

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 5

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

#### Twenty-Sixth Session

#### PROPOSED DRAFT CONSOLIDATED CODEX GUIDELINES RELATED TO EQUIVALENCE

(Comments of Burundi, Ghana, Morocco, Thailand and Uganda)

#### Burundi

**Comment:** Burundi appreciates the work done by the EWG chaired by New Zealand and its co-chairs USA and Kenya.

Burundi supports the adoption of the guidelines to step 5/8, and recommends taking into consideration the comments raised below.

#### Section 2 (Purpose/Scope)

**Comment:** Burundi proposes splitting the Purpose and Scope into two separate sections with paragraph 6 as the Purpose and paragraph 7 as the Scope.

**Justification:** The separation of Scope and Purpose will serve to provide clarity.

#### Section 3

**Comment:** Burundi proposes revision of the definition for sanitary measure to read as follows: Any measure applied to protect human life or health within the territory of the country from risks arising from additives, contaminants, toxins or disease-causing organisms in food or feedstuffs, or from risks arising from diseases carried by foods obtained from animals and plants or from risks arising from any other hazards in foods (Adapted from CXG 53:2003).

**Justification:** The definition provided in the draft consolidated guidelines is limiting and excludes other key elements of a Food Control System. In addition, inclusion of foods obtained from animal and plants will align the guideline to the One Health Approach that calls for collaborative efforts to ensure optimal health for people, animals and the environment.

Burundi proposes that reference is made to relevant international standards/guidelines/recommendations instead of referring to only ISO guidelines.

#### Section 4

##### Principles – Demonstration of equivalence

**Comment:** Burundi proposes retention of Demonstration of Equivalence as a separate principle, and proposes realignment of the principles so that all principles related to equivalence are close together. Therefore, “Demonstration of Equivalence” should be the 2nd principle. In addition, the realignment will improve coherence and sequential flow of related information.

To provide a balancing statement/principle in obligations for both the importing and exporting countries.

**Justification:** To provide a balancing statement/principle in obligations for both the importing and exporting countries.

#### Section 5

**Comment:** Burundi proposes that reference is made to relevant international standards/guidelines/recommendations instead of referring to only ISO guidelines, to read:

- the alignment with relevant international standards, guidelines, recommendations, and conformity assessment practices;

**Justification:** This is to ensure consistency with the WTO SPS Agreement and to not limit the applicable “standards/guidelines” to ISO guidelines.

#### Section 6 Step 1 Para24

**Comment:** Burundi proposes to rearrange the statement for clarity as the word trade has been repeated unnecessary.

**Justification:**To read as 'The conditions of trade considered to be unnecessarily restrictive;

### Section 7

**Comment:** Burundi supports the proposal to add a separate section relating to maintenance of equivalence recognition. CXG 34:1999, Para 23 in addition to the text provided in section 7 can offer guidance.

**Justification:**To provide guidance on how countries can maintain established equivalence agreements.

### Appendix 1

**Comment:** Burundi supports the provision of a flow diagram for the stages of the equivalence recognition process.

**Justification:** A flow diagram provides an easy-to-understand overview of the different stages of the equivalence recognition process.

### Additional Information on the course of Action when the decision for establishment of equivalence is negative.

**Comment:** Burundi observes the absence of a text on the course of action when the final decision for establishment of equivalence is negative. Burundi would like some guidance on the next steps when the final equivalence decision is negative and recommends addition of a text guiding the course of action in the event that the final equivalence decision is negative under step 6.

**Justification:**To guide both the importing and exporting countries on the course of action in the event that the final decision is negative.

### Section 7 Para 61

**Comment:** Burundi proposes to include the duration (timeline /grace period) for reassessment and implementation of the substantive change.

**Justification:**To read as 'The exporting and importing countries will agree on the reasonable duration (timeline /grace period) for reassessment and implementation of the substantive change'.

## Ghana

### Section 2

**Position:** Ghana proposes a separation of the Purpose from the Scope with paragraph 6 as the Purpose and paragraph 7 as the Scope

**Rationale:** The scope and purpose have different functions in a Standard or Guideline and therefore the need for separation to give clarity to the standard.

