

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 4

CRD7

Original Language Only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Twenty-seventh Session

DRAFT CONSOLIDATED CODEX GUIDELINES ON RELATED TO EQUIVALENCE

(Comments of Ghana, Japan, Kenya, Morocco, Nigeria, Republic of Korea, Rwanda, Thailand, United Republic of Tanzania, and East African Community)

Ghana

Questions 1 & 2 – Section 4: Definitions

Position

- 1) Ghana supports the current approach and wording provided in the definition for decision criteria.
- 2) Ghana supports the current proposed wording

Rationale

The current approach and wording provided in the definition section are comprehensive and exhaustive as well as takes into consideration the different terminologies used in the various Codex texts on equivalence under consolidation.

Question 3 – Section 4: Principles

Position

Ghana supports the revised proposed wording for principle “f” on demonstration of equivalence.

Rationale

The proposed wording is clear and not restrictive. It also promotes specificity towards the measures required by the importing country to achieve its objectives in protecting consumer health and fair practices in food trade

Questions 4, 4a and 5 – Section 6: Process steps

Position

Ghana does not support a provision of separate sections for ‘assessment process for systems equivalence’ and for ‘equivalence of measures’.

Rationale

The section 5 is exhaustive and where there is the need to vary the assessment process in relation to a specific guidance, the section can be amended.

Japan

GENERAL COMMENTS

Japan thanks chair and co-chairs for their hard work to consolidate and update the document. We suggest to decide whether Committee keeps or deletes existing documents before completion of this work and to avoid missing importance concepts which CCFICS reached consensus while developing existing documents over past decades.

SPECIFIC COMMENTS

SECTION 4: DEFINITIONS

Decision Criteria: Those factors used to objectively determine whether the exporting country's NFCS or the relevant part achieve the objectives and related outcomes or level of protection of the importing country's NFCS or the relevant part for the products under consideration [~~New definition derived~~ ~~Adapted from CXG 101-2023~~].

COMMENT: Same definition as GXG 101 should be used or clearly stated as new definition.

Outcomes: Intended effects or results that contribute to achieving the ~~relevant~~ NFCS objectives. Outcomes may be categorized at different levels, such as ultimate, high-level, intermediate, preliminary, or initial. [~~From CCFICS26 NFCS Equivalence guidance and CXG 91-2017~~].

COMMENT: Same definition as CXG 91 should be used.

Requirements: ~~are the criteria~~ conditions set down by the ~~importing country~~ competent authorities relating to trade in food ~~stuff~~ covering the protection of ~~health~~ consumers ~~health~~ and conditions of ensuring fair practice in the food trade. [~~New Definition derived~~ ~~Adapted from CAC/GL 34-1999~~]

COMMENT: Same definition as GXG 34 should be used or clearly stated as new definition.

Sanitary measure: Any measure applied to protect human life or health from risks arising from additives, contaminants, toxins or disease-causing organisms in food. [~~New Definition derived~~ ~~Adapted from CXG 53-2003 and Annex A of the WTO SPS Agreement removing reference to the health of live animals and plants,~~]

COMMENT: Should be stated as new definition unless same definition is used from original text.

Technical measure: Any measure other than a sanitary or phytosanitary measure to ensure the protection of the health of consumers or fair practices in the food trade. [~~New Definition~~ ~~Derived from the WTO TBT Agreement~~]

COMMENT: Should be stated as new definition unless same definition is used from original text. Similar definition can not be found in the WTO TBT Agreement.

SECTION 4: PRINCIPLES

F: Demonstration of Equivalence

~~Importing countries should accept the equivalence of the exporting country's specified measures where~~ ~~the~~ exporting country should objectively demonstrates that their specified measures achieve the same objectives as achieved by the importing country's measures.

COMMENT: Japan suggests to revise text. To demonstrate equivalence is an action to show and explain how to achieve same objectives. Import country may or may not accept it through decision process.

SECTION 5: INITIAL DISCUSSIONS

10. The initial discussions should review the nature and relevance of the requirements for trade that the exporting country considers same level of protection is achievable by different approaches ~~to be unnecessarily restricting~~.

COMMENT: Japan suggests to revise text. Equivalence process will apply to those measures importing country and exporting control differently to achieve the same objective. It means that exporting country also consider the objective is necessary. When exporting country considers that some measures are unnecessarily restrictive, it should go to the difference channel other than equivalence recognition.

Appropriateness of an equivalence process

12. The following can be included in the discussions as to whether an equivalence process may be the most appropriate for the matters under review:

- the nature and impact of the requirements for trade which the exporting country considers ~~are unnecessarily restrictive~~ same level of protection is achievable by different approaches;

COMMENT: Same comment as Para 10.

