

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANISATION  
OF THE UNITED NATIONS

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ORGANISATION



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**Agenda 4**

**CX/FICS 10/18/3**

**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**

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

**(NO-2008)**

**(At Step 3)**

**India's Comments:**

**General Comments**

The draft document is an improvement over the draft discussed in the 17<sup>th</sup> Session of the CCFICS, Philippines, 24 – 28 November 2008. India's comments on the previous version of the document were presented in our written comments for the Physical working group meeting held at Miami in July, 2009. Some of our comments have been addressed in the current draft.

During the physical working group meeting, there was a discussion regarding the terminology used in the proposed document. The committee agreed to replace the terms "audit" and "inspection" with "assessment" throughout the draft document. India would like to suggest that this modification may be incorporated at all relevant places in the text. In addition, the current draft also has some provisions that are not clear, and, therefore, require appropriate amendment to make the guidance clear and unambiguous.

## **Specific Comments**

### **SECTION 2 SCOPE**

It is proposed to amend the text as follows:

“This annex provides guidance for use by competent authorities of both importing and exporting countries to ensure an effective, efficient, transparent<sup>7</sup>, **coordinated** 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.”

*Rationale: It is necessary to have coordination among the competent authorities of the importing and exporting countries while conducting the assessment.*

**Principle C:** Amend the text as follows:

“The importing and exporting countries should agree on an appropriate ~~tool~~ **methodology** 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.”

*Rationale: “Methodology” is an appropriate terminology.*

**Principle E:** It is proposed to amend the text as follows:

“The plan incorporating the rationale, objective, scope, **duration**, assessment ~~tools~~ **methodology** 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.”

*Rationale: To maintain consistency with Principle C*

**Principle F :** Amend the text as follows:

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

*Rationale: The term “corrections” should be included along with the corrective action as correction means action taken to eliminate the detected*

*non-conformities.*

**Paragraph 7:** Amend the text as follows:

“Where there are multiple competent authorities in an importing country **and / or exporting country** these authorities should coordinate their assessments in order to avoid any duplication.”

Rationale: There may be multiple competent authorities in the exporting country also.

### **CONDUCT OF ASSESSMENTS**

**Paragraph 10:** Amend the text as follows:

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

*Rationale: Editorial change and to bring in the concept of assessment of systems instead of indivisual units.*

**Paragraph 12:** Amend the text as follows:

“The anticipated costs for undertaking the assessment should be ~~understood~~ **agreed to by** both competent authorities in advance of undertaking the assessment.”

*Rationale: To ensure transparency in the assessment.*

**Paragraph 13:** The text should be read as follows:

“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.~~”

Rationale: The cost incurred in undertaking an assessment should be borne

by the importing country.

**Paragraph 14:** The text should be read as follows:

“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.~~”

Rationale: The cost incurred for supporting of an assessment should be borne by the exporting country.

**Principle C :** Amend the text as follows:

“The importing and exporting countries should agree on an appropriate ~~tool~~ **methodology** 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.”

*Rationale: As mentioned in Principle C*

**Paragraph 17, Second sentence:** Amend the text as follows:

“In selecting the assessment ~~tool~~ **methodology**, 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.~~”

Rationale: The first sentence of the paragraph includes all the aspects mentioned in the second sentence.

**Paragraph 19:** It is proposed to amend the second sentence as follows:

“When mutually agreed inspections ~~can~~ **could** also be an appropriate assessment ~~tool~~ **methodology**.”

Rationale: To maintain the transparency in assessment.

**Paragraph 23:** Delete the phrase ‘or other elements as appropriate’ so that the amended text would read as follows:

“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.~~”

*Rationale: The inclusion of the phrase ‘or other elements as appropriate’ makes the guidance ambiguous and open to interpretation and this might lead to conflicts in its implementation by the countries. The boundary and scope of audits have been clearly specified in Section 2 Scope, and all elements to be examined during audit have to be consistent with this, and have been outlined in the Section 6 already.*

**Paragraph 24:** It is proposed to delete second line of paragraph and modify the text as follows:

“The inspection tool, assesses individual elements of the **country’s** food ~~production~~ **inspection and certification** 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 situation where there is a need to verify whether one or more specific elements of an inspection or certification system meet the requirements.

