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FOOD AND AGRICULTURE
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Agenda Item 4

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

Eighteenth Session

Surfers Paradise, Australia 1 – 5 March 2010

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

(NO-2008)

(At Step 3)

(prepared by a physical working group led by Australia with the assistance of Belize, Brazil, Canada, China, Denmark, Ethiopia, European Commission, France, Germany, Indonesia, Japan, Republic of Korea, Mexico, the Netherlands, New Zealand, Norway, Saint Lucia, South Africa, Spain, Switzerland, Thailand, United States of America, Zambia, OIE, and ICGMA)

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments on the following subject matter are invited to do so **no later than 16 November 2009** to: Codex Australia, Australian Government Department of Agriculture Fisheries and Forestry GPO Box 858, Canberra ACT, 2601 (fax: 61.2.6272. 4389; E-mail: codex.contact@daff.gov.au - *preferably*), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Via delle Terme di Caracalla, 00153 Rome, Italy (Fax No + 39 06 5705 4593; E-mail: codex@fao.org - *preferably*).

Format for submitting comments: In order to facilitate the compilation of comments and prepare more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments in the format outlined in the Annex to this document.

BACKGROUND

1. The 15th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) (Mar del Plata, Argentina, November 2006) during its consideration of possible new work, considered the Project Document¹ prepared by Australia, proposing that the committee consider the need to undertake new work on the development of Guidelines for the Conduct of Foreign On-Site Audits and Inspections. The Committee expressed general support for the proposal in view of the increasing use of foreign on-site audits and inspections and considered it would be very useful to collect in a single document the relevant provisions contained in various CCFICS texts and to develop principles and guidance with respect to the conduct of foreign audits including the purposes of such foreign on-site audits and inspections. It was observed that “audit” and “inspection” are not equally understood by countries and that the guidelines should also aim at clarifying their meaning and scope.

2. The 16th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (Surfers Paradise, Australia, November 2007) considered a discussion paper prepared by an

¹ CRD 11

electronic working group led by Australia² which outlined the scope, justification and rationale for new work on the development of principles and guidelines for the conduct of foreign on-site audits and inspections. The proposed work aimed at developing guidance for the conduct of foreign on-site audits and inspections, thus providing a transparent and consistent framework in which exporting country food inspection and certification are assessed. The work was justified by the increasing use of foreign on-site audits and inspections and assessments of compliance with equivalence determinations or agreements of those systems. The Committee unanimously expressed support for this new work.

3. The 31st Session of the Codex Alimentarius Commission approved new work on the proposed draft Principles and Guidelines for the Conduct of Foreign On-site Audits and Inspections (N07- 2008).

4. At its 17th session the Committee considered the proposed draft principles and guidelines for the Conduct of Foreign On-site Audits and Inspections, which had been revised by a physical working group led by Australia, at Step 3.

5. The Committee had a lengthy discussion on the scope of the paper and it was agreed that both audit and inspection should be included in the revised document. The Committee noted that the current structure of the proposed draft principles and guidelines could be appropriate for a stand-alone document. However, as the document was also closely linked to the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997), especially Section 9 “Assessment and Verification of Inspection and Certification Systems”, the Committee agreed that it should replace the current Annex of these guidelines. The Committee agreed to return the proposed draft principles and guidelines for the Conduct of Foreign On-site Audits and Inspections (N07-2008) to Step 2 for redrafting, circulation for comments at Step 3 and further consideration at Step 4 at the next Session of the CCFICS (Alinorm 09/32/30 para. 37).

6. In order to facilitate the discussion at its 18th session, the Committee agreed to establish a physical working group, chaired by Australia and hosted by the United States of America, working in English, French and Spanish to prepare revised proposed draft principles and guidelines. In preparing the redrafted document, it was also agreed that the working group should take into account the comments made at the 17th session³; discuss the detailed descriptions of the principles; build the new text on the basis of the parent document; and ensure that no useful concepts included in the existing Annex of the parent document be lost.

REPORT OF THE PHYSICAL WORKING GROUP

7. A Physical working group Chaired by Australia and hosted by the United States of America met in Miami, Florida, from 7 to 9 July 2009. The working group was attended by 58 delegates from 24 member countries, 1 member organisation, 1 international governmental and 1 non-governmental organisations a full list of participants can be found at Appendix 2. The working group considered a revised document taking into account the previous discussions in the committee and comments submitted by members of the electronic working group led by Australia⁴.