Step 4: Exporting country documents its case for equivalence

31. The submission should ~~only~~ cover that additional relevant information and evidence that the importing and exporting countries have agreed is not already covered by existing knowledge, experience, and confidence.

COMMENT: Japan suggests to delete 'only'. It is necessary to provide additional information to determine what is covered or not covered by existing knowledge. It is better not to limit when submit.

36. ~~Existing experience, knowledge, and confidence can reduce both the potential scope and intensity of the assessment process. Accordingly, appropriate use and reference to existing experience, knowledge, and confidence can reduce the resources required and facilitate a timelier assessment.~~

COMMENT: Japan suggests to delete Para 36. The similar content is already covered in Para 14.

Para 54. The importing and exporting country should also agree on what level of substantive change will necessitate a reassessment in whole or in part of the recognition. Generally, recognition agreements / arrangements continue to apply while any such reassessments are progressed. Such changes may for example include:

- ~~a drop in the level of protection achieved by the exporting country ; and / or~~

COMMENT: Japan suggests to delete the 2nd bullet point or move to under Para 55. Immediate notice to importing country is necessary when a drop in the level of protection is confirmed, and the agreement should be on hold while reassessments are progressed. This example is one of the situations that urgent actions are necessary and fits well under Para 55.

Kenya

Proposed draft consolidated Codex guidelines related to equivalence-CX/FICS 24/27/4

Position:

1. On Section 4: Definition:

a) Q1 and Q2 Position: Kenya supports and agrees with the current approach and wording. They are well supported by the guidelines in CXG 101-2023 and have a basis with the following minor amendments

I. Retain the definition of Decision criteria as defined by CXG101-2023. The original definition is sufficient. The addition is superfluous.

II. Editorial amendment to the definition of Requirements as: are the conditions set down by the importing country competent authority relating to trade in food covering the protection of the health of consumers and ensuring fair practices in the food trade. Justification: an editorial amendment.

III. Definition of measure adequately covers sanitary and technical measures. Therefore, Kenya proposes their deletion.

b) Q3: Position: Kenya supports the revised proposed wording.

c) Q4: Position: Kenya supports that separate sections are not needed with the assessment.

2. Overall Conclusion: Kenya thanks the chair and its co-chairs for the work and recommends progressing the development of draft consolidated guidance relating to equivalence. GE

Morocco**SECTION 4: DEFINITIONS :**

Morocco proposes some changes regarding the definition of the term “requirement” as follow: “**Requirements**”: are the **control measures, actions and activities** set down by the importing country competent authority relating to trade in food covering the protection of the health consumers and ensuring fair practices in the food trade.

Rationale: CAC/GL 34-1999 define the requirements **as criteria** and CAC/RCP 1-1969 outline the requirements as control **measures** which are any **action and activity** that can be used to prevent or eliminate a food safety

hazard or reduce it to an acceptable level. Taking into account the above, Morocco proposes to replace "conditions" with "control measures, actions and activities" to the extent that the use of the term "measure" is appropriate for defining "requirements"

SECTION 6: PROCESS STEPS :

Step 5: Assessment process to reflect the difference in the pressure of the evaluation when it comes to measurements or the entire system :

1-Morocco proposes the addition of a new paragraph to reflect the difference in the pressure of the assessment when it comes to specified measures or the entire NFCS

38 bis. The assessment process should follow simple steps when it comes to the equivalence of certain specified measures and introduce, obviously, further steps if part or all of the NFCS is being assessed.

2- Morocco proposes to introduce the possibility of doing remote audits in accordance with the new codex guidelines CXG 101-2023 in paragraph 40 ----- - whether an in-country visit **or/and remote audit** will likely be necessary. 40. An in-country visit **or/and remote audit** may be justified and required as part of an assessment, for example in situations where:

SECTION 8: MAINTENANCE OF EQUIVALENCE RECOGNITIONS

The addition of the amendments shown in bold in paragraph 54 :

54. **Maintaining the ongoing currency of equivalence recognitions requires a proactive and collaborative approach between the importing and exporting country. In this regard, the** importing and exporting country should also agree on what level of substantive change will necessitate a reassessment in whole or in part of the recognition. Generally, recognition agreements/arrangements continue to apply while any such reassessments are progressed. Such changes may for example include: - a change to the importing country's **NFCS objectives, and related outcomes** or level of protection; and / or - a drop in the **NFCS objectives, and related outcomes** or level of protection achieved by the exporting country; and / or - a substantive change to the exporting country's NFCS or relevant part; and / or - any proposed significant changes to the laws, regulations, **requirements, procedures, actions** or performance measures underpinning the components of either country's NFCS covered by the recognition of equivalence arrangement.