*Rationale: The modified sentence as proposed encompasses the subsequent part of the paragraph.*

**Paragraph 25:** It is proposed to modify the text as follows:

“Inspections may **also** involve the examination of system to assess;

*Rationale: to make it very clear that inspection of establishment is done only in the context of assessment of food inspection and certification system and not as an end by itself.*

## **ASSESSMENT PROCESS**

### **Principle D**

**Paragraph 26:** It is proposed to amend the text as follows:

“The transparency and consistency of the assessment process may be facilitated by good **appropriate** 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.”

*Rationale: “Appropriate” is the correct terminology, which is frequently used in various codex documents*

**Paragraph 28:** Amend the text as follows:

“Processes and protocols for addressing assessment findings and recommendations should be documented and agreed **between the competent authorities of importing and exporting countries** prior to the assessment.”

*Rationale: To maintain transparency in the process of assessment as mentioned in the scope of the document.*

## **Principle E**

**Paragraph 29:** It is proposed to modify the text as follows:

“When establishing the rationale, objective, scope, ~~frequency~~ **duration** of assessment and assessment ~~tools~~ **methodology**, the importing country’s competent authority should take into account ~~the established level of experience, knowledge and confidence together with~~ the history of previous assessment(s), **if any**, the period since the last assessment and any other relevant factors.”

*Rationale: To facilitate the process of assessment.*

**Paragraph 30 :** Amend the text as follows:

“The following information should be exchanged ~~during the initial request to undertake an~~ **prior to commencement of** assessment of a country’s official inspection and certification system.”

*Rationale: To maintain transparency in the process of assessment as mentioned in the scope of the document.*

**Paragraph 30 b) :** Amend the text as follows:

“The objective of the assessment, for example is to verify the effective

application / implementation of specific measures or  
.....  
.....  
conduct an investigation of outbreaks of foodborne diseases related to  
imported / exported food and to follow up **correction and** corrective  
action resulting from previous assessment or of situations derived from  
food safety issues. The risk assessment  
.....  
a risk management approach.”

**Paragraph 30 c) :** Amend the text as follows:

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

*Rationale: The proposed deletion is to avoid repetition as this has been  
proposed to be added in the opening lines of the paragraph 30.*

**Paragraph 30 d) :** Amend the text as follows:

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

*Rationale: As mentioned in Principle C*

**Paragraph 32:** Modify the text as follows:

“A plan for undertaking the assessments, including timeframes and  
exchange of required information should be ~~prepared and communicated  
to the exporting country’s~~ **mutually agreed by the** competent authority **of  
both the countries** well in advance.”

*Rationale: To maintain transparency in the process of assessment as  
mentioned in the scope of the document.*

**Paragraph 32, bullet e):** The text may be amended as follows:

“A contact .....~~lead auditor/inspector~~ **audit team leader,**  
specialists, **and their qualifications, experience and affiliations.**”

*Rationale: Information on the qualification, experience and affiliations of  
the team members form important information for the country whose  
system is being audited.*

The term 'lead auditor' could confuse the reader, as it is a term generally used to indicate the certification status of the auditors. Also, the term 'lead inspector' is not clearly understood. These terms can be appropriately replaced with the term "Audit Team Leader".

**Paragraph 33:** Insert additional text at the end of the paragraph as indicated below:

" 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 **mutually agreed** ~~communicated by the proposing party to the other party as soon as possible.~~"

*Rationale: While the need for this flexibility is appreciated, it is necessary that the other party agrees to the changed emphasis for the audit as scheduled or is provided adequate time to make necessary arrangements, where necessary, to facilitate audits of such additional aspects.*

**Paragraph 34:** It is proposed to use 'assessment' instead of 'evaluation' as mentioned below:

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

*Rationale: In order to maintain consistency in the text.*

**Paragraph 42, bullet (b):** Add the following additional provision at the end of the text of bullet b):

**"An agreement should be reached on the timeframes for, and follow-up procedures to assess, corrective actions if applicable."**

*Rationale: The above guidance is useful and was included in the previous drafts.*

Principle F and **I-G** cover assessment

*Rational: appropriate substitution is G in place of I.*

**Paragraph 44:**

**Sub Para (f):** It is proposed to add "corrections" prior to "corrective

actions” to modify the text as follows:

“Take into account how **corrections and** corrective actions will be communicated and agreed to, including how follow-up verification will be completed.”

