

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 4

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

(NO7 – 2008)

(Comments at Step 3)

(Brazil, Bolivia, Canada, Dominican Republic, Iran, Mexico, New Zealand, United States of America, IACFO,
ICBA and ICGMA)

BRAZIL

Regarding the proposed draft, Brazil would like to make the following considerations:

Section 1 – Introduction

Brazil would like to include reference to the work environment that should motivate the process of conduct of foreign audits and inspection.

“The conduct of foreign audits and inspections between countries shall be based on mutual benefit, common understanding and good faith taking into account the willingness to achieve practical results.”

Section 2 – Objective

Paragraph 4 – Brazil considers there is a need to maintain reference in the objective, to the conduct of foreign systems-based audits of an exporting country’s official inspection and certification systems and their ability to achieve the importing country’s appropriate level of protection (ALOP). We understand that is the center point of the discussion of the proposed guidelines.

We suggest maintaining the sentence as it was firstly pointed:

4. The objective of this paper is to develop principles and guidelines for the conduct of foreign systems-based audits of an exporting country’s food safety control systems and their ability to achieve the importing country’s appropriate level of protection (ALOP)

Section 3 – Definitions

In order to maintain coherence, and once the definition of Audit is in the document, Brazil thinks it would be benefic to also have the definition of Inspection according established at CAC/GL 34-1999.

Section 4 – Principles

a) An importing country may conduct audits of an exporting country’s official inspection and/or certification systems.

It is important to let the importing country evaluate and decide the extent of the audit it will conduct.

~~e) The parties involved should have in place an agreed dispute resolution process.~~

We strongly support the deletion of this bullet. As it is not part of Codex competences, the dispute resolution process should not be part of these principles and guidelines. It is a matter to be dealt under WTO system. The whole process has to be based on common understanding between countries and if there is an unsolvable issue, the WTO DSU can be used.

Principle C

~~The parties involved should have in place an agreed dispute resolution process.~~

~~15. All outstanding issues should be discussed between the parties using the agreed dispute resolution process.~~

The whole Principle C should be eliminated, once the dispute resolution process should not be part of these principles and guidelines, as it is not part of Codex competences. It is a matter to be dealt under WTO system. The whole Codex process has to be based on common understanding between countries and if there is an unsolvable issue, the WTO DSU can be used.

Principle E**Paragraph 19**

19. In order to prepare and carry out an audit, ongoing and transparent communication will be required. Consultation should occur between importing and exporting countries at all points in the process, from developing the audit plan through to final reporting and, if needed, resolution of any disputes.

For the same reasons highlighted for the deletion of Principle 4.c) and Principle C.15., Brazil expects this wording will be deleted.

Principle G

A plan for undertaking the audit, including the criteria for assessment of the exporting country's official inspection and certification system should be prepared in advance and agreed between importing and exporting countries.

It is necessary to have a common understanding between countries to make possible the conduct of the audit and inspection.

Paragraph 23

- a) **The rationale or need to conduct an audit. (It 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 to follow up on a food safety incident.)**
- b) **The objective of the audit. (e.g. to verify the effective application/implementation of specific measures and technical requirements of the exporting country's inspection and certification system; to verify compliance with measures of the importing country that the exporting country is implementing; to assess compliance with equivalency agreements.) {The risk assessment component of an exporting country's food control system may be audited where it is necessary to support a risk management approach.}**

We suggest wording adjustments in order of clarity. At the end of b), we suggest to remove the brackets and keep the wording as it is.

Paragraph 24

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

It would be benefic to highlight the idea to make the process as fast as it can be. That is why we suggest including the wording "*in a timely manner*".

Paragraph 28

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

It is important to guarantee the possibility to conclude the audit at any time of the process. We believe we are already in a position to assume the text as it is.

Principle I**Paragraph 41**

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

The publication of audit is a controversial issue among Countries. It is not a consensus of how and what can be publicized. Brazil believes that this subject need to be part of the principles and guidelines for the conduct of foreign audits and inspections and that the Countries involved in the process need to discuss and dived how to proceed in each case. Besides, there is no need or advantage to have this consideration “*Publication of material relating to audits may be of assistance to other Codex members*” in this document and we would like to see it deleted.

BOLIVIA

SECTION 1 - INTRODUCTION

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

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

Bolivia requests that the square brackets be removed from points 1 and 2.

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

Bolivia suggests retaining the reference to the ALOP

SECTION 4 - PRINCIPLES **[AND GUIDELINES]**

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

- a) An importing country may conduct audits of an exporting country’s official inspection and certification systems.
- b) Audits should be independent, evidence-based and conducted in a cooperative, ethical and professional manner.
- c) The parties involved should have in place an agreed dispute resolution process. [*working group felt that this is a high level principle and the Committee may consider it needs to develop further supporting text*]
- d) The audit should be systems-based, unless an alternative approach is agreed to by both importing and exporting country.
- e) The audit process should be transparent, consistent and fully documented.
- f) The rationale, objective, scope, and timeframe of the audit should be clearly identified in advance of undertaking the audit.
- g) A plan for undertaking the audit, including criteria for assessment of the exporting country’s official inspection and certification system should be prepared in advance.
- h) Agreed corrective actions, timeframes and follow-up verification procedures should be clearly established and documented.
- i) The final audit report should incorporate the comments by the appropriate authorities of the exporting country and may be published.

With regard to this point, Bolivia considers that only sub-paragraphs b) and e) set out principles, the others form part of the actual audit guidelines.

Principle C

The parties involved should have in place an agreed dispute resolution process. [The working group considered this to be a high level principle that may need further supporting text.]

15. All outstanding issues should be discussed between the parties using the agreed dispute resolution process.

Bolivia agrees with the working group about the need to draw up a document regarding the audit dispute resolution process.

19. In order to prepare and carry out an audit, ongoing and transparent communication will be required. Consultation should occur between importing and exporting countries at all points in the process, from developing the audit plan through to final reporting [and, if needed, resolution of any disputes].

It is suggested deleting the dispute aspect as this principle focuses on permanent consultation.

Notification

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

- a) The rationale or need to conduct an audit, 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 to follow up on a food safety incident.

This sub-paragraph bears no relation with the audit planning stage. It is suggested deleting sub-paragraph a).

Pre-Audit

25. As part of the audit plan, the parties should reach agreement on how the results of the evaluation will be conveyed to the exporting country, [including findings {repeated as 'results' in Spanish}, non-compliance and recommendations].

Delete the repeated results section.

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

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

This sub-paragraph should be treated as a separate point; it has no relation with the exchange of information. Also, delete the square brackets.

31. The exporting country should have primary responsibility for the logistical aspects of the audit including advising on internal travel and accommodation arrangements.

Audit Opening/Entry Meeting [and finance]

Finance to perform the audit should also be considered in this stage of the process.