Nigeria

Nigeria appreciates the work done by the electronic working group led by New Zealand, the United States of America and Kenya.

Nigeria supports the proposal for the continuation as well as progression of the work to the next step of the Codex procedure through the current EWG to:

- i. progress the development of draft consolidated guidance relating to equivalence; and
- ii. report to CCFICS28 with a revised draft text for progression in the Codex step process

Rationale The work has made significant progress since CCFICS24 and the text can still be updated

Republic of Korea

General Comments

Republic of Korea would like to thank each and every working group for all the dedication put into the work on CCFICS. It was a massive job to coordinate various voices of member countries and I send my applaud to the job well done.

Section 4. Definition 'Sanitary measures':

It is of ROK's opinion to delete the phrase in the square bracket [Adapted from CXG 53-2003 and Annex A of the WTO SPS agreement removing references to the health of live animals and plants] and use the existing definitions of CXG 53-2003 for consistency in terms used in Codex and CCFICS in the consolidated guidelines. In addition,

it is argued that the health of animals and plants should also be included because feed is included in the scope of the Codex.

Section 4. Definition ‘Technical measures’:

The existing CCFICS guidelines on equivalence do not include WTO TBT content. It is questionable whether to include WTO TBT content, which is not in the existing guidelines, in the consolidated guidelines currently being worked on is consistent with the purpose of the guidelines.

Opinion on deleting the phrase ‘for facilitating trade’ in para 19:

The primary purpose of the equivalence process is to protect one's own country, thereby facilitating trade. But the proposed phrase is interpreted as if the equivalence process exists only for facilitating trade, therefore we propose to delete the phrase.

Rwanda

Question 1: Is the current approach and wording supported?

Rwanda supports the current approach and wording

Section 4: definitions

Rwanda supports the definitions provided under section 4

Thailand

Thailand appreciates the continuous and diligent efforts of the EWG (led by New Zealand with the United States of America and Kenya) for preparing the “Proposed Draft Consolidated Text on the: Principles and Guidelines for the Recognition of the Equivalence of Specified Measures or the Whole or a Part of National Food Control Systems for consideration (at Step 3/4) (CX/FICS 24/27/4, Appendix).

Our comments on this document are as follows:

General comments

For consistency and accuracy of the document, we recommend that:

1. The contexts should be consistent with the title, thus “specified measures, NFCS or relevant part” should be replaced with “specified measures, or the whole or a part of NFCS” throughout the entire document.
2. Any revisions to the document should be reflected in corresponding sections. For example, in case where the definition of equivalence is revised, relevant contexts should be amended accordingly.
- 3 Consistent terms should be used throughout the entire document. For instance, “exporting party” and “exporting country”, “both parties” and “both countries”

Specific comments

SECTION 4: DEFINITIONS

“Equivalence”

1. We support the current definition of “Equivalence” that focuses on “achieving the same objectives”, not “achieving relevant objectives, and related outcomes or level of protection”. This also complied with the definition of “Equivalence of NFCS” as indicated in CXG 101-2023, focusing on only “achieving the same objectives”.

2. For consistency, relevant contexts regarding “relevant objectives, and related outcomes or level of protection” should be amended accordingly to the current definition throughout the document.

“Measure”

1. We do not support the current proposed definition of “measure”. As, the implementation of measures may achieve the level of protections related to the protection of the health of consumers or ensuring fair practices in the food trade. Meanwhile it may not achieve NFCS objectives, and related outcomes.

2. As a consequence, the definition of “measure” should be revised to read:

“a type of control designed to achieve ~~NFCS objectives, and related outcomes or~~ level of protection as they relate to the protection of the health of consumers or ensuring fair practices in the food trade.”

“NFCS Objective”

The definition of “NFCS Objective” is unnecessary and should be removed, since the scope in section 3 sufficiently provides a comprehensive explanation, covering and addressing NFCS objective.

“Requirements”

We do not support determining the definition for “Requirements”, as the word is commonly understandable, meanwhile it may cause confusion with the definition of “Measure”. However, if it is considered that the definition of “Requirements” is needed, it should be in accordance with those indicated in CXG 34-1999.

SECTION 4: PRINCIPLES

F: Demonstration of Equivalence

We do not oppose the revised wording for “Demonstration of Equivalence”.

