

CODEX ALIMENTARIUS COMMISSION



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Agenda Item 4

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

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DRAFT PRINCIPLES AND/OR GUIDELINES FOR THE EXCHANGE OF INFORMATION (INCLUDING QUESTIONNAIRES) BETWEEN COUNTRIES TO SUPPORT FOOD IMPORT AND EXPORT

(Comments at Step 3 from Brazil, Canada, Chile, Ecuador, El Salvador, Ghana, Indonesia, Japan, Kenya)

BRAZIL

Brazil would like to thank New Zealand and Mexico for the highly significant work they have done and, in an effort to strengthen even further the capacity of the document to facilitate trade in food, we are pleased to provide some brief comments.

Specific comments:

- SECTION 5 - PRINCIPLES

Paragraph 11.

c) Be in either the importing country's language, and English or in a third language if mutually agreed.

Rationale: Our proposal is intended to clarify that the exchange of information should take place in the language of the importing country and in English. In the original format, it is not clear that, if a third language is not agreed, the importing country must submit the documents in its official language and in English.

- ~~SECTION 7 - INFORMATION EXCHANGE CONTENT~~

~~Paragraph 15. To facilitate a level of harmonization of content, information exchanged may include broad overviews under the following headings, as appropriate:~~

Rationale: In the spirit of facilitating the harmonization of content and expediting information exchange, Brazil suggests to replace Section 7, paragraph 15, with an annex constituted by a simplified questionnaire template. Items "e" and "k" of the this section were excluded from the attachment because they were considered repetitive, since they are already comprised in the other listed items (item "e" is comprised in items "a", "b", "c" and "d"; item "k" in "f", "g", "h", "i", "j", "l", "m" and "n" of the section 7, paragraph 15).

The exchange of information during negotiations for access, maintenance and expansion of markets is of utmost importance to all importing and exporting countries. Hence, CX/FICS 16/22/3 is a strategic document for the international trade in agribusiness products.

As it is well known, the currently used questionnaires are not standardized. There are, as expected, specific elements related to different kinds of products that require specific and technically restricted information for that kind of production process and related risk controls concerning human and animal health. Likewise, consideration should be given to the different organizational structures of each country's governmental institutions responsible for the verification procedures in human and animal health and inspection.

Nonetheless, there is a series of common and horizontal data and questions, usually present in most questionnaires used in the negotiations between exporting and importing countries.

The annex proposed by Brazil is intended to facilitate the elaboration of questionnaires by importing countries, favor the exchange of information between exporting and importing countries and enhance the standardization of this kind of tool, thus, providing conditions to shorten the delay in this phase of the negotiation process, making it more efficient.

ANNEX

Simplified basic questionnaire to evaluate inspection systems

1. In order to facilitate the level of harmonization of content, information exchanged may include broad overviews under the following headings, as appropriate:

- a) Exporting country name
- b) Products to be exported

Regarding the products to be exported:

- c) Legislative or administrative framework
 - i- What is the legislation that structures the official service?
 - ii- Are there decentralized inspection units? What is the role of these units?
 - iii- Are there regional official bodies? What is their autonomy? What legislation regulates the issue at different levels of official control and what is the role of each entity in the process?
 - iv- Describe the organizational structure of the Central Competent Authority (organizational chart), demonstrating the attributes of each area involved in official controls.
- d) Competent authority capability, resourcing and organizational design
 - i- How many professionals are involved, by vocational training area, in the inspection of establishments at central and regional level, where applicable, in the areas responsible for official controls? (Inform, separately, the amount of inspection professionals directly linked to the government and third parties involved in the inspection of establishments).
 - ii- What is the origin of the funding of actions?
 - iii- What was the annual budget for the last three years to the supervisory activities of the exported products?
- e) Roles and responsibilities of all relevant parties
 - i- Are there officially accredited institutions responsible for the official control of the product(s) to be exported? What legislation regulates this matter?
 - ii- What are the duties of the parties, governmental and non-governmental organizations, involved in the control of the product to be exported??
- f) Maintained of the independence and credibility of the Competent Authority responsible for certification
 - i- How is the process and what are the criteria used to hire official and private inspection professionals involved in the inspection of establishments? What legislation regulates this matter?
 - ii- Which rules guarantee the independence and credibility of the third-party inspection professionals involved in the inspection of establishments? What is the applicable national legislation?
 - iii- Is the certification private of the Competent Authority or is there decentralization? In case of decentralization, how is the control and audit for issuing the licenses by the Competent Authority?
 - iv- What legislation regulates the Official Sanitary Certificate?
- g) Official controls and standards
 - i- What legislation regulates the registration, manufacturing and export of these products?
 - ii- Is there an official monitoring program of products to be exported?
 - iii- To which laboratory tests is the product subjected ?
 - iv- What is the number of samples analyzed per year?
 - v- What legislation deals with the maximum levels of residues and contaminants (antimicrobial residues, heavy metals, mycotoxins, dioxins/furans, microorganisms, pesticides, etc.) in products to be exported