32. An opening or entry meeting should be held.

- b) Agreement should be reached on the methods to ensure continuous liaison and communications between the parties during the audit.

There are no provisions for the on-site audit; it is suggested establishing guidelines for performing on-site audits.

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

If the text is approved, the square brackets should be deleted.

DOMINICAN REPUBLIC

The Dominican Republic is grateful for the opportunity to make these comments on the **PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF FOREIGN ON-SITE AUDITS AND INSPECTIONS (N07-2008)**, in order to strengthen the document:

Specific observations:

Text in bold and struck through: suggested deletions.

Text in bold: proposed new text.

Text in italics: text quoted from the original document.

Section 2 - Objective

The Dominican Republic believes the appropriate levels of protection (ALOP) considered in the Objective should be retained.

Section 3 - Definitions

The Dominican Republic proposes including the following definitions:

Inspection

On-site visit

On-site inspection

Evaluation

Section 4 – Principles

AUDIT PROCESS

The audit process is described in principles E to G.

Principle G

Pre-audit

The Dominican Republic suggests making the following changes:

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

- a) ~~¶~~ *the pre-audit request should be focused and related to the stated scope and objectives.;*
- b) ~~¶~~ *the purpose of data and information requested should be stated, including how the data will be used.;*
- c) ~~¶~~ *in general a review of documents describing the system including legislative support should be conducted prior to commencing the audit.;*
- d) [~~¶~~ *in some cases the audit may be suspended or concluded prior to the on-site visit depending on the nature of information provided by the exporting country and in which case the reason should be communicated clearly to the exporting country by the importing country.;*]

Audit exit meeting

Paragraph 33. *A closing or exit meeting should be held. ;*

AUDIT REPORTING

Principles H and I cover audit reporting.

Principle I

The Dominican Republic proposes including the following text in paragraph 37, such that it reads:

Paragraph 37. *Reporting audit findings and conclusions should be standardized [refer to the standard, if it exists, for the presentation of the audit results and conclusions] as much as possible to make the approach to audit more uniform and transparent*

CANADA

Canada thanks Australia for leading the physical working group (WG) in charge of preparing the current draft of the *Proposed Draft Principles and Guidelines for the Conduct of Foreign On-Site Audits and Inspections* for the Committee's consideration. We continue to strongly support the development of this text, as there would be significant benefits to member countries in light of the increasing number of international audits and inspections.

We support the overall Objective (Section 2) of the document as recommended by the WG, i.e., to provide guidance to governments on a standardized and consistent approach to the conduct of audits of exporting countries' official inspection and certification systems, or component parts thereof. However, we believe it is not necessary to retain a reference to ALOP in this Section as the document is principally a "procedural guidelines" to ensure a standardized and consistent approach to audits.

We support the current organization of the principles, i.e., starting with general (high-level) principles that cover the conduct of the audits, followed by principles that cover the audit process and reporting. We also support the replacement of the existing Annex to CAC/GL 26-1997 with the proposed principles and guidelines

In order to provide further clarity in the flow of the document, we suggest including a new “header” immediately before “Conduct of Audits”. This proposed header would be as follows:

“SECTION 5 APPLICATION/IMPLEMENTATION OF PRINCIPLES”

We also suggest that an introductory/transition paragraph be inserted immediately following this proposed header as can be found in our specific comments below.

SPECIFIC COMMENTS

Section 1- Introduction

While we support retention of existing Paragraph 1, we do not see the need to retain current Paragraph 2 which is focused on the concept of equivalence. We believe there is sufficient CCFICS guidance on this subject and that it is not necessary to repeat text found in other CCFICS guidelines. Instead, we propose replacing existing Paragraph 2 with the following introductory remarks, more specifically positioning this CCFICS guidance in terms of its need and use in the international context as follows:

“There is an increasing use of foreign on-site audits and inspections by competent authorities. This guidance is intended to promote more transparent and consistent framework/approach in which exporting country food inspection and certification are assessed. Its use should result in more predictability and clarity on how audits are planned and conducted.”

Section 2 – Objective

In the second paragraph of this section, it is indicated in square brackets that the WG discussed whether it is necessary to retain a reference about “achieving the importing country’s appropriate level of protection (ALOP)” but was unable to reach a conclusion. Canada is of the view it is not necessary to retain such reference as this text is principally a “procedural guidelines” document to ensure a standardized and consistent approach to foreign audits and inspections.

Section 4 - Principles

Conduct of audits

We suggest adding an introductory/transition paragraph to further clarify the linkage between Section 4 Principles, and the further elaboration/application of these principles in the subsequent text. This transition paragraph could be added immediately before the heading CONDUCT OF AUDITS, and before the sub-heading – Principles A to D cover the conduct of audits:

“The following sections are intended to further clarify how the Principles listed in Section 4 should be applied and implemented. The general principles 4 a) to 4 i) have been grouped into 3 categories, namely Conduct of Audits, Audit process and Audit reporting.”

Section 4 - Principle A

Paragraph 6 c): We suggest that the word "will" be replaced with "should". This would be more consistent with the rest of the document. The sentence would read as follows:

“If differences arise as to the purpose, scope or other aspects (e.g. timing) the parties ~~will~~ should work to resolve such issues.”

Section 4 – Principle B

Paragraph 10: We suggest the insertion of further supporting text as follows,

“Parties should discuss and agree on confidentiality of information exchange, and the principle of confidentiality of information relating to the audit should be adhered to”.

Section 4 – Principle C

We propose the addition of further supporting text to the chapeau statement as follows:

“The parties involved should have in place an agreed dispute resolution process. It is important to agree upon such a process in advance of the parties undertaking an audit”.

Section 4 - Principle D

Paragraphs 17 f) and g): We suggest merging paragraphs f) and g) into one new 17 f) sub item which could read as follows:

“17.f) review of laboratory capability (e.g. scope of testing, competency) and test results.”

Section 4 - Principle E

Paragraph 18 (bis): We suggest the insertion of a new paragraph after existing Paragraph 18 to further clarify the meaning of the term consistent. The new paragraph would read as follows:

“18 (bis). The actions of all members of the audit team should be consistent with documented/established procedures.”

Paragraph 19: We suggest the following underlined text be added to Paragraph 19 as follows:

“In order to prepare and carry out an audit, ongoing and transparent communication will be required. Consultation should occur between importing and exporting countries at all points in the process, from developing the audit plan, audit process, through to final reporting and, if needed, resolution of any disputes.”

Section 4 – Principle I

Paragraph 41: We support retention of the square-bracketed sentence, but with a modification as follows:

“the importing and exporting country should discuss and—~~if possible,~~ based on pre-established actions/procedures, agree how and when.....”

IRAN

Title

It is recommended to keep the reference “on site” in the title of the document, since audits cannot be limited to undertaking a desk study or desk audit, commonly called documentation review (as mentioned in Para.12, page3), but the audit process will be completed after on-site audit.