### Section 3 - Definition of sanitary measure

**Position:** Ghana proposes a revision of the definition for sanitary measure to read as follows:

Any measure applied to protect human life or health within the territory of the country from risks arising from additives, contaminants, toxins or disease-causing organisms in food *or feedstuffs*, or from risks arising from *diseases carried by foods* **obtained from animals and plants** or from risks arising from any other hazards in foods (*Adapted from CXG 53:2003*).

**Rationale:** The definition provided in the draft consolidated guidelines is limiting and excludes other key elements of a Food Control System. In addition, inclusion of foods obtained from animal and plants will align

### Section 4: Principles – Demonstration of equivalence

**Position:** Ghana supports the retention of f(bis) as a separate principle as well as the obligation of the importing party to ensure their measure is only applied to the extent necessary to achieve their level of protection relative to the bilateral risks.

### Section 5 - Initial discussions, Experience Knowledge and Confidence

**Position:** Ghana proposes that reference is made to relevant international standards/guidelines/recommendations instead of referring to only ISO guidelines, to read:

- the alignment with relevant international standards, guidelines, recommendations, and conformity assessment practices; and/or

**Rationale:** This is to ensure consistency with the WTO SPS Agreement and not limit the applicable "standards/guidelines" to ISO guidelines.

## SECTION 6: PROCESS STEPS

### Step 5a: Assessment process – System equivalence

### Step 5b: Assessment process – Equivalence of measures

**Position:** Ghana supports the retention of 5a and 5b in the Standard.

**Appendix 1:** Is a flow diagram useful and are additional flow diagrams for different types of equivalence assessment required?

**Position:** Ghana supports the provision of a flow diagram for the stages of the equivalence recognition process as well as different types of equivalence.

**Rationale:** A flow diagram provides a simplified overview of the different stages of the equivalence recognition process.

### Morocco

**Le Maroc soutient la progression de l'élaboration du projet de texte et sa présentation dans la procédure des étapes du Codex.**

**Question : Section 2 (Objet/Champ d'application)** - Cette section devrait-elle être scindée en deux sections, l'une sur l'Objet et l'autre sur le Champ d'application ?

Le Maroc pense, dans un objectif de clarification et de structuration, de réserver deux sections distinctes pour l'objet et le Champ d'application.

**Question : Section 3 - Définition** - Le Comité est invité à indiquer si d'autres définitions devraient être incluses OU si l'une quelconque des définitions ci-dessous n'est pas nécessaire.

1. Le Maroc propose de garder la définition de mesure sanitaire adopté dans les directives CAC/GL 53:2003 avec quelques améliorations :

« Toute mesure appliquée pour protéger, sur le territoire du pays, la vie ou et la santé humaine vis-à-vis des risques découlant des additifs, contaminants, toxines ou organismes pathogènes présents dans les denrées alimentaires ou les aliments pour animaux, ou de risques provenant de maladies véhiculées par les aliments d'origine animale, végétale ou les tout produits dérivés ou de risques provenant de tout danger présent dans les aliments ou aliments pour animaux »

« Any measure applied to protect human life or and health within the territory of the country from risks arising from additives, contaminants, toxins or disease-causing organisms in food or feedstuffs, or from risks arising from diseases carried by foods which are animals, plants, or all by-products' products thereof or from risks arising from any other hazards in foods and feed. »

**Justification :** Le Maroc considère que la définition déjà incluse dans les directives CAC/GL 53:2003 est claire et complète (avec les quelques propositions de changement avancés). La proposition actuelle, dans l'avant-projet de consolidation de directives du Codex relatives à l'équivalence (CX/FICS 23/26/5), est restrictive.

2. Le Maroc propose d'ajouter une définition relative à la « preuve objective ».

**preuves objectives :** données démontrant l'existence ou la véracité de quelque chose. Les preuves objectives sont obtenues par observation, mesure, essai ou par un autre moyen et peuvent consister en enregistrements, énoncés de faits ou d'autres informations pertinentes pour les critères d'évaluation et vérifiables. [SOURCE:ISO 9000:2015, 3.8.3]

le Maroc propose, en outre, d'uniformiser l'utilisation du terme de « preuve » dans l'avant-projet en adoptant le terme « preuve objective » dans tout le document (10 fois)

**Justification :** Le Maroc considère que l'ajout de la définition de « preuves objectives » va apporter plus de clarté et de transparence des échanges entre les pays importateurs et les pays exportateurs dans l'avant-projet comme aussi l'adoption du terme « preuve objective » au lieu du terme uniquement « preuve » sans qualificatif d'objective.

