of assessment and assessment tools, the importing country's competent authority should take into account the established level of experience, knowledge and confidence together with the history of previous assessments, the period since the last assessment and any ~~other relevant factors~~ progress in addressing non-conformities, and any other status changes (e.g. new technical requirements).*

Rationale: provides more specific examples to consider when establishing the rationale.

Paragraph 30 (a) – Make the following changes to this paragraph: delete the words “may arise from a number of reasons including” and replace with “for example:”; place a semi-colon after “obligations” and delete “or”; place a semi-colon after “countries” and a comma after “or”. The sentence would then read:

*“The rationale or need to conduct an assessment, ~~may arise from a number of reasons including, for example:~~ an importing country's legal obligations; ~~or~~ the need to understand the respective roles of the competent authorities in both the importing and exporting countries; ~~or~~ the need to verify the adequacy of an exporting country's system or food production/processing facilities.”*

Rationale: for consistency with (b) and editorial.

Paragraph 30(b) – In the first line, put a colon after “example” and delete “is”. In the fifth line put a semi-colon after “systems” and insert “to” before “conduct”. In the sixth line, insert a “semi-colon after “food”.

Rationale: editorial.

Paragraph 30(b). Delete the last sentence relating to auditing the risk assessment component.

*Rationale: This document is a process document, describing the process for undertaking assessments of foreign official inspection and certification systems. The guidance does not relate to determining whether a particular risk management measure is correct, but rather whether the measure is being implemented properly. Whether or not a measure is, in fact, correct, is a different activity and outside the scope of this document.*

Paragraph 30(b). List the examples in bulleted format. The paragraph would read:

*The objective of the assessment, for example, is to:*

- *Verify the effective application/implementation of specific measures or technical requirements of the exporting country's inspection and certification systems;*
- *Verify compliance with measures of the importing country that the exporting country is implementing;*
- *Assess compliance with equivalency agreements or other types of mutual acceptance of systems;*
- *Conduct an investigation of outbreaks of food borne diseases related to imported/exported food; and*
- *Follow up corrective action resulting from previous assessments or of situations derived from food safety issues.*

Rationale: Formatting change.

Paragraph 30(c); Delete “should be defined prior to the commencement of the assessment”. The phrase would read:

*“The scope of the assessment, that is, whether the assessment is to cover a whole system or its sub-components, measures, technical requirements, or products. ~~should be defined prior to the commencement of the assessment.~~”*

Rationale: The chapeau statement to this paragraph states the timing of the activity covered and needs not be repeated in the sub-parts.

Paragraph 30(d). Insert “The identification of” before “The assessment tool” and delete “should be identified”. The sentence would read:

*The identification of the assessment tool intended to be used including the requirements against which the official inspection and certification system of the export country will be assessed. ~~should be identified.~~*

Rationale: for consistency with the structure of the other sub-parts of this paragraph.

Paragraph 33. In the first sentence, the United States suggests deleting the phrase “in emphasis” as well as “or during” in the first sentence of this paragraph. The sentence would then read:

*While efforts should be made to adhere to the assessment plan it should be designed to be flexible in order to permit changes ~~in emphasis~~ based on information gathered prior to, ~~or during~~ the audit.*

Rationale. The United States believes that the intent of this paragraph is to allow for changes to the assessment plan. These changes would not be restricted to the emphasis of the assessment. This paragraph sits under the sub-heading “Assessment Preparation”, which suggests that the information is gathered in advance of the audit. If necessary, changes made during the course of the audit should be addressed under sub-heading “Assessment Logistics

Paragraph 35. There are two paragraphs numbered 35; the second should be numbered 36.

Paragraph 35-2<sup>nd</sup> (actual paragraph 36) (c). Delete the terms “auditee” and “auditor”. Additionally delete the hyphen between “information” and “request”. The sentence would then read:

*If the purpose of an information request is not clear to the exporting country (~~auditee~~) and the exporting country has some concerns about the requested information, it may seek clarification from the importing country (~~auditor~~) as to the purpose and use of such information.*

Rationale: These terms are not previously used in the document nor are they used subsequently. The use of the terms “exporting country” and “importing country” are used throughout the document and there is no need to provide a synonym for these terms. Editorial re: deleting the hyphen.