It is recommended to delete the term “inspection” from the title, since the term “inspection” is not commonly used for systems but it is used for product or consignments compare to “audit” which is commonly used for systems.

It is also considerable that this document is all about auditing process and does not have any explanation about inspection procedures, after all auditing and inspections are two different subjects and it is not appropriate to incorporate them in one document.

SECTION 2 OBJECTIVE

Para. 3, first line

Replace “these principles and guidelines provide guidance...” by “this document provides principles and guidelines...”

Para. 3, bracket

Replace [to achieve the importing country’s appropriate level of protection (ALOP).] by [to insure if the importing country’s appropriate level of protection is achieved]

SECTION 3 DEFINITIONS

Official accreditation:

Delete these terms and the related definition, since there are no references to these terms in the text.

Officially recognized inspection systems and officially recognized certification systems:

Delete this phrase and the related definition, since there are no references to these terms in the text.

Risk analysis:

Delete these terms and the related definition, since there are no references to these terms in the text.

It seems useful to explain and clarify the differences between the terms “audits”, “assessment” and “inspections”

CONDUCT OF AUDITS

Principle A, Para. 5

Replace “Audits are one tool” by “Auditing is a tool”

Principle A, Para. 5, second line:

Replace “to assess an exporting country’s food inspection and certification system” by “to assess the competency of an exporting country’s food inspection and certification system”

Principle B

It seems necessary and useful to have more explanation about the technical term "independent" in one or two clauses, having in mind that clause number 9 is about impartiality and not "independence"

Principle D, Para. 16, Claus a

Replace "audit should focus on the implementation..." by "audit should focus on the documentation and the implementation..."

Principle D, Para. 17

Delete "Review of" from all clauses "b" to "f", since the term "examination" in the heading sentence fulfils the purpose.

AUDIT PROCESS

Principle G, Pre-Audit

Replace "Pre-Audit" by "preparation for the audit" since Pre-Audit is a technical term having specific meaning as "a type of audit conducted before an official audit".

Principle G, Pre-Audit, Para. 24, Claus g

Replace this clause by the following:

"Audit schedule including dates and times for opening/closing meeting, all stages of the audit and reporting element dates".

Principle G, Pre-Audit, Para. 26

Replace "identify the standards against which the audited party is to be assessed" by "identify the audit criteria and standards against which the auditee is to be assessed".

Principle G, Pre-Audit, Para. 28, Claus a

Replace "pre-audit request" by "the audit request", explanation given in number 15above.

Principle G, Audit exit meeting

Replace "Audit exit meeting" by "Audit closing meeting", which is more commonly used.

Principle G, Para. 23, Claus b

Replace the term "verify" in the first and second example by the term "assess".

Noting that audits or assessments will not always end up with verification, but it may end up to minor or major non conformances which preclude verification.

AUDIT REPORTING

Principle I, Para. 24

Replace "." by "," after the bracket and convert the two sentences into one sentence.

MEXICO

Mexico is grateful for the opportunity to make the following comments regarding the Proposed Draft Principles and Guidelines for the Conduct of Foreign On-Site Audits and Inspections.

Paragraphs 1 and 2- It is suggested changing the following terms so that the context of the introduction is consistent with the document's objectives and content.

1. Foreign audits/inspections may be beneficial for the procedure to determine the equivalence of exporting countries' food inspection and certification systems (Para. 34 of the Annex to the recently approved CAC-53).
2. Foreign audits/inspections may also be a useful tool for verifying the effective application/implementation of the specific measures and technical requirements of the exporting country's inspection and certification system; checking compliance of specific importing country measures being implemented by the exporting country; assessing the compliance of equivalence agreements, confirming the validity of certificates issued by the exporting country; performing testing for outbreaks of food-borne diseases attributable to imported/exported food and monitoring corrective action arising from previous audits or situations relative to food safety.
3. For the performance of the foreign audit/inspection, the provisions of paragraphs 4.2 and 4.3 of the Annex to CAC-26 should be considered.

Paragraph 3.- It is suggested deleting the text referring to the ALOP, as foreign audits/inspections can be used to assess the extent to which health measures meet or help meet the ALOP, and may be achieved using other measures as referred to above.

Paragraph 4a) - This principle is interpreted as a right that countries have to assess the exporting country's food inspection and certification systems; Article 4 of the SPS Agreement refers rather to the exporting country having to provide the importing country requesting inspections with proof and other relevant procedures to objectively demonstrate to the importing country that the measures applied reach the importing country's appropriate level of health and phytosanitary protection.

The agreement also indicates that the importing country's measures only apply insofar as they are necessary to protect the health and life of people and animals, or to protect plants, when based on scientific principles and will not be upheld without sufficient scientific evidence, and indicates that the health and phytosanitary measures must not be applied in such a way as cause a veiled restriction on international trade.

Further, it should be considered that where a national law assists an authority in performing foreign audits/inspections and said law might be imposed as a requisite for exporting, that the exporting country's inspection and certification systems should be audited. In practice, this situation may become a trade barrier for many countries, as they would have to wait to be audited before they could export their products. Accordingly, audits should be performed within a reasonable timeframe, it being emphasised that the importing and exporting countries should consider an alternative mechanism for the exporting country to demonstrate compliance with the requirements pending the audit/inspection's taking place, such that the exports are not unjustifiably delayed/detained.

Under these arguments, while reference is made to the principle regarding the right to perform audits, a corresponding principle should also be included indicating that foreign audits/inspections should not be established as a prerequisite for food trade.

Paragraph 23b) - Consideration should be given to a better alternative to auditing the risk assessment component (documentary inspection, working meeting or both), given that the risk assessment is more of an office task than field work.

Paragraph 28d) - Requires clarification: In what cases could this situation arise?

Principle H- Change as follows: "The corrective actions, how to proceed...

Paragraph 35e) - Change: "...the corrective actions, how to proceed, shall be advised..."

Paragraph 39- Change "~~Should~~ If a corrective plan ~~be~~ is required..."

NEW ZEALAND

New Zealand was a member of the working group that developed this draft and would like to acknowledge the leadership of Australia and the Chair of CCFICS in facilitating the work undertaken in Brussels.

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

New Zealand supports the proposal that this document when completed should replace the existing Annex to CAC/GL 26-1997 – Guideline for the Design, Operation, Assessment, Accreditation of Food Import and Export Inspection and Certification Systems.