General Discussion and Introduction

8. The working group had a general discussion on the use of the terms ‘audit’, ‘inspection’, ‘evaluation’ and ‘assessment’ and recognised that audit, inspections and visits were tools that could be used in the assessment of exporting country’s official inspection and certification system. It was agreed to use the term ‘assessment’ throughout the document, which would also enhance compatibility with the parent document (CAC/GL 26-1997) where Section 9 and its annex refers broadly to ‘assessment of inspection and certification systems’. The title of the proposed draft was also changed to reflect the use of the term ‘assessments’.

² With the assistance of Argentina, Brazil, Canada, China, Czech Republic, European Community, Germany, Kenya, Japan, Malaysia, New Zealand, Norway, Philippines, Spain, Sweden, Switzerland, Thailand and the United States of America

³ CX/FICS 08/17/4 Add. 1 (Comments of Bolivia, Brazil, Canada, Dominican Republic, Iran, Mexico, New Zealand, United States of America, IACFO, ICBA and ICGMA); CX/FICS 08/17/4 Add. 2 (Comments of Colombia, Ecuador, Japan, Kenya and Mali); CRD 6 (Comments of Costa Rica, European Community Member States, India, Japan and Thailand); CRD 8 (Comments of Indonesia and Norway); CRD 9 (Comments of the Philippines); CRD 10 (Comments of Republic of Korea)

⁴ With the assistance of Brazil, Canada, European Community, Germany, India, Iran, Japan, New Zealand, the Netherlands, South Africa, Switzerland, the United States of America, Zambia, ICGMA, OIE and OIML

9. The working group also amended the Introduction section to reflect that assessment activities should concentrate primarily on the effectiveness of the inspection and certification systems in order to determine the exporting country's competent authority(s) ability to have and maintain control and deliver the required assurances to the importing country and that a number of tools are available for the conduct of assessments (including but not limited to audits, inspections and visits).

10. In respect of additional tools that can be used during an assessment the working group included reference to the use of inspections and visits which is in line with previous discussions in the Committee. In this context, the working group also recalled that the use of experience, knowledge and confidence had been explored at length during the development of the Annex to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003)* and that 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, therefore a reference to the use of experience, knowledge and confidence in determining the appropriate tool for undertaking the assessment was also included in the Introduction.

11. In recognition of the role that animal production plays in contributing to food safety outcomes it was also agreed to reference the appropriate sections of the *OIE Performance of Veterinary Service Tool for Evaluation of Veterinary Services, Chapter 3.1* of the *OIE Terrestrial Animal Health Code* in the Introduction.

Scope

12. In recognising the increasing demands being placed on exporting country's as a result of increased audits, inspections and visits, the Scope of the document was amended to reflect that the document could also apply to other visits or requests for information that may be part of an assessment which has the ability to impact (either negatively or positively) on the exporting country.

Definitions

13. In accordance with Codex decision not to repeat existing definitions, the section on definitions was deleted however a footnote was inserted in the Introduction at the first reference to 'official inspection and certification system' referring to the definitions contained in the parent document (CAC/GL 26-1997).

Principles

14. The working group had an extensive discussion on the principles and agreed to insert a preamble to the Principles to clarify that the principles would apply regardless of whether the assessment was an audit or an inspection. In order to reflect the discussion over the last few sessions of the Committee on the need to ensure that the principles remained high level, the working group made the following changes:

- Deleted existing Principle A (*The competent authorities of the importing and exporting country should reach an agreement relating to the conduct of an assessment prior to its initiation*) as it was covered by Principle F (now Principle E).
- Principle C (now Principle B) replaced the word 'during' with 'throughout'.
- Principle F (now Principle E) included the words 'plan incorporating' before the words 'rationale, objective and scope' to reflect the need for planning in the initial stages of the request from the importing country.
- Deleted Principle G as it was reflected in the amended Principle C.

15. The working group felt that using sub-titles to group the Principles would provide some clarity as to the specific sections. Therefore it was agreed to add the following sub-titles to the Principles Sections:

- Principles A to C apply to the conduct of the competent authorities of the importing and exporting countries throughout the assessment process; and
- Principles for the assessment process are provided in Principles D to G.