*Rationale: As mentioned in Principle F*

Add the following provisions:

**“(l) mention the dates and places where the onsite audits were conducted.**

**“(m) include a list of personnel interviewed during the audit process.”**

*Rationale: A record of the above details in the audit report would be useful for future reference.*

**Paragraph 45: The amended text is as follows:**

The time frame and protocol for any follow up verification should be clearly stated. Verification of **corrections and** corrective actions may include :

**Paragraph 45: The amended text of bullet c) is as follows:**

Review of stated **correction and** corrective actions in a subsequent assessment.

**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**

**COMMENTS ON PROPOSED DRAFT PRINCIPLES AND  
GUIDELINES FOR NATIONAL  
FOOD CONTROL SYSTEM (S)**

**(N06-2009)**

**(Comments at Step 3)**

**India's Comments:**

**General Comments**

The draft document provides guidance for establishment of national food control systems. There are, however, some provisions on which India has concerns that have been elaborated in the specific comments below. It is also observed that several provisions have been repeated in the document. The repeated provisions should be retained only at one place, where they are more appropriate, in the document. The numbering should be continued from '7' from the Section 'Principles for a National Food Control System' onwards rather than starting from '1' again.

Further, reference of WHO guidelines has been provided in paragraphs 37, 40, 49 and 56 in the form of footnotes 11, 13, 14 and 18 respectively. The Codex Alimentarius Commission has already adopted the relevant document 'Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/RCP 62-2007)' that provides necessary guidance on risk analysis for application by the national food safety authorities. Therefore, the reference to the FAO-WHO document should be changed to the relevant Codex document in these paragraphs, appropriately.

**Specific Comments**

**PRINCIPLE FOR A NATIONAL FOOD CONTROL SYSTEM**

**Principle 2:** *The text should be modified as under:-*

*"The national food control system should be risk based, science based and harmonised to the ~~greatest~~ extent possible with ~~international~~ the codex standards.*

*Rationale: The national food control system should be harmonized to the extent with the codex standards instead of the greatest.*

**Principle 3:**

The text should be read as follows:

"Fitness for purpose – **National Food Control** Inspection system should be fully effective in achieving their designated objectives having regard to the determination of the acceptable level of protection which is required **country's appropriate level of protection.**"

*Rationale: It is important to note that an 'acceptable level of protection' has not been defined and there are no scientific guidelines to establish it. Under these circumstances, currently the countries are free to establish 'acceptable level of protection' that is commensurate with their capacity to achieve it and not necessarily with a rational level of required public health protection. This contradicts one of the important intended purposes of the publication of Codex Alimentarius, that is, to assist in harmonization of food standards and in doing so to facilitate international trade. (Codex Procedural Manual, 18<sup>th</sup> edition, P. ~~17~~ **16**). Further, it may be noted that use of 'acceptable level of protection' as the objective of food safety is not very common, especially among developing countries. In countries where an explicit expression of an 'acceptable level of protection' is not a practice, other adequate food safety standards and control measures are generally in place and used as a means to meet their food safety requirements. A reference to 'acceptable level of protection' in this document would appear to limit application of the final document to those few countries that have established 'acceptable level of protection'.*

*In the rationale Codex Procedural manual 18<sup>th</sup> edition it should be Page No. 16 instead of Page No.17.*

**Section Guidelines- Framework For A National Food Control System**

**Paragraph 7:** The text in italics in the square brackets asks whether the GL 47 – 2003 paragraph 6, 7 and 8 could be drawn on to expand the section. In our opinion, there is no need of doing so.

*Rationale: To avoid repetition of provisions as the Paragraph 2 in the Section 'Introduction' mentions that the document is to be read in conjunction with, among others, the GL 47 – 2003.*

**Paragraph 8 and Alternate Paragraph 8:** We propose that the Paragraph 8 be deleted and the Alternate Paragraph 8, which has been taken from an existing Codex code of practice (CAC/RCP 1 -1969, Rev. 4 (2003)), be retained with the following modification:

- Everyone including farmers and growers, manufacturers and processors **and** food handlers ~~and consumers~~, has a responsibility to ensure that food is safe and suitable for consumption.