and what are the inputs needed to produce? Present regulatory limits allowed for each residue and contaminant in products and inputs.

- h) Verification programmes
 - i- Describe succinctly the methods of audits carried out by the Competent Authority.
- i) Enforcement and compliance programmes
 - i- How is the frequency of inspections established in manufacturer establishments by the official body?
 - ii- Inform compliance percentages in the number of inspections scheduled in exporting establishments in the past two years.
 - iii- Describe succinctly the methods employed in compliance programs by the Competent Authority.
 - iv- What legislation defines the applicable sanctions and penalties to those who violate the rules?
- j) Laboratory capacity and capability
 - i- Describe the organizational chart of the laboratory network in the official structure of the country.
 - ii- What legislation defines the criteria for the accreditation of private laboratories to carry out official analyses?
- k) Emergency preparedness and response and recall systems
 - i- What legislation regulates the procedures for gathering product?
 - ii- How many occurrences of this nature happened in the last two years?
- l) Training and competency assessment requirements
 - i- Describe succinctly the training programs of the inspection professionals responsible for the inspection of products
- m) Monitoring, self-auditing and system review
 - i- Describe succinctly the monitoring program, internal audit and system review.
 - ii- Is there any legislation that regulates it?
- n) Evidence supporting the achievement of specified outcomes and key performance characteristics
 - i- What is the compliance rate observed in audit procedures, supervision and laboratorial analysis (physico-chemical and microbiological of products and water) in the exporting establishments?
- o) Criteria for registering and approving specific food business operators including where such lists may be available
 - i- What are the procedures of registration/qualification of manufacturers of the products to be exported?
 - ii- What are the registration procedures of the products to be exported?
 - iii- Is there an expiry date for the registration of establishments and products? How long is it?

CANADA

GENERAL COMMENTS

Canada thanks the eWG led by New Zealand, Brazil and Mexico for circulating a revised proposed draft document, reflecting the discussions in the physical working group held in London. We support advancement of this text to the next step and have some specific comments.

SPECIFIC COMMENTS

We have the following additions in **bold**:

Section 1- Introduction:

3. The exchange of information and associated assessments may be required where the risks associated with the traded commodity are high, whether they relate to food safety or fair practices in the food trade or **where as a result of these risks, the exchange of information is required to meet the importing country's regulatory obligations**, and the necessary assurances cannot be gained by other mechanisms.

Rationale: Regulatory obligations may guide a specific conduct of the assessment, leading to the request of specific information in order to meet importing country's regulatory objectives.

Section 4- Exchange of information and assessment

9. Information exchange is justified when **pre-market assessment are mandated by the regulatory requirements and/or** the risks posed by the specific food product or group of products to food safety or fair practices in the food trade are such that an assessment of whether the relevant component(s) of the NFCS of the exporting country is appropriately managing the risks, is required and the assurance is not able to be attained by other means.

Rationale: An importing country's National Food Control System may set out regulatory requirements for pre-market assessment to manage risks associated with granting market access for certain foods or food groups, such as meat for example, that present significant risks to public health. In such cases, the pre-market assessment is normally guided by an established process.