New Zealand offers the following specific comments on Appendix 1 to CX/FICS 08/17/4:

Title

New Zealand suggests that 'and Inspections' should be deleted from the title of the Annex. New Zealand has concerns about the term 'inspection' that we have previously expressed in relation to other CCFICS work. We continue to believe this is an old term and while the CCFICS definition does include 'examination of ... systems for food control' the common interpretation on 'inspection' tends to a hands-on, visual observation or detailed examination that does not fit comfortably with the more modern concepts of verification and validation that are now a key part of underpinning a country's 'Food Import and Export Inspection and Certification Systems'. Also the development of this draft annex has a focus on audit not inspection. Section 2 (paragraph 3) clearly states the objective of the document is 'to ensure a standardized and consistent approach to the conduct of **audits** of an exporting country's official ... inspection and certification systems ...'. Further, the draft promotes a systems-based approach (Principle D) where, in our view, the key component is the role of the competent authority and its ability to provide credible assurances to the importing country relevant to the product concerned and the circumstances/environment in which it was produced or processed. Assessment of a competent authority does not, in our view, involve 'inspection' as it is commonly understood. The amended title of the Annex would be:

Proposed Draft Principles and Guidelines for the Conduct of Foreign Audits and Inspection (footnote retained)

Section 1 Introduction

New Zealand suggests that revision of the text in this section may best be undertaken after review of the rest of the draft document.

Section 2 Objective

New Zealand does not consider that this section is the appropriate place to make reference to a country's appropriate level of protection (ALOP). If any such reference is to be made it would seem better to make it in the Introduction, noting that such a decision is probably best made after the entire draft text has been reviewed.

Section 3 Definitions

New Zealand notes the comments in paragraph 17 of the main agenda paper CX/FICS 08/17/4 that the intention is to remove the current content of this section from the final text given that the terms are either in the Codex Procedural Manual or in CAC/GL 26-1997 (to which this document is to be annexed). New Zealand supports this proposal and also suggest that to ensure there is no potential for future confusion the Codex Secretariat be requested to consequentially remove the definitions in CAC/GL 26-1997 relating to Risk Analysis, Risk Assessment, Risk Management and Risk Communication should the proposed annex be adopted by the Commission having completed the step process. These terms are now defined in the Procedural Manual to apply to all Codex texts and therefore supersede those in CAC/GL 26-1997.

New Zealand notes that the term 'official inspection and certification systems' is currently used extensively throughout the draft text. As noted above New Zealand remains concerned about the term 'inspection'. New Zealand does, however, acknowledge that revision of the current CCFICS definitions is not within the scope of this work. Given, therefore, the current CCFICS definitions for 'Official inspection systems and official certification systems' and 'Officially recognized inspection systems and officially recognized certification systems' New Zealand suggests that the term 'official inspection and certification systems' should be defined to remove any doubt or confusion as to its meaning.

A definition could also ensure that both the already defined terms are captured in the annex and remove the necessity to repeat both in full throughout the document. The following is offered for consideration by the Committee:

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 CAC/GL 26-1997.

Section 4 Principles

New Zealand suggests that the paragraph 4 introduction be redrafted so as to clearly identify that the principles apply to the conduct, process and reporting of an audit. These three areas were identified during the working group discussion and the guidance provided to member governments in the draft annex is set out under these headings. The following is offered for consideration by the Committee as a redraft of paragraph 4:

4 The following principles apply to the conduct of, process for and reporting of ~~In conducting~~ audits of an exporting country's official inspection and certification systems ~~the following principles apply:~~

Conduct of Audits

New Zealand suggests that this section should be numbered 'Section 5' and an expanded introductory paragraph be added to replace the current subtitle. The following is offered for consideration by the Committee:

This section expands on Principles A to D and provides guidance relating to the conduct of audits.

Paragraph 5

In line with our earlier comment relating to Definitions, New Zealand suggests that the word 'food' be replaced with the word 'official' as in 'official inspection and certification system'. New Zealand also suggests that this paragraph be amended to include reference to the use of a third country's audit findings to provide the assurances or confidence that an importing country is looking for in respect of a particular exporting country. New Zealand does not believe it is necessary or desirable to establish or promote the idea that every importing country must undertake its own audit of every exporting country. Such an approach would have significant and unsustainable resource implications for exporting and importing countries. An amended paragraph 5 would read:

5 Audits are one tool that an importing country may use before or after commencement of trade to assess an exporting country's ~~food~~official inspection and certification system. An importing country may use the audit findings of a third country, where these are available, to assess an exporting country's official inspection and certification system.

New Paragraph 9 Bis

New Zealand suggests the following additional text be placed between the current paragraphs 9 and 10:

9 Bis Auditors should respect occupational health and safety requirements and the rights of the operators of establishments and other facilities.

New Paragraph 15 Bis

In respect of the dispute resolution process (Principle C) New Zealand offers the following text for consideration by the Committee:

15 Bis The key elements of a dispute resolution process should be agreed prior to the commencement of the audit. This should include the mechanism for communication between the parties should a dispute arise, including how the final outcome of the process is to be communicated, and the timeframe for completion of the dispute resolution process, including any appeal process. Consideration could also be given to identifying an independent arbitrator or facilitator who may be called upon should this be necessary to achieve resolution.

Paragraph 16

New Zealand considers that the concept of a systems-based audit is central to these guidelines. We also believe that the systems referred to are those administered or approved by the exporting country competent authority(s) or responsible government agency(s). This is how the terms ‘official inspection system and official certification system’ and ‘officially recognized inspection systems and officially recognized certification systems’ are defined. While it may well be that an importing country competent authority may wish to examine documentation relating to establishments that are processing animals or products intended for export to their country, or to actually visit some such establishments, this should not be the prime focus of a systems-based audit. To ensure that this concept is clearly expressed New Zealand suggests that a new paragraph be inserted before the two sub paragraphs 16 a) and b). The new paragraph to read:

16 Bis A systems-based audit should be designed to check the effectiveness of the exporting country’s official inspection and certification system, by assessing the competency of the responsible government agency(s) and the ability of such agency(s) to provide credible assurances to the importing country relevant to the product concerned and the circumstances/environment in which it was produced or processed.

The Committee may also wish to consider if the two sub paragraphs 16 a) and b) are still required or if they could be deleted and replaced with the above proposed new paragraph 16 Bis.

Paragraph 17

New Zealand suggests that this paragraph be redrafted to provide general guidance rather than a list of possible activities. Given that an audit can only give a ‘snapshot’ view of a system it is important to ensure that those aspects of the system that make it self sustaining and effective on an ongoing basis are the main focus. We suggest that the current paragraph 17 (and the sub-paragraphs a – h) be deleted and replaced with the following:

17 A systems-based audit would normally focus on a documentary check of all or any of the aspects of the exporting country’s official inspection and certification system. Such an audit may be conducted with or without visiting the exporting country. An importing country may utilize the findings of a third country audit as an alternative to visiting the exporting country. If necessary a systems-based audit may be supplemented by visits to a sample of establishments, laboratories and other facilities to confirm that the exporting country’s official inspection and certification system or components thereof are properly implemented and functional.