SECTION 5: INITIAL DISCUSSIONS

Initial scope discussions

- Paragraph 13

• Bullet 1

Both exporting country and importing country can seek a recognition of the equivalence, hence this bullet should be revised to read:

“Identify the range of products ~~for which the exporting country is seeking a recognition of the equivalence of its control measures~~ for which the exporting country is seeking a recognition of the equivalence”

SECTION 6: PROCESS STEPS

Step 1: Scope of request discussed and documented

- Paragraph 20

• Bullet 3

To be clear, this bullet should be revised to read:

“a brief description of the exporting country’s specified alternative measures, or the whole or a part of ~~NFCS or relevant part~~ for which the exporting country is seeking an equivalence determination.”

Step 2: Importing country describes the basis of its requirements for trade

- Paragraph 22

• Bullet 3

We would like to seek for clarification for the meaning and intention of “level of control”, and methods or approaches for expressing its related information.

Step 3: Discussing and documenting the decision criteria

- Paragraph 24

1. For consistency with the title and the definition of “equivalence”, this paragraph should be revised to read:

“The decision criteria provide the objective basis for comparison. Decision criteria should also further explain the type of evidence the exporting party should provide to demonstrate that its specified measures, or the whole or a part of ~~NFCS or relevant part~~ achieves the importing country’s ~~relevant NFCS~~ objectives. ~~, and related~~”

~~outcomes or level of protection.”~~

2. For clarity and avoid confusion, terms used in the document should be consistent throughout the entire document. For example, “exporting party” and “exporting country”.

- Paragraph 25

To be clear, this paragraph should be revised to read:

“Once the formal request for consultations on a recognition of equivalence ~~of a NFCS or the relevant part~~ has been made, discussions should occur between the exporting and importing country to assist the development of, and better understanding of, the decision criteria to be applied, which where possible should be agreed between both countries”

- Paragraph 26

For consistency with the definition of “Equivalence”, this paragraph should be revised to read:

“the importing country whether or not the exporting country’s system design and implementation achieves the importing country’s ~~relevant~~ objectives, ~~and related outcomes or level of protection~~, associated with the scope of the request.”

- Paragraph 27

• Bullet 1

This bullet should be revised to be consistent with the definition of “Equivalence”. Thus, it should be:

“the relevant importing country ~~NFCS~~ objectives, ~~and related outcomes or level of protection~~,”

Step 4: Exporting country documents its case for equivalence

- Paragraph 29

To be consistent with the title and the definition of “Equivalence”, this paragraph should be revised to read:

“The exporting country should submit or make available appropriate information and evidence, including relevant references that demonstrates how its specified measures, ~~or the whole or a part of~~ NFCS ~~or relevant part~~, achieves the importing country’s ~~relevant NFCS~~ objectives, ~~and related outcomes or level of protection~~ for the foods and requirements for trade within the scope of the equivalence request.”

Step 5: Assessment process

- Paragraph 42

We do not oppose the current text in this paragraph, while the text proposed in the previous draft document (version: 15/11/2023) should be reverted and placed under this paragraph. As, it is useful and in practice, exporting country should have the opportunity for explanation and correction for any errors before the importing country’s assessment is finalized.” Thus, this section should read:

“42. Other overarching considerations relevant to the assessment process may include:

- freedom from conflicts of interest;
- transparency of decisions and actions;
- how the exporting country NFCS maintains the three characteristics of: situational awareness proactivity and continuous improvement⁷; and
- the availability of resources and infrastructure to continue to implement the NFCS or the relevant part .

“At the conclusion of the assessment process the importing country should summarise its assessment findings. The exporting country should be given the opportunity to correct any errors of fact before the importing country finalizes its assessment.”

Step 6: Decision process and final decision

- Paragraph 46

For consistency with the title, this paragraph should be revised to read:

“The draft decision document should be consulted with the exporting country. The importing country should allow the exporting country to correct any error of fact. In the case where the exporting country’s specified measures, or the whole or a part of NFCS ~~or relevant part~~, is initially assessed as not equivalent the two countries may, if they wish, agree to a plan and timeframe for the exporting country to provide any additional information or controls for the identified parts of the NFCS that were determined not to be equivalent.”

SECTION 7: DOCUMENTING THE AGREEMENT AND IMPLEMENTING THE DECISION

- Paragraph 52

To avoid confusion and misunderstanding, terms should be used in consistency throughout the entire document, including “both parties” or “both countries”.