Section 6- Process

13. f) Provide appropriate resources (**e.g. subject matter expertise**) and interactively engage with the exporting country where additional information or clarity is needed so as to ensure any assessment process can be concluded in a timely manner.

Section 7- Information exchange content

15. Canada would like to add the following bullets:

p) Industry and Community Relations

Rationale: "Industry and Community" heading describes the key elements for outreach and education activities that foster communication and information exchange among stakeholders (i.e. among regulators, academia, and industry).

g) International Communication and Harmonization

Rationale: "International Communication and Harmonisation" heading describes the key elements pertaining to engagement and activities with international partners regarding events/issues of mutual concern.

CHILE

The standard provides useful guidance to countries. Chile does not have any problems with the project advancing after consideration of some specific comments.

Specific Comments:

Section 4 – Exchange of information and assessment

Number 10, item e): Amend as follows: "**make available** involve only the level of ~~detailed~~ information that is essential to gain the necessary ~~certainty~~ ~~assurances~~ **with regard** to food safety and fair practices in ~~food~~-trade, as opposed to routinely requiring detailed information, on **specific food business operators**¹."

Rationale. To ensure consistency with the English version.

¹For the purpose of this document, food industry operators includes producers, manufacturers, wholesalers, distributors, importers, exporters and retailers.

Section 5 – Principles

Number 11, item c): Amend text as follows: “c) Be in a mutually agreed language between the importing and exporting countries or in English”;

Rationale: One of the difficulties faced by exporting countries is the diversity of questionnaire languages. It would seem reasonable that in order to help simplify the exchange of information, both countries be given the possibility to find a language in common and, where they cannot agree, use English.

Number 11, item d): Insert the words “and promote” after “allow” to read: “d) allow for **and promote** electronic transmission, including the ability to appropriately reference information already supplied or that may be readily available online”.

Rationale: Adding the word “promote” would enhance the principle.

Section 6 – Process

Number 12: Amend as follows: “12. Where the necessity of exchanges of information and assessments has been established, **which are required to trade in food**, in accordance with paragraph 9 above, ~~and are required to trade in food,~~ the following processes should be observed by the competent authorities of the importing and exporting countries”.

Rationale: The text is easier to understand with the suggested amendments.

Number 13, item b): Replace the entire text as follows: “**b) Make itself available to review the information relating to previous exchanges, publications or existing experiences and any further information from the exporting country, that may be necessary to fill information gaps.**”

Rationale: The new text clarifies the contents.

Number 13, item c): Delete in full.

Rationale: The text imposes too much burden for the importing country and does not facilitate trade.

Number 13, item f): Delete the first part of the text: “Provide appropriate resources and”.

Rationale: This imposes a major burden on developing countries.

Number 13, item g): Delete the words “constructive comments” and insert the word “feedback”, as follows: “g) Establish a deadline for review of responses and for ~~constructive comments~~ **feedback** on such review to the exporting country.”

Rationale: The change is consistent with the English version.

Section 7 – Information exchange content

Number 15, item a): Add the text in e). The text would read as follows: “a) legislative or administrative framework; **relevant administrative policies and procedures;**”

Rationale: Items a) and e) refer to the same subject; therefore there is no justification for having them in separate paragraphs.

Number 15, item d): Delete the text.

Rationale: Item b) already refers to the authority, so d) is unnecessary.

Number 15, item e): Transfer this text to item a).

Rationale: Items a) and e) refer to the same subject; therefore there is no justification for having them in separate paragraphs.

Number 15, item n): Delete.

Rationale: This text is redundant, since item m) deals with this subject and in more general terms. The standard on performance monitoring is still being developed.

ECUADOR

General Comments

Throughout the document please include in the relevant paragraphs, both “exporting country and importing country” (except in Section 6 where procedures are clearly specified by stakeholder); this is because documents should deal with both exporters and importers on an equal footing.

For example:

Section 4 – Exchange of information and assessment - Paragraph 10 - Item a)

a) not impose an outcome, a standard or a process in excess of what is being applied within the importing country without justification. #

Translator’s note: change in Spanish only.