17 Bis The frequency and depth of an audit should also reflect the degree of confidence the importing country has in the exporting country’s systems and the relevant competent authority, which in turn will relate to the length of their trading relationship and previous history.

New Paragraph 17 Bis Bis

New Zealand suggests that an additional paragraph is added to indicate that an audit may be following up on matters identified from a previous audit. The following is proposed for a new paragraph 17 Bis Bis:

17 Bis Bis Where a follow-up audit is being conducted to verify the correction of deficiencies identified in a previous audit, it may be sufficient to examine only those parts identified as being in need of correction.

Audit Process

New Zealand suggests that this section should be numbered ‘Section 6’ and an expanded introductory paragraph be added to replace the current subtitle. The following is offered for consideration by the Committee:

This section expands on Principles E to G and provides guidance relating to the audit process.

Paragraph 21

New Zealand suggests that this paragraph be amended to remove the implication that the importing country has perfect foresight as to matters that may arise during the audit. We also suggest that the word ‘visit’ be replaced with ‘audit’ as it is not always necessary for an audit to include a visit to the exporting country. An amended paragraph would read:

21 The importing country should advise in advance of all issues that ~~may be raised~~ they wish to raise during the ~~visit~~ audit.

Paragraph 23 a)

The sub-paragraph needs to be broken into two sentences to clarify what information it is being suggested should be exchanged, in this instance ‘the rationale or need to conduct an audit’, and then the examples of what this might be. An amended sub-paragraph would read:

23 a) The rationale or need to conduct an audit. This may arise from a

Paragraph 23 b)

New Zealand does not believe that the text in square brackets relating to risk assessments needs to be retained. Should consideration of information relating to a risk assessment be relevant to an audit then application of Principle E and Principle F should ensure that this is clear. We suggest that this text be deleted.

Paragraph 24

It is unclear if or how the ‘criteria for assessment’ in sub-paragraph 24 d) is different from the ‘standards’ referred to in paragraph 26.

New Zealand also suggests that sub-paragraph 24 f) be amended as follows:

f) offices, establishments, laboratories and other facilities and locations to be visited (although this task may be completed at the audit opening meeting);

Paragraph 28 d)

New Zealand suggests that the text in sub-paragraph should be retained and the square brackets removed.

Audit Reporting

New Zealand suggests that this section should be numbered ‘Section 7’ and an expanded introductory paragraph be added to replace the current subtitle. The following is offered for consideration by the Committee:

This section expands on Principles H and I, and provides guidance relating to audit reporting.

Paragraph 35

New Zealand suggests that paragraph 35 be moved to between the current paragraphs 39 and 40.

Paragraph 39

New Zealand suggests that paragraph 39 be expanded to address the need for immediate corrective action should an audit reveal a serious risk to human health. The amended paragraph 39 to read:

39 Should a corrective action plan be required, there should be an agreed method for approval and follow-up of the plan. Where an audit reveals a serious risk to human health (either directly or via an animal health issue) or to the validity of assurances provided by the exporting country then immediate corrective action should be taken by the exporting country. The importing country may take safeguard measures if the corrective actions are grossly inadequate.

Paragraph 41

New Zealand suggests that the square brackets in the first sentence be removed and the text retained.

UNITED STATES OF AMERICA

The United States expresses its thanks to the Working Group for the development of the current draft of the *Proposed Draft Principles and Guidelines for the Conduct of Foreign On-Site Audits and Inspections*.

The United States supports the development of Codex guidance on the conduct of foreign audits and inspections. With the substantial growth in global food trade, importing countries must increasingly rely on the capabilities and competencies of food safety systems of exporting countries. In this regard, there is a corresponding increasing need for

importing countries to assure themselves of the adequacy of food safety systems of the countries from which they receive food. These assurances often take the form of foreign audits and inspections. The development of Codex guidance on undertaking foreign audits and inspections can help assure that these audits and inspections are undertaken in a competent and uniform manner.

The United States notes the three questions posed under “RECOMMENDATIONS” in paragraph 21 of CX/FICS 08/17/4 and provides the following responses to these questions.

- a. **The proposed draft *Principles and Guidelines for the Conduct of Foreign On-Site Audits and Inspections* (Attachment 1) address the points in paragraph 6(a) to (e) above.** (We presume this is referring to paragraph 5 rather than to paragraph 6.)

The United States believes that the principles and guidance presented in Appendix 1 generally, but not entirely, respond to the points raised in 5 a-e. We note that information presented in Appendix 1 does not define “systems-based”. In this regard, we believe that the development of a definition for this term would be helpful. We also note that definitions for “on-site visit”, “on-site verification and “access” are not provided in the text and further discussion on the need for definitions of these terms might be appropriate depending on the nature of the discussion that occurs regarding the further development of Appendix 1.

Regarding the issue of scope of the document the United States notes that the title of the document includes both foreign audits and inspections in the scope of the guidance. However, the guidance provided largely refers to audits. We believe that audits and inspections are two different activities. The Committee should discuss the scope of the document and whether it should cover both foreign inspections as well as audits. The United States would support the scope including both audits and inspections. If both are to be included text will need to be added, either in narrative form and/or in the form of definitions to clearly delineate the difference between an audit and an inspection and the guidance sections will need to be carefully reviewed to ensure that, where necessary, the distinction between audits and inspections is made clear. Additionally regarding scope, we note that Working Group agreed that the scope of the Paper would include both “on-site” audits, and “desk-audits”. Portions of the guidance may need to be adjusted to reflect that they relate primarily to one audit type or the other.

We believe other points noted in 5 a-e including the areas of costs, pre-audit activities, use of on-site audits, and reports are adequately covered in Appendix 1. We observe that the issue of consecutive multiple and identical audits and inspections is not covered in the guidance developed and we have made a specific comment on that issue (see below).

- b. **The proposed principles and guidelines should replace the existing Annex to CAC/GL 26-1997.**

The United States believes that proposed principles and guidelines should replace the Annex in CAC/GL 26-1997, noting that minor consequential amendments to the text of CAC/GL 26-1997 will be needed. We believe that a separate stand-alone guidance document on the conduct of foreign audits and inspections is a preferred approach as it provides for easier use for those employing the guidance. We note, however, that certain items in the Annex to CAC/GL 26-1997, for example guidance relating to confidentiality as provide under Annex Section (2) (Preparation) are not explicitly covered in the guidance currently being developed. A careful examination of the Annex should be made to be sure that all guidance elements included in the Annex to CAC/GL 26-1997 are brought forward in the current guidance being developed.