*Rationale: It is not clear how the academics and scientific institutions, included in the Paragraph 8 could be held responsible for complying with the requirements and ensuring safety of food. The guidance pertaining to the consumer's responsibility in ensuring food safety is indicated in Paragraph 9 be retained.*

**Paragraph 12, the alternative wording for 13 (read12) and Paragraph 24:** We suggest deleting the Paragraph 12, its alternative wording and the paragraph 24.

*Rationale: The meaning of expressions 'consistent delivery', 'uniform and consistent manner' and 'uniform application', used in the referred paragraphs is not clear. If it means uniform application in respect of domestically produced food and imported food, then we do not subscribe to this for the reason provided below.*

*One of the main requirements for food standards is that it should protect human health and hence should be based on risk analysis. This basic principle for human health standard is stated in the WTO SPS Agreement Articles 2.1, 2.2 and 3.2. The Guidelines and standards developed by Codex are based on scientific risk analysis. However, some importing countries, especially developing countries, might have infrastructural and technical limitations in ensuring conformance of its domestically produced food products to the minimum safety standards prescribed by the Codex. Yet, they have a right to demand minimally safe imported food which can be guaranteed by its conformance to Codex standards. As already explained, such an approach is consistent with the above-mentioned provisions of the SPS Agreement. The provision in Paragraph 12, its alternative wording and the Paragraph 24 are in violation of these provisions of SPS.*

**Paragraph13:** Amend the text as follows:

"Verification of the national food control system may involve the competent authority or ~~either~~ **its** recognized bodies at any relevant point in the food chain."

*Rationale: To improve clarity.*

**Paragraph 14:**

The 1<sup>st</sup> line of the paragraph indicates that the responsibilities of the competent authority (ies) should be defined. It should also include the dissemination of the responsibilities among the interested stakeholders. The text could be modified as follows:

"The competent authority (ies) involved in national food control system should have clearly defined responsibilities, **which should be communicated to all concerned for effective national food control system.**"

*Rationale: The responsibilities of the competent authority (ies) should be known to all concerned persons for ensuring better delivery of services.*

**Paragraph 16:** Delete the Paragraph

*Rationale: To ensure food security is not the objective of these guidelines.*

**Paragraph 17:**

The following addition is suggested:

A national food control system must be supported by the necessary legislative framework, controls, procedures, facilities, equipment, laboratories, **inspection, certification,** transportation, communications, personnel and training.

*Rationale: Inspection and certification are important aspects of a National Food Control system.*

**Paragraph 19:** The 2<sup>nd</sup> sentence of text should be read as follows:

"A National food control system.....to ensure the protection of health of consumers and ensure ~~of~~ fair practices in trade.

*Rationale: To make appropriate.*

**Paragraph 20: 1<sup>st</sup> bullet point :** the text should be read as follows:

- Monitoring and surveillance programmes for diseases and **food safety** hazards, as appropriate;

*Rational: To improve clarity*

**Paragraph 21: Delete the paragraph except the last bullet point.**

*Rationale: To avoid repetition of the guidance included in the Paragraph 57 and also add the last bullet point in paragraph 57 where it is a more appropriate.*

**Paragraph 22:** Delete the Paragraph.

*Rationale: To avoid repetition of the guidance included in the Paragraph 34 where it is more appropriate.*

**Paragraph 23:** Delete the Paragraph.

*Rationale: The guidance is included in the Paragraph 36 where it is more appropriate.*

**Paragraph 27: Last two sentences:** Delete the phrase 'and equipment'.

*Rationale: The reference of 'equipment' in the last two sentences of the paragraph appears to be redundant as the word 'facilities' does effectively cover this.*

**Paragraph 31:** *The text should be read as follows:*

*"The competent authority retains the fundamental responsibility to verify ~~and provide assurances as to~~ the conformity of food and the associated production with requirements."*

*Rationale: This is in line with paragraph 30 in which the Food Business Operator has primary responsibility of food safety.*