- Change all paragraphs to the present tense, as some are in the conditional.

Specific Comments:

Section 1 – Introduction – Paragraph 1

Most trade in food occurs without countries requiring an exchange of information on their National Food Control Systems (NFCS). However, under some circumstances, importing countries may require an exchange of information for the initiation or maintenance of trade in food. #

Translator’s note: change in Spanish only.

Section 1 – Introduction - Paragraph 4.

The use of Codex guidance by importing and exporting countries alike ~~would help facilitate~~ **should help facilitate** any necessary assessment of the relevant component(s) of the NFCS. #

Translator’s note: change in Spanish only.

Section 3 – Scope – Paragraph 8

These guidelines address situations where information exchange may be required for the assessment of relevant component(s) of an exporting country’s NFCS that may cover a product or group of products prior to the initiation or ~~maintenance of trade~~ **in the stages of its trade.**

Section 5 – Principles – Paragraph 11 – Item a)

a) Be between the relevant competent authorities of the exporting and importing countries. a designated **impartial** coordinating contact point should be appointed.

Section 5 – Principles – Paragraph 11 – Item b)

11. The following principles should apply to the exchange of information and/or the associated assessment process:

b) Be transparent, structured, **focused**, interactive and timely.

RATIONALE: It is important to indicate what “focused” refers to, and where there is no agreement on this qualifier, it could be deleted.

Section 6 – Process – Paragraph 13 – Item b)

b) On request make itself available to discuss what information may already be available from previous exchanges, publications or existing knowledge, confidence or experience and what further information may be necessary from the exporting country to fill information gaps **or to clarify any conflicting information.**

Section 5 – Principles – Paragraph 11 – Item e) – Footnote on page 4

11. The following principles should apply to the exchange of information and/or the associated assessment process:

e) Recognize existing experience, knowledge and confidence already gained or possible to extrapolate from assessments by other countries or international organizations, and

[Footnote 11 from CAC/GL 26-1997] Experience, knowledge and confidence in an exporting country's food inspection and certification system by an importing country includes the history of food trade between two countries and the history of compliance of foods with the importing country's requirements, particularly the relevant food products involved. Further examples that may inform the importing country's experience, knowledge and confidence are listed in paragraph 10 points (a) to (n) in the annex to CAC/GL 53-2003.]

RATIONALE: Clarify the term 'relevant food products', indicate the products this would cover.

Section 6 – Process – Paragraph 13 – Item g)

g) Establish a deadline for review of responses and for constructive comments **or suggestions for change** on such review to the exporting country.

Section 7 - Information exchange content – Paragraph 15

To facilitate a level of harmonization of content, information exchanged may include broad overviews under the following headings, **taking into consideration current and previously determined information**, as appropriate:

Section 7 - Information exchange content – Paragraph 15 – Item i)

i) **Official, ISO-standard** laboratory capacity and capability.

EL SALVADOR

El Salvador welcomes the document prepared by the electronic working group chaired by New Zealand, Brazil and Mexico

General remarks:

Draft recommendations submitted by the EWG is supported to move through the Codex Step Procedure.

GHANA

Ghana appreciates the efforts by the eWG led by New Zealand, Brazil and Mexico in drafting the document to guide the exchange of information between countries in the food trade.

We support the draft document as it elaborates the principles and guidelines governing the exchange of information between trading countries. The document also simplifies and harmonizes questionnaires used in food trade. We therefore recommend the advancement of the draft document to the next step of the Codex Step Process.

INDONESIA

General Comments:

Indonesia thanks New Zealand as chair of EWG, Brazil and Mexico as co-chair for preparing the draft discussion paper. Indonesia also thanks members of EWG for contributing to the draft Principles and Guidelines for the Exchange of Information (Including Questionnaires) between Importing and Exporting Countries to Support the Trade in Food.

Indonesia supports this draft and considers that it will be useful as a reference to exchange of information between importing and exporting countries in relation to the initiation or maintenance of trade for a product or group of products.