16. Following the reorganisation of the Principles the working group proceeded to re-organise the draft text under each principle to ensure that the flow of the document provided more clarity and reflected the discussion concerning the essential elements required, to ensure that the draft document did not paraphrase or duplicate the parent document.

17. In re-ordering the paragraphs the working group considered that the overarching principle that the preferred approach to assessments, should be systems-based audits that are conducted in an open and transparent manner. The working group also agreed that the following key areas should be addressed through the proposed draft principles and guidelines:

- Planning and preparation including identifying the rationale and objective for the assessment;
- Ensuring an agreed process is available to resolve issues arising from the assessment;
- Open communication between the importing and exporting countries is required at all stages of the assessment;
- Protection of intellectual property;
- Reasons for undertaking an assessment;
- The inclusion of explanatory text in relation to audit and inspection tools and the assessment process (including notification, preparation, logistics, opening and exit meetings and reporting).

18. The proposed draft Principles and Guidelines for the Conduct of Assessments of Foreign Official Inspection and Certification Systems as revised by the working group can be found at Appendix 1.

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*.

20. The Committee at its 18th Session in March 2010 will consider the text in Appendix 1 at Step 3 together with comments at Step 4.

GENERAL GUIDANCE FOR THE PROVISIONS OF COMMENTS

In order to facilitate the compilation of comments and prepare more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments under the following headings:

- (i) General Comments
- (ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in **underlined/bold font** and deletion in ~~strikethrough font~~.

In order to facilitate the work of the Secretariats to compile comments, Members and Observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied / pasted into a consolidated document.

In order to reduce the translation work and save paper, Members and Observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.

Example of how comments should be prepared

SECTION 2 OBJECTIVE

Paragraph 4 - At the end of the last sentence add the words “and can be applied as relevant to any inspections of establishments or other facilities that may occur as part of an audit.” So the last sentence would read “This annex applies equally to assessments carried out onsite or by documentary review alone **and can be applied as relevant to any inspections of establishments or other facilities that may occur as part of an audit**”.

Rationale: To remove duplication of concepts – standardized and consistent. Efficiency is an outcome of following these guidelines and should be included here. To clarify the use of inspection as an associated tool not the prime focus.

Appendix 1

**PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF ASSESSMENTS
OF FOREIGN OFFICIAL INSPECTION AND CERTIFICATION SYSTEMS****(NO7-2008)****(At Step 3)****SECTION 1 INTRODUCTION**

1. In the context of a relationship between two countries, an importing country may determine that it is necessary to assess or verify an exporting country's official inspection and certification systems⁵. This annex is not intended to mandate such assessments or verifications but to provide guidance in the case that they are used.

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 confidence⁶ 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.

3. 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*.

SECTION 2 SCOPE

4. This annex provides guidance for use by competent authorities of both importing and exporting countries to ensure an effective, efficient, transparent⁷, and consistent approach when using audits or inspections for assessment of an exporting country's official inspection and certification system(s), or component parts thereof. This annex should also apply to any other visit or request for information that may be part of an assessment which has the ability to impact on the exporting country.

SECTION 3 PRINCIPLES

5. The competent authority of an importing country may conduct an assessment of an exporting country's official inspection and certification system with the agreement of the exporting country. In conducting assessments, whether audits or inspections, of an exporting country's official inspection and certification systems, the following additional principles apply.

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

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

B. The importing and exporting countries should have an agreed process to address any issues that may arise throughout the assessment process.

⁵ *Official inspection and certification systems* refers to both 'Official inspection systems and official certification systems' and 'Officially recognized inspection systems and Officially recognized certification systems' as defined in the parent document

⁶ 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.

⁷ CAC/GL 20 1995, paragraphs 13-16, and CAC/GL 26-1997, paragraph 58

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.

Principles for the assessment process are provided in Principles D to G

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

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

G. The final assessment report should be accurate and transparent and may be published respecting confidentiality of information, where appropriate.

CONDUCT OF ASSESSMENTS

Principle A

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

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 are supported by objective evidence or data which can be verified as accurate and reliable.

7. Where there are multiple competent authorities in an importing country, these authorities should coordinate their assessments in order to avoid any duplication.