## Section 4 : Principes

### Commentaire sur le principe de « Diligence »

Le Maroc propose une révision au principe de diligence comme suit : « d. Les demandes de reconnaissance d'équivalence devraient être formulées par écrit par le pays exportateur et doit être traitées , par les pays importateurs, avec diligence. Le processus d'évaluation et décisionnel doivent être conduit dans des délais raisonnable. »

**Justification :** Le Maroc considère que la **durée de traitement** du processus d'équivalence est un élément capital pour faire aboutir des demandes des pays exportateurs. L'ajout d'une mention relative à cette durée en la qualifiant de raisonnable peut apporter un équilibre entre les pays exportateurs et importateurs.

### Commentaire sur le principe de « Transparence ~~et coopération~~ »

f. Les pays importateurs et exportateurs ~~devraient coopérer pour~~ mener à bien le processus de manière transparente ~~et de bonne foi~~, fondée sur des données probantes et axée sur les résultats.

**Justification :** Le Maroc propose de supprimer la coopération de ce principe pour raison d'incompatibilité avec la notion de transparence. Le Maroc considère que la notion de coopération peut être traité dans le principe (h - Assistance technique/coopération réglementaire) avec quelques modifications (voir ci-dessous).

Aussi, le Maroc a ajouté le principe de bonne foi qui est un principe juridique reconnu en matière d'échange entre les pays.

### Question : Section 4 : Principes

#### f. bis - Démonstration de l'équivalence

Le Comité est invité à donner son avis sur :

i) la pertinence de l'alinéa f(bis) en tant que principe distinct ou s'il serait préférable de l'énoncer dans le texte principal en tant que composante du processus d'évaluation ; et

ii) le besoin d'une déclaration ou d'un principe concernant l'obligation de la partie importatrice de veiller à ce que sa mesure soit uniquement appliquée dans la limite nécessaire pour atteindre son niveau de protection par rapport aux risques bilatéraux

**Commentaire :** Le Maroc propose de conserver la démonstration de l'équivalence en tant que principe distinct.

**Justification :** L'obligation de démonstration est un élément essentiel dans la transparence du processus d'équivalence.

### Commentaire sur le principe « Assistance technique / Coopération réglementaire »

Le Maroc propose de revoir le titre du principe à « **Coopération** » avec quelques modifications dans le point (h) comme suit :

« h. Les pays importateurs et exportateurs devraient coopérer efficacement pour mener à bien le processus d'équivalence. Les pays importateurs devraient, sur demande, envisager de fournir une assistance technique à un pays en développement ou moins développé exportateur, afin de faciliter l'évaluation et la reconnaissance de l'équivalence.

**Justification :** Le Maroc considère que l'assistance technique et la coopération réglementaire sont des sortes de coopération et par conséquent il serait cohérent de l'intégrer dans un principe global qui serait « coopération ». Par ailleurs, par cette proposition ouvre la porte à toutes autres types de coopération (administrative, technique, scientifique...) qui serait efficace et pourra faire avancer rapidement le processus de coopération.

### Question: Section 6 : étapes du processus - Étape 5a et 5b

Le Maroc considère que l'étape 5 ( Processus d'évaluation) est assez développée et valable aussi bien pour l'équivalence du système que pour l'équivalence de mesures ( pas besoin d'étape 5a et 5b).

### Question - Section 7 : Ajout d'informations relatives au maintien d'une reconnaissance d'équivalence

**Commentaire :** Le Maroc soutient la proposition d'ajouter une section additionnelle et distincte relative au maintien d'une reconnaissance d'équivalence en apportant des directives et orientations sur le processus de réévaluation pour le maintien de la reconnaissance de l'équivalence .