- c. **There is a need to include a reference in the objective, to the conduct of foreign systems-based audits of an exporting country’s official inspection and certification systems and their ability to achieve the importing country’s appropriate level of protection (ALOP).**

The United States would prefer not to explicitly reference ALOP in the guidance. The guidance relates specifically to the conduct of audits and inspections and, in this regard, is primarily a process-related document. That is, the document is intended to provide guidance on how to ensure that measures applied by an exporting country are, in fact, being met, irrespective of the ALOP they present. Inclusion of references to ALOP makes the guidance more complex than needed and may confuse the user of the guidance.

SPECIFIC COMMENTS

Title:

Depending upon the determination as to scope (see discussion above relating to audits and inspections), and if the guidance is limited to audits, the title may have to be adjusted.

Section 1 Introduction

The United States suggests that this section, as drafted, can be confusing. The conduct of foreign audits and inspections does not relate primarily to export certification. Additionally, since verification and validation are different concepts, referencing such concepts without clearly explaining and differentiating them, creates difficulties. We believe a simpler construct for this section is better, which would also resolve the issue with the brackets. Our suggestion for the introduction section is as follows.

1. Food inspection and certification systems ensure that the exporting country's particular food safety measures remain fully implemented and food safety outcomes are met.
2. Assurance of the safety of exported foods may be achieved through the application of a country's domestic food safety system. Although the food safety systems of importing and exporting countries may utilize different approaches to their food safety controls, an importing country may recognize the exporting country's food safety system, accept the differences as equivalent provided the same level of public health protection is achieved and maintained, or require an exporting country to apply certain of the importing country's measures for those food products exported to the importing country.
3. In any of these instances, an importing country may wish to undertake an audit of the exporting country's food safety system, or component parts thereof, to ensure that the exporting country's system is operating appropriately and/or that the exporting country is properly applying the importing country's measures.

Section 2 Objective

The United States notes the bracketed language following paragraph 3 and notes our preference, discussed above, that there be no reference to ALOP in the text. Paragraph 4 can be deleted.

Section 3 Definitions

The United States notes that Principle B speaks to "systems-based" audits but the term is not defined. For clarity we believe that a definition for this term would be helpful and offer the following for consideration within the context of the document.

Systems-based audit means an audit of all pertinent components of the food control system that are administered or officially recognized by the government agency responsible for assuring that requirements are met.

Section 4 Principles

Principle (a): The United States suggests that, for the purposes of a Codex text, that it be made clear that audits can be undertaken for reasons relating to food safety and/or the facilitation of trade. We would suggest that Principle (a) be modified to read:

"An importing country may conduct audits of an exporting country's official inspection and certification systems to ensure that its requirements relating to food safety and/or the facilitation of trade are being met."

Principle (b). For clarity we suggest that the Principle (b) be reworded as follows:

"Audits should be independent and evidence based, and auditors should conduct the audit in a cooperative, ethical and professional manner.

Principle (i): The United States suggests that this principle, as written, is not a principle but rather guidance. We suggest that the language originally in the document considered by the Working Group be used. The concept that the country that was audited be able to provide comments and that these comments are included in the published report are included in paragraphs 40 and 41. The revised Principle would read:

"A report of the findings resulting from the audit should be prepared and published."

Conduct of Audits

Title of Section: We note that this section and others following are unnumbered. For clarity and consistency, sequential numbering should be applied.

Paragraph 6: The United States notes that this paragraph provides that either the importing country or exporting country can initiate the request for an audit; however the subsequent sections are written from the perspective that the importing country is conducting the audit. We suggest that, in paragraph 6 and consequentially in subsequent sections of the text, it would be appropriate to change the language to "country undertaking the audit" and "country being audited"

Paragraph 6, item (a): Delete the word "later" as the word is unneeded.

Paragraph 6, item (c): Delete the words "work to" and add **"prior to the start of the audit"** to the end of the sentence, so the item would read:

"If differences arise as to the purpose, scope or other aspects (e.g., timing) the parties will resolve such issues prior to the start of the audit."

New paragraph: Comments noted during previous CCFICS discussion brought forward the point that countries undertaking the audit should avoid consecutive multiple and identical audits and inspections. The United States generally supports this concept, recognizing an appropriate timeframe between audits will need to be discussed and that this concept excludes audit activities related to follow-up verification of corrective actions to previous audit findings. We recommend the addition of a new paragraph at the end of this section, to read as follows.

“Countries should not be subject to consecutive multiple and identical audits and inspections within a short timeframe (e.g. less than a year) unless new concerns are identified or follow-up verification to previous audit findings is needed.

Paragraph 9: It is important that auditors not only be free of conflict of interest but also that they be competent. The United States recommends adding the words “competent and” “after “should be”, so that the paragraph would read.

*“Auditors should be **competent and** free of conflict of interest.”*

Paragraph 10: Since confidentiality is currently not included as a principle and, additionally, not all information relating to an audit will be confidential in nature, we recommend deleting the words “The principle of” at the start of the sentence and inserting “as appropriate” after “information”, so that the sentence will read.

“Confidentiality of information, as appropriate, relating to the audit should be adhered to.”

Paragraph 17: The following changes are recommended:

Item (a): Since it will normally be the case that some, but not all, of the compliance records will need to be examined during an audit, we suggest adding the word “**relevant**” before “compliance”.

Item (d): To simplify and to recognize that often more than one establishment is included in an audit, modify the item to read: “**review of establishment(s) operations, including appropriate operation records**”;

Item (e) and (f): A systems-based audit should focus on the effectiveness of the process controls in place, we suggest replacing the current text as follows:

(e) “**Review of inspection results, including ingredient, in-process, and finished product sample analyses/examinations, and subsequent enforcement actions taken.**”

(f): “**Review of laboratory programs and procedures, including test methodologies and results**”.

Item (g): This item can be deleted, as it is addressed in the proposed (f).

As part of the auditing process it will likely be necessary to ensure that portions of the food chain system prior to and after the processing establishment are operating properly. It may also be necessary to verify that finished products meet requirements. The United States suggests that the following items be added to the list of items given in paragraph 17.

- Raw material production systems.
- Ingredient and product transportation systems.
- Warehousing and distribution facilities

New Paragraph: Foreign audits generally include visits to establishments. We recommend that the following new paragraph be added to the end of this section, providing guidance regarding visits to exporting establishments or other pertinent facilities.

“In conducting audits, a review of establishments or other facilities and their records may be necessary. Such reviews should:

- Be identified in the initial audit plan and agreed to by both parties;
- Be preceded by communication to the establishment from the party with regulatory authority over the establishment;
- Include authorities representing both parties;
- Respect existing food safety and security measures at the establishment or facility;
- Avoid unnecessary disruption to on-going facility operations;
- Respect business confidential information;
- Limit document review to that necessary to achieve the objectives of the audit; and,
- Provide the results of the audit review for that facility to the facility’s designated representative.

Audit Process

Paragraph 22: For clarity we suggest modifying this item to read: “The audit should use evaluation criteria clearly defined in the audit plan.”