8. The exporting country's competent authority or authorities should cooperate and assist in the performance of the assessment so that the assessment objectives are achieved.

9. Throughout the course of the assessment, all issues arising should be dealt with in a cooperative, ethical and professional manner by the competent authorities.

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.

11. The principle of confidentiality of information relating to the assessment, including photographic information should be adhered to. To this end, commercial confidentiality and intellectual property rights should be respected. For countries with specific laws relating to confidentiality, it will be the responsibility of the two parties to reach agreement as to how the laws will be adhered to, in order to proceed.

12. The anticipated costs for undertaking the assessment should be understood by both competent authorities in advance of undertaking the assessment.

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

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

Principle B

The importing and exporting countries should have in place an agreed process to address any issues that may arise throughout the assessment process.

15. Prior to the commencement of the assessment the key elements of a process to address issues that may arise throughout an assessment should be agreed. Where they are available, the competent authorities of the importing and exporting countries should use existing processes to resolve issues arising from the assessment to the extent possible. The competent authorities of the importing and exporting country should aim to resolve any issues which may arise in the course of the assessment in an open, transparent and cooperative manner. If any issues remain outstanding they should be indicated in the assessment report with appropriate justification.

Principle 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 a part.

16. The most efficient and effective tool that can assess the effectiveness of the exporting country's official inspection and certification system including the exporting country's competent authority(s) ability to have and maintain control and deliver the required assurances to the importing country should be selected.

17. In selecting the assessment tool, it is important to consider the reason the assessment is undertaken. Assessments can, for example, be part of a risk analysis prior to commencement of trade, can assess the official inspection and certification system, or controls for a particular component e.g. commodity (e.g. dairy, fish or meat) or controls for a particular element (e.g. chemical residues) or specific exporting establishments.

18. The importing country's experience, knowledge and confidence⁸ in an exporting country's official inspection and certification systems, should be considered in selecting an assessment tool.

19. In general, the preferred assessment tools would be audits of all or part of an exporting country's official inspection and certification system including the ability of the competent authority. Inspections can also be an appropriate assessment tool. In some instances, where competent authorities use other terms to describe assessment activities, e.g. visits, information exchanges, such activities should also be subject to these guidelines.

Audit Tools

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

21. Systems-based audits rely on the examination of a sample of system procedures, documents or records and where required sites within the scope of the system under audit, as opposed to examining all procedures.

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.

23. In conducting a systems-based audit, the audit may involve examination of the elements as contained in Section 6, Inspection and Certification System Infrastructure or other elements as appropriate.

Inspection Tool

24. 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. The use of inspections may be considered in

⁸ Paragraphs 9-14 of the Appendix to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* CAC/GL 53-2003 provides additional guidance relating to what constitutes experience, knowledge and confidence and expands on information presented in paragraph 10-12 of that Guideline.

situations where there is a need to verify whether one or more specific elements of an inspection or certification system meet the requirements.

25. Inspections may involve the examination of:

- a) How establishments meet requirements, including review of specific work and product specifications, observation and review of establishment operations and appropriate operating records;
- b) Establishment's personnel capabilities, when specified in requirements;
- c) Inspectors' capability, if specified in requirements.

ASSESSMENT PROCESS

Principles D to G cover the assessment process.

Principle D

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

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

27. In order to prepare and carry out an assessment, ongoing and transparent communication is required. Consultation should occur between the competent authorities of the importing and exporting countries at all points in the process, from developing the assessment plan through to final reporting and resolution of any issues arising during the assessment. To ensure ongoing and transparent communication the competent authorities of the importing and exporting country should nominate responsible contact persons or contact points for assessments.

28. Processes and protocols for addressing assessment findings and recommendations should be documented and agreed prior to the assessment.

Principle E

The plan incorporating the 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.

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.

Notification

30. The following information should be exchanged during the initial request to undertake an assessment of a country's official inspection and certification system:

- a) The rationale or need to conduct an assessment, 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, 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.

31. In all cases, the competent authority of the importing country should provide the competent authority of the exporting country with sufficient notice of the intended assessment, in order to enable it to make the necessary arrangements such as logistics and information gathering. If the rationale for the assessment is a critical public health issue the advance notice should reflect the urgency related to the public health risk.