**Justification :** le Maroc considère que cette nouvelle section doit mettre l'accent sur cette question et doit orienter les pays importateurs à instaurer des processus de réévaluation accélérée ( voir notre proposition pour le document CX/FICS 23/26/4). Aussi, cette nouvelle section pourrait fournir des orientations pour les pays exportateurs pour maintenir la reconnaissance établie, mais aussi les directives concernant l'établissement d'échanges efficaces lors de la validité de la reconnaissance.

**Question : Annexe 1 - Un organigramme est-il utile ? Dans l'affirmative, des organigrammes supplémentaires sont-ils nécessaires pour les différents types d'évaluation de l'équivalence ?**

**Commentaire :** Le Maroc soutient l'établissement d'organigrammes pour les étapes du processus de reconnaissance d'équivalence et les différents types (évaluation initiale, évaluation de maintien)

**Justification :** Les organigrammes facilitent l'assimilation et la compréhension des différentes étapes du processus de reconnaissance des équivalences et la différence entre les différents types d'équivalence.

### Thailand

Thailand wishes to express our appreciation to an electronic working group (led by New Zealand with the United States of America and Kenya) for the continuation of effort in preparing the Proposed 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 (CX/FICS 23/26/5, Appendix I).

Our comments on this matter are as follows;

#### **General comments**

1. To be clear, we would like to seek for clarification that when a single consolidated text is completed and adopted by CAC whether the three existing texts, including 1) Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification System (CXG 53-2003) 2) Guidelines for the Development of Equivalence Agreement Regarding Food Import and Export Inspection and Certification Systems (CXG 34-1999) and 3) Draft Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems (CX/FICS 23/26/4) will be superseded or included as an annex to the consolidated text.

2. If the consolidated text supersedes the three existing texts, its scope should address those covered in the three texts without extended scope, for example:

- Technical measures and technical regulations other than those included in the three texts should be excluded.

- To be consistent with CXG 34 : Section 5 – considerations before entering into bilateral or multilateral discussions, multilateral agreements should be additionally included to the single consolidated text.

3. The content for sections in the consolidated text should be comprehensive for the 3 texts. However, when needed (for example, when there are differences among the 3 texts), specific details or information for the individual text should be separately provided in the sections for clarity.

#### **Specific comments**

##### **SECTION 2: PURPOSE/SCOPE (of guideline)**

**Question to CCFICS26: Should this section be split into a section on Purpose and a separate section on Scope?**

To be clear, this section should be split into a section on Purpose and a section on Scope.

##### **SECTION 3: DEFINITIONS**

**Question to CCFICS26: The Committee is asked to indicate if there are additional definitions that should be included OR if any of the below are not required.**

1. To cover the types of equivalence considered in all 3 texts, the definition of "Equivalence" should be revised to read:

"Equivalence: The capability of different NFCS, in whole or in part, or different specified measures, to achieve the same objectives **or appropriate level of sanitary protection and related outcomes or level of protection.**"

2. The term "Equivalence of NFCS" with its definition from CX/FICS 23/26/4 should be added as follows:

"Equivalence of NFCS: The capability of different NFCS or parts of NFCS to achieve the same objectives."

3. The term “Equivalence of specified sanitary measures” should be replaced with “Equivalence of sanitary measures” as defined in CAC/GL 53.

4. The term “Equivalence of specified technical measures” should be removed, as it is not included in the scope of the 3 documents.

#### **SECTION 4: PRINCIPLES**

##### **• Alignment with International Standards**

This section should be amended to be in accordance with Section 4: Principle, Alignment with International Standards, paragraph 6c of CX/FICS 23/26/4. So, the section should then read:

##### **“Alignment with International Standards**

e. Recognition of equivalence may be facilitated by the use of Codex standards, guidelines, and/or codes of practice, or other relevant international standards, recommendations and guidelines by both importing and exporting countries.”

##### **• Demonstration of Equivalence**

f (bis) The obligation to objectively demonstrate equivalence rests with the exporting country

##### **Question to CCFICS26: The Committee is asked to provide a view on:**

**i) the appropriateness of f(bis) as a separate principle or whether it is better stated in the main text as a component of the assessment process; and**

Paragraph f (bis