Specific Comments

Section 1 - Introduction

Paragraph 2 – Indonesia suggests to modify the sentence, so that it becomes “These guidelines is not intended to mandate such exchange of information as a necessary prerequisite ~~for trade occurring~~ **to trade** between countries”.

Rationale: to make more appropriate grammatically

Section 3 - Scope

Indonesia suggests to insert new paragraph before paragraph 8 as follow:

8. This Guidelines provides guidance for responding such exchange of information between competent authorities in importing and exporting countries, including but not limited to the appropriate use of questionnaires.

Rationale: to emphasize the scope that the exchange of information is conducted between the competent authorities of the exporting and importing countries.

Section 4 - Exchange Information and Assessment

Paragraph 10 point a) and d) – Indonesia needs clarification and definition for the term “outcomes”

Rationale: to have a common understanding on term “outcome” in this guideline, since each country has different outcomes of the National Food Control System (NFCS).

Section 5 - Principles

Paragraph 11 – Indonesia suggests to modify the sentence, so it becomes:

The ~~following principles should apply to the~~ exchange of information and/or the associated assessment process **should be:**

- a) ~~Be~~ between the relevant competent authorities of the exporting and importing countries. ~~Where multiple authorities are involved a designated coordinating contact point should be appointed.~~
- b) ~~Be~~ appropriately transparent, structured, focused, interactive and timely.

Be use either in the importing country’s language, English or a third language as mutually agreed.

- c) Allow for electronic transmission, including the ability to appropriately reference information already supplied or that may be readily available online.
- d) Recognize existing experience, knowledge and confidence already gained or possible to extrapolate from assessments by other countries or international organizations.
- e) Not require the submission of commercially sensitive information unless essential to assess the public health objective, in which cases, it should be protected from inappropriate use or disclosure to other parties.

Rationale:

- a) *Some countries appointed competent authorities based on the type of product. So each of the competent authority has its own authority within their regulated products / mandated function.*

b) *To make easier understanding.*

Section 6 - Process

Paragraph 13 point a) – delete term “why it is required” so it becomes:

- a) Clearly outline the information required, ~~why it is required~~, and the process and methodology to be followed, including anticipated timelines.

Rationale: Detail description of information requested clearly outlines in point b) to point h).

JAPAN

Japan is pleased to submit the specific comments as follows,

Section 4-Exchange of information and assessment

Para 9

Information **is exchanged** ~~exchange is justified~~ when the risks posed by the specific food product or group of products to food safety or fair practices in the food trade are such that an assessment of whether the relevant component(s) of the NFCS of the exporting country is appropriately managing the risks, is required and the assurance is not able to be attained by other means.

Rationale: The word: “justified” should be deleted since it is not clear who decides the information exchange to be justified. The aspect of “justify” is not included in the project document, should be deleted in the entire document.

Section 6 – Process

Para 14

Add a new point

(e) Provide appropriate resources and interactively engage with the importing country where additional information or unclarity is identified so as to ensure any assessment process can be concluded in a timely manner.

Rationale: Since both exporting country and importing country are responsible for providing appropriate resources, we propose to add this additional bullet point in line with the para13(f).

KENYA

Kenya appreciates the good work done by the EWG Led by New Zealand, Brazil and Mexico in coming up with this draft standard for the committee members to comment on. However, Kenya has no specific comments to this draft at this step.

Specific Comment

Kenya proposes that the CCFICS committee to consider revising the following existing Codex standards indicated below to capture the clauses, which the new draft Codex standards makes references to. This will ease the implementation process of these standards and reduce the cost of the implementer/industry from buying all the reference Codex standards to make reference to during implementation.

We have also noted that some of these Codex standards are also old and they might need to be revised to keep a breast with new technology and at the same time fill the missing gaps required in the exchange of information by the exporter and importer countries.

Codex texts of particular relevance include:

- CAC/GL 82-2013 Principles and guidelines for national food control systems;
- CAC/GL 47-2003 Guidelines for Food Import Control Systems;
- CAC/GL 20-1995 Principles for Food Import and Export Inspection and Certification;

- CAC/GL 53-2003 Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems; and
 - General Principles Food Hygiene (CAC/RCP1-1969).
-