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:

- a) 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;
- b) Items/ elements to be reviewed/ undertaken which may include records and assessment checklists;
- c) The anticipated timeframe within which the assessment will be conducted and reported;
- d) Criteria against which the assessment of the exporting country's official inspection and certification system will be carried out;
- e) 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;
- f) 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 opening/entry meeting);
- g) The dates for the conduct of the assessment, the dates of the opening and closing meeting and the anticipated date for reporting the observations of the assessment;
- h) Travel schedules and other logistics; and
- i) Provisions for respect of commercial confidentiality and intellectual property rights.

33. 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. 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.

34. As part of the assessment plan, the parties should reach agreement on how the results of the evaluation will be conveyed to the exporting country, such as findings, non-compliance and recommendations.

35. Advanced agreement should be reached on the language that will be utilised during the assessment including, translation, availability of impartial and knowledgeable interpretation and resources.

35. 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.

- a) The assessment preparation request should be focused and related to the stated scope and objectives.

- b) If this is a follow-up assessment, then the exporting country should only need to provide any information that has changed since the previous assessment or that has not been requested during a previous assessment;
- 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.
- d) In general a review of documents describing the system including legislative support should be conducted prior to commencement of the assessment. 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 authorities of the exporting countries.

37. In some cases the assessment may be suspended or concluded prior to the 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.

38. Agreement should be reached in advance concerning the use of information sharing from assessments and the parties with whom information can be shared.

Assessment Logistics

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

40. 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.

Assessment Opening/Entry Meeting

41. An opening or entry meeting should be held.

- a) The meeting should be held at a place designated by the competent authority of the exporting country.
- b) The meeting should review all aspects of the assessment plan and is intended to provide an overview of the official inspection and certification system of the exporting country and to confirm the parameters and logistics of the assessment.
- c) Agreement should be reached on the methods to ensure continuous liaison and communications between the parties during the assessment.

Assessment Exit Meeting

42. A closing or exit meeting should be held.

- a) The meeting should be held at a place designated by the competent authority of the exporting country.
- b) The meeting should summarize all findings and observations, identify non-conformities, outline the objective evidence to support the non-conformities. 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.
- c) This meeting provides an opportunity for the competent authority of the exporting country to raise questions or seek clarification of the findings and observations provided at the meeting.

ASSESSMENT REPORTING**Principles F and I cover assessment reporting.****Principle F**

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

Principle G

The final assessment report should be accurate and transparent and may be published respecting confidentiality of information, where appropriate.

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

44. The report of assessment should provide a balanced picture of the findings and include conclusions and recommendations that accurately reflect those findings. It should:

- a) Describe the purpose, scope, and outcome;
- b) Describe the criteria and assessment process;
- c) Include assessment findings with supporting evidence for each conclusion, along with any details of significance discussed during the closing meeting;
- d) Be made available as agreed to between the importing and exporting country's competent authorities, including and addressing the comments made by the competent authority of the exporting country to enhance the accuracy of the report;
- e) Take into account the timeframe for the finalisation of the report and response procedures agreed upon between importing and exporting countries' competent authorities;
- f) Take into account how corrective actions will be communicated and agreed to, including how follow-up verification will be completed;
- g) Include any checklists of elements evaluated, where required to support the findings;
- h) Include a summary of the assessment outcome;
- i) Include outstanding matters and issues arising during the assessment in the report if there is no agreement on the conclusions and the corresponding corrective actions;
- j) Include uncertainties and/or any obstacles encountered that could affect the reliability of the assessment conclusion; and
- k) Indicate any areas not covered in the assessment process, though within the scope, and the reasons for such deviation from the agreed scope.

45. The timeframe and protocol for any follow-up verification should be clearly stated. Verification of corrective actions may include:

- a) Review of assurances provided by the competent authority of the exporting country;
- b) Review of documentation provided by the competent authority of the exporting country; or
- c) Review of stated corrective action in a subsequent assessment.

46. Commercial confidentiality must be respected in the preparation and subsequent distribution of the assessment report.

47. The assessed party should have the opportunity to review the draft report in an agreed timeframe, provide comments and correct factual errors before its finalization. The final report should incorporate, or be accompanied by, the comments provided by the competent authority of the exporting country.

48. Once an assessment report has been finalised 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.

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