Paragraph 23, item a: For editorial clarity and consistency, put a semi-colon after “audit” and insert “The rationale or need” before “may” so the first part of the item will read:

“The rationale or need to conduct an audit; the rationale or need may arise from...”

Paragraph 23, item b, the last sentence currently in brackets: The United States would prefer that this sentence be deleted. We believe that an importing country should have prior knowledge of an exporting country’s food control system/measures and that an audit should simply verify that measures that have been put in place are operating properly. Determining whether or not a particular control measure was effective as a risk management measure we believe would usually be part of a different activity.

Paragraph 24, item (a): for consistency and linkage back to the principles, insert “rationale/” in front of “purpose” so the item reads: “rationale/purpose and scope of the audit.”

Paragraph 24, items (e), (f), (h): The United States notes that these items are specific to on-site audits. Since the scope of the document has been broadened to include “desk” audits as well as on-site audit, the Committee will need to discuss how to adjust the text so that it is clear to what items pertain to on-site audits and which pertain to desk audits. Adjustments will also need to be made elsewhere in the text in this regard, for example, those sections dealing with opening and exit meetings.

Paragraph 27: We suggest inserting “and” between “translation” and “availability” and deleting the words “and resources” as they are not needed. Additionally we suggest adding a sentence regarding who should supply the translators and interpreters; normally the country requesting the audit would provide these services. The paragraph would then read.

“Advance agreement should be reached on the language that will be utilized during the audit including translation **and** availability of impartial and knowledgeable interpretation.” **Translators and interpreters should normally be provided by the country requesting the audit unless otherwise agreed.**

Paragraph 28, item (d): The United States supports this provision and recommends removal of the brackets.

New Paragraph: We suggest a new paragraph be added between “*Audit Opening/Entry Meeting*” and “*Audit Exit Meeting*” dealing with communications during the audit. The title and text of the new paragraph would be as follows.

Communications During the Audit

The auditing country should disclose daily audit results to the competent authority of the country being audited.

Audit Reporting

Paragraph 41: The United States believes that reports of foreign audits should be published and supports the removal of brackets on this provision. Additionally, the United States believes it is important to ensure that proprietary information is protected as appropriate to national laws and regulations. In this regard the United States recommends inserting the words “consistent with national laws and regulations relating to the protection of proprietary information.” The first sentence of paragraph 41 would then read.

“Once an audit report has been finalized the importing and exporting country should discuss and if possible agree how and when any or all of the report will be published **consistent with national laws and regulations relating to the protection of proprietary information**”.

IACFO

The International Association of Consumer Food Organizations (IACFO) is an association of a dozen national non-governmental organizations serving consumer interests in the areas of nutrition, food safety, and related food policy matters.¹ IACFO members work on food policy concerns unique to diverse populations and regions, including India, Uganda, Malaysia, Japan, and others.

We thank the members of the Working Group for their thoughtful consideration of the many issues involved with foreign on-site audits in preparation of the proposed text. We appreciate that the resulting document incorporates many different views. These comments reflect the views of consumers with regard to the proposed text, and suggest areas and issues for the consideration of the Codex Committee on Food Import and Export Inspection and Certification Systems at its 17th Session.

¹ Members of IACFO are: Center for Science in the Public Interest (CSPI), United States and Canada; Japan Offspring Fund, Japan; The Food Commission, United Kingdom; Consumers Association of Singapore; Union for the Protection of Consumers' Rights, Armenia; Lingue pour la Défense du Consommateur au Benin; Pro Teste, Brazil; Voluntary Organization in Interest of Consumer Education (VOICE), India; Consumer Association of Penang, Malaysia; Consumer Education Trust (CONSENT), Uganda; Zambian Consumers Association, Zambia; International Baby Food Action Network (IBFAN).

Section 2 Objective

Paragraph 4

We strongly support the right of each member country to determine its own appropriate level of protection (ALOP), and thus we believe it is critically important that this section of the document ensure that right is not fettered. As such, we believe the language of Section 2, paragraph 4 should clarify that a review of risk assessments by an inspector would only be appropriate to review the assessment's support for a particular risk management approach in use by a particular country—not as a tool to determine the adequacy of or justification for the ALOP of the exporting country. Since ALOPs may vary from country to country, reviewing risk assessments used to support specific ALOPs could result in fruitless discussions during the audits. Therefore their review should be limited in the document.

Section 3 Definitions

The definitions are not needed since the text is intended as a replacement to the existing Annex to CAC/GL 26-1997, which also defines the terms. The Committee should delete the definitions in favor of relying on those definitions in the guideline document. This would avoid any confusion of meaning where the definitions differ.

If the Committee does not delete the definitions, then it should conform the definition of “Risk Management” to the definition provided in CAC/GL 26-1997. That guideline document defines risk management as “the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures” without reference to the promotion of fair trade. This is the definition adopted on an interim basis by the 22nd Session of the Codex Alimentarius Commission as an effort “to apply risk analysis more consistently and uniformly with a particular emphasis on risk management” (*ALINORM 97-37*).

While we recognize that the definition of risk management in the text is identical to the one in the Codex Alimentarius Procedural Manual,² we believe it is a significant factor that the language departs from the definition in CAC/GL 26-1997, to which this text may be annexed. Conforming the definition of risk management avoids confusion that it establishes an inappropriate balancing test between considerations of consumer safety and fair trade. A balancing test is contrary to the policy of the Codex Alimentarius that “Codex decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers” (*Procedural Manual*). We believe countries may seize upon the difference in the definitions to argue that inclusion of “promotion of fair trade practices”³ as a relevant factor for consideration in the risk management process at this point opens a door to challenges to specific prevention and control options selected by the importing country. Such challenges would thwart the goals of the Codex Alimentarius by furthering dispute rather than cooperation in assuring food in international commerce is safe.

Section 4 Principles

Paragraph 4 and paragraph 15

We agree that dispute resolution in subparagraph (c) is a high level principle that should be developed further by the Committee. In considering supporting text, the Committee should include requirements that dispute resolution procedures (1) be transparent, producing a public record, findings and decision; (2) prohibit any person from assisting in or arbitrating the dispute resolution if they have a conflict of interest in respect of or otherwise stand to benefit financially from the decision; and (3) include an appeal process.

Paragraph 4

Transparency is essential to assuring consumers that the certification system is operating to protect their safety. For that reason, the Committee should replace “may be published” with “shall ordinarily be published” where it appears in principle (i) at paragraph 4 and in the heading for Principle I. The change allows discretion on the part of the importing and exporting countries, but emphasizes a preference for publication of audit reports. Publication permits higher assurances of the integrity of the process; allows consumers in an importing country to review documentation; increases confidence in the audit process; alerts whistleblowers in the exporting country to potential issues inspectors overlooked; and adds transparency.