SECTION 8: MAINTENANCE OF EQUIVALENCE RECOGNITIONS

- Paragraph 57

To be consistent with the title, this paragraph should be revised to read:

“These audits should focus on how the exporting country’s NFCS is continuing to assure the specified measures, or the whole or a part of NFCS ~~or relevant part~~, as recognized as equivalent are continuing to be effectively applied.”

ANNEX 1: Flow Diagram

- Figure 1: Equivalence of National Food Control Systems Process

1. For consistency with the title, the name of Figure 1 and introductory text should be revised to read:

- **Name:** “Figure 1: Equivalence of Specified Measures or the whole or a Part of National Food Control Systems Process

- **introductory text:** Simplified flow chart for recognition and maintenance of equivalence of specified measures or of the whole or a part of NFCS”

2. Name of steps in Figure 1 should be amended to be consistent with the relevant steps in the main text. For example, step 2 should be “Description of Importing country describes the requirements for trade relevant to scope”.

United Republic of Tanzania

Proposed draft consolidated Codex guidelines related to equivalence-(CX/FICS 24/27/4)

Position: TANZANIA thanks the EWG chair and its Co-chairs for their efforts to prepare the proposed draft consolidated Codex guidelines related to equivalence. TANZANIA supports the consideration of the proposed draft guidelines at CCFICS27 and requests the following proposals as the document proceeds to Step 5.

On Section 4: Definition:

Question 1 Position: TANZANIA supports and agrees with the current approach and wording. They are well supported by the guidelines in CXG 101-2023 and have a basis with the following minor amendments:

For the term ‘equivalence’ to be defined as ‘The capability of different NFCS, in whole or in part, or different specified measures, to achieve the same objectives, and related outcomes or level of protection”.

Rationale: To align with CXG 101-2023.

Question 2 Position: TANZANIA Supports retention of both definitions of the terms “Measure” and “Requirements”

Rationale: In the text, requirements have been used in section 6 step 2, removing it will have an impact on the rest of the document. As noted, ‘measure’ can apply to either the importing or exporting country and ‘requirements’ only apply to the importing country’s conditions for trade.

On Section 4: Principles:

Position: TANZANIA notes that the section related to principles is 5 not 4 and proposes proper numbering which should be extended to the entire guideline.

Justification: In numbering sections, the sections on “Principles” and “Definition” have the same number 4.

Question 3: Position: TANZANIA supports the inclusion of ‘Demonstration of Equivalence’ as a principle.

Justification: It is an important principle regarding safety and compliance where additional information/data can be provided. The text as provided is not restrictive and at the same time promotes specificity towards the measures required by the importing country to achieve its objectives in protecting consumer health and fair practices in food trade.

Questions 4, 4a and 5:

Position: TANZANIA does not agree on the need for separate assessment process sections for systems equivalence and equivalence of measures.

East African Community

Position: EAC thanks the EWG chair and its Co-chairs for their efforts to prepare the proposed draft consolidated Codex guidelines related to equivalence. EAC supports the consideration of the proposed draft guidelines at CCFICS27 and requests the following proposals as the document proceeds to Step 5.

On Section 4: Definition:

Question 1 Position: EAC supports and agrees with the current approach and wording. They are well supported by the guidelines in CXG 101-2023 and have a basis with the following minor amendments:

For the term ‘**equivalence**’ to be defined as ‘The capability of different NFCS, in whole or in part, or different specified measures, to achieve the same objectives, **and related outcomes or level of protection**’.

Rationale: To align with CXG 101-2023.

Question 2 Position: EAC Supports retention of both definitions of the terms “Measure” and “Requirements”

Rationale: In the text, requirements have been used in section 6 step 2, removing it will have an impact on the rest of the document. As noted, ‘measure’ can apply to either the importing or exporting country and ‘requirements’ only apply to the importing country’s conditions for trade.

On Section 4: Principles:

Position: EAC notes that the section related to principles is 5 not 4 and proposes proper numbering which should be extended to the entire guideline.

Justification: In numbering sections, the sections on “Principles” and “Definition” have the same number 4.

Question 3: Position: EAC supports the inclusion of ‘Demonstration of Equivalence’ as a principle.

Justification: It is an important principle regarding safety and compliance where additional information/data can be provided. The text as provided is not restrictive and at the same time promotes specificity towards the measures required by the importing country to achieve its objectives in protecting consumer health and fair practices in food trade.

Questions 4, 4a and 5:

Position: EAC does not agree on the need for separate assessment process sections for systems equivalence and equivalence of measures.

Justification: EAC supports that any specific guidance related to a difference in the assessment process should be included as additional or amended text in the current Step 5. EAC has no additional content regarding Step 5 as the flow is adequate.