Paragraph 35-(d) Second Sentence – Change authorities to authority and countries to country in the second sentence. The sentence would then read:

*This is to allow most efficient and effective use of time spent on-site i.e. to reduce the burden of assessments on the competent authorityies of the exporting countryies.*

Rationale: To correct the plural to single.

Paragraph 37 – Separate the last sentence into a new paragraph. The new paragraph 37-bis would read:

*37. bis The competent authority of the exporting country should have the opportunity to clarify any information provided.*

Rationale: to broaden the application of clarifying information beyond instances when the assessment is being suspended or concluded prior to the on-site visit.

Paragraph 41 (b). Place a comma after “plan” and insert the phrase “including any final adjustments,”. The sentence would then read:

*The meeting should review all aspects of the assessment plan, including any final adjustments, 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 of the assessment.*

Rationale: the opening meeting should include coverage of any final adjustments to the assessment plan.

Paragraph 42 (b). In the first sentence, after “non-conformities” insert “and timeframes for corrective action if appropriate, and”. The sentence would then read:

*The meeting should summarize all findings and observations, identify non-conformities and timeframes for corrective action if appropriate, and outline the objective evidence to support the non-conformities.*

Rationale: for some non-conformities it may be appropriate to designate a timeframe for corrective action.

### **Assessment Reporting**

Section Heading: The heading sets out a section. Thus, the heading should be: **Section 6 Assessment Reporting**. Additionally, the sub-heading listing the Principles should read “Principles F and G” rather than Principles F and I”.

Rationale: proper formatting of the document; editorial.

## **World Organisation for Animal Health (OIE)**

### **Section 1 Introduction**

Paragraph 2. These assessment activities should concentrate primarily on evaluating the effectiveness of the official inspection and certification systems in order to determine the ability of the exporting country's competent authority(ies) to control and deliver the required assurances, based on the relevant international standards forms of CODEX and the OIE, and to the importing country. A number of tools are available for the conduct of an assessment of an exporting country's official inspection and certification system these include, but are not limited to, audits, inspections and visits. The level of experience, knowledge and confidence<sup>6</sup> the importing country has in the exporting country's official inspection and certification system is important in determining the appropriate tool to undertake the assessment. For the evaluation of Veterinary Services, importing countries should take into account the results of any evaluation of the Performance of Veterinary Services that may have been carried out by the OIE using the OIE PVS Tool.

**Rationale:** importing countries that are WTO Members have an obligation to base their animal health and food safety requirements on the relevant international standards of the OIE and Codex.

**Rationale:** The OIE PVS Evaluation is based on the relevant international standards set out in the OIE Terrestrial Animal Health Code, which is a reference for WTO Members under the SPS Agreement and on which the OIE PVS Evaluation is based. This tool is highly relevant to the evaluation of veterinary services and should be mentioned in the introduction.

### **Audit Tools**

Paragraph 20. the word implementation should have a lowercase 'I'

The audit tool, described as 'systems based audit' should focus on assessing whether the ~~I~~implementation of the official inspection and certification system or components thereof in operation in the exporting country is capable of meeting its objectives.

### **Inspection Tool**

Paragraph 24. The inspection tool assesses individual elements of the food production system (e.g. ~~establishments, farms, aquaculture, establishments, abattoirs, processing plants~~) to verify that they conform to requirements and can in some instances be used to confirm the effectiveness of the controls in the exporting country. The use of inspections may be considered in situations where there is a need to verify whether one or more specific elements of an inspection or certification system meet the requirements.

**Rationale:** Farms and aquaculture establishments covers the production phase for terrestrial and aquatic animals respectively. Abattoirs and processing plants covers subsequent phases of food production for products derived from animals.

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<sup>6</sup> Experience, knowledge and confidence in an exporting country's food inspection and certification system by an importing country includes the history of food trade between two countries and the history of compliance of foods with the importing country's requirements, particularly the food products involved. Further examples that may inform the importing country's experience, knowledge and confidence are listed in paragraph 10 points a to n in CAC/GL 53-2003.