Paragraph 17

The right of a country conducting an audit to select an establishment for a verification inspection should be protected. The Committee should amend the requirement in subparagraph (d) to permit review of an establishment “selected by the auditing country.” This is needed to ensure a representative establishment is inspected, and avoid charges that the exporting country steered auditors to a “Potemkin village”.

² The Procedural Manual defines Risk Management as “The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.”

³ The Procedural Manual clarifies that ensuring fair practices in the food trade references internal, discriminatory levels of health protection, stating: “Unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.” (*Procedural Manual*). The text provides no such clarification.

Paragraph 23

Minor changes are needed in subparagraphs (a) and (d). The Committee should redraft subparagraph (a) for context. As presented, it is a general statement about why a rationale or need may arise. In the context of notification, it should be a declaration of information that must be exchanged. We recommend:

“a) The rationale or need to conduct an audit.”

The redundant phrase in subparagraph (d) “prior to the commencement of the audit” should be deleted or set off in parentheses if the Committee believes it is necessary to clarify that agreement on the timeframe is to be negotiated and agreed prior to the audit.

Paragraph 28

The Committee should accept the bracketed material at subparagraph (d). In earlier comments to the Working Group, we noted the need for additional discussion and clarification of the grounds for a failed audit. While subparagraph (d) does not fully address this, it preserves the right of the auditing country to suspend its audit prior to an on-site visit. This permits a finding that information submitted by the audited country supports a determination that it will be unable to comply, and by implication sets a standard for when there is a failed audit. We continue to urge inclusion of a provision that clearly protects the right of the auditing country to determine whether and when a system’s failure will result in a failed audit.

Paragraph 41

The Committee should strengthen this provision consistent with the recommended revision of Principle I discussed above. We suggest replacing the subparagraph (including bracketed language) with:

“Once an audit report has been finalized the importing and exporting country should publish it in a manner that assures it is readily accessible to the public. This publication of material relating to audits assists in building public confidence in the auditing process and may be of assistance to other Codex members.”

We respectfully submit the above comments and look forward to working with the Committee to finalize Appendix 1 and provide standards for the conduct of foreign audits and inspections and protect consumers from unsafe foods.

ICGMA

ICGMA, a recognized INGO before the Codex Alimentarius Commission, represents the interests of the consumer packaged goods industry including several hundred food companies that trade food products globally. ICGMA strongly supports the work of Codex Alimentarius and promotes the harmonization of scientific standards and policies concerned with health, safety, packaging, and labeling of foods and beverages. ICGMA member companies are asked to participate in establishment reviews done by foreign audits and have an interest in this work. ICGMA has reviewed the draft document and offers the following brief comments.

In response to the questions posed in the working document paragraph 21.**a) Does the proposed draft address points raised in paragraph 6 a to e?**

Systems Based Approach: The elements of a system based approach are listed in Principle D, paragraph 16 and 17 but it is not clearly defined nor what “an alternative approach” may be. ICGMA suggests that “systems based approach” should be concisely defined within Section 3.

Definition for terms: The various terms referenced in (b) are not defined or clarified. In fact, the draft document proposes principles and guidelines for the conduct of audits and inspections. However, each of the principles applies only to audits. The document should clarify the difference between an audit and inspection and how the principles would apply. Definitions should also be provided for any of the other terms used in the draft guidelines.

b) Should the proposed principles and guidelines replace existing annex to CAC/GL 26-1997?

CAC/GL 26-1997 contains several elements that are not entirely addressed in the proposed draft including some of the elements of “preparation” including the reference to confidentiality requirements and identification of the audit team and section 4.2 on on-site verification. ICGMA would not support the deletion of the annex in CAC/GL 26 unless those elements can be appropriately addressed in the new document.

c) Is there a need to include a reference in the objective to achieving the country’s appropriate level of protection (ALOP)?

ICGMA does not believe that there is a need to include a reference to the ALOP as this concept is adequately addressed in other CCFICS and WTO documents. However, if it is included in the document reference should accurately reflect the meaning of this term as defined in the SPS agreement and how it may be relevant to the guidance under consideration.

Additional Comments:

Title: Is the guidance about audits and inspections or only audits?

Definitions: These should include 1) systems based approach; 2) inspection and other terms listed in paragraph 5 b.

Principles:

- **An importing country may conduct audits of an exporting country's official inspection and certification system.** This should be qualified with a reason related to food safety systems and trade facilitation, for example: "...when there is a stated need to verify equivalency of the food safety system in order to facilitate trade between parties."
- **The parties should have in place...**In principle c "parties" should be clarified in that the "parties" refer to the competent authorities of the governments and not establishments to be visited.
- In principles f and g, it should be clarified that the audit plan should be developed that specifically satisfies the rational, objective, and scope identified.
- In principle i, it should be clarified that audit reports, if published, must protect business proprietary information.

Establishment Visits

Foreign on-site audits and inspections generally include visits to private establishments. Within the draft guidelines, establishment review is addressed only in paragraph 17d without any guidance on how such reviews should be handled. Foreign on-site audits can be very disruptive to operations and even compromise food safety and security. ICGMA believes it would be appropriate to create a separate paragraph under Principle D as follows:

18. In conducting audits, a review of establishments during operation and appropriate records may be necessary. Establishment review should:

- Be identified in the initial audit plan and agreed by both parties;
- Be preceded by communication to the establishment from the party with regulatory authority over the establishment under review;
- Include authorities representing both parties;
- Respect existing food safety and security measures at the establishment;
- Avoid unnecessary disruptions to on-going facility operations;
- Respect business confidential information;
- Limit document review that necessary to achieve the objectives of the audit;
- Copy the establishment with results of the audit.

ICGMA appreciates the opportunity to submit these comments and welcomes the opportunity to continue to work on this project in CCFICS.

ICBA

The International Council of Beverages Associations (ICBA) is a nongovernmental organization that represents the interests of the worldwide non-alcoholic beverage industry. The members of ICBA operate in more than 200 countries and produce, distribute, and sell a variety of non-alcoholic beverages, including sparkling and still beverages such as soft drinks, juice-containing drinks, bottled waters, and ready-to-drink coffees and teas. ICBA is pleased to provide the following comments for consideration in response to CX/FICS 08/17/4.

Page 7 / Principle D / 16 a) "Normally a systems-based audit should focus on the implementation of the inspection and certification system or components thereof in operation in the exporting country". Our suggestion is to amend this as follows: "Normally a systems-based audit should focus on the **design, implementation and effectiveness** of the inspection and certification system or components thereof in operation in the exporting country".

Page 9 / 33 a) "The meeting should formalize all findings and observations,...". We suggest defining in the document what "findings" and "observations" are. If "findings" are "audit findings", our suggestion is to define it as "result of the evaluation of the collected audit evidence against audit criteria". In the absence of a definition, we are not sure what is meant by "observations".