**Paragraph 33:** *The text should be read as follows:*

*"Effort should be made to improve capacity of regulatory authorities, particularly those of developing countries, ~~Capacity building for developing countries~~ either through bilateral arrangements or with assistance of international organizations should be directed toward implementation of these principles and guidelines."*

*Rationale: To have clear meaning of the paragraph.*

**Paragraph 36:** *The text should be read as follows:*

*"As appropriate, clearly defined and transparent legislation, **guidelines** and operating procedures should be developed which allows for the establishment of the competent authority (ies) and the processes and procedures required to verify the conformity of products against requirements."*

*Rationale: The guidelines are one of the requirements of national food control system.*

**Paragraph 37:** *It is proposed to delete the part 'where such .....competent authority' from the sentence so that the amended text would read as follows:*

*"Requirements .....standards **developed / specified by the Codex or other intergovernmental organizations.** ~~where such requirements achieve the appropriate level of protection established by the competent authority."~~*

*Rationale: The rationales are provided below-*

*Firstly, it is important to note that there are no scientific guidelines to establish an ALOP. Under these circumstances, currently, countries are free to establish ALOP that is commensurate with their capacity to achieve it.*

*Secondly, the Guidelines and standards developed by Codex are based on scientific risk analysis considering global data and should, therefore, be acceptable as benchmark for harmonization. A Codex document, such as the one under consideration, should not appear to undermine Codex standards by linking the requirement to harmonize national standards with those of Codex for the achievement of ALOP,*

which is a non-science-based expression, and often works as a non-tariff barrier to trade, especially against the developing countries. Thirdly, it would be desirable to qualify the international standards referred as those elaborated by the Codex or other intergovernmental organizations, which are essentially developed through a transparent and inclusive process.

**Paragraph 38:** Delete Paragraph 38.

*Rationale:* To avoid repetition of the guidance included in the Paragraph 42 where it is more appropriate.

**Paragraph 40:** Delete the Paragraph.

*Rationale:* To avoid repetition of the guidance included in the Paragraph 56 where it is more appropriate.

**Paragraph 42:** The text may read as follows:

"The voluntary utilization of quality assurance systems **and food safety systems** by food businesses should be encouraged in order to achieve greater confidence in the quality **and safety** of products."

*Rationale:* This will make the National Food Control System more effective.

**Paragraph 48:** New bullet may be added in the text:

- **Roles of various organizations involved in the system**

**Paragraph 49:** Delete the Paragraph.

*Rationale:* To avoid repetition of the guidance included in the Paragraph 37.

**Paragraph 50, 3<sup>rd</sup> bullet:** Amend the text as follows:

- "Recognizing accredited or accredit laboratories **inspection bodies/certification bodies in accordance with internationally recognized standards;**

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**Paragraph 50, 5<sup>th</sup> bullet:** Amend the text as follows:

"• Verification may be used to ensure that programs and, **where relevant** HACCP plans are being implemented as documented and are effective on a continuous basis."

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*Rationale:* As per the Paragraph 42, the HACCP system should be used where relevant.

**Paragraph 50, 7<sup>th</sup> bullet:** Amend the text as follows:

"• Providing for tracing of ~~foods products~~<sup>15</sup> ~~15~~ and for the recall of unsafe ~~food products~~ **and food which does not meet the requirements of the regulations established by the country's competent authority (ies)**"

*Rationale:* The food which is not as per the requirements of the regulations established by the country's also need to be recalled.

**Paragraph 51-** The text should be read as follows:

"A number of these responsibilities should ~~provide~~ proactive prevention of **prevent** breaches of a national food control system."

Rationale: To have clear meaning.

**Paragraph 53- 2<sup>nd</sup> bullet point:** The text should be read as follows:

"• In the most serious or persistent cases, **detention or seizure or de-registration/ cancelation of licence** of the producer **and/or** closure of the producing establishment."

Paragraph 55- The text should be read as follows:

Where the competent authorities use third<sup>17</sup> party providers as officially accredited bodies to implement controls, **such bodies** ~~to be officially accredited, the body~~ should be assessed against objective criteria.

Rationale: To have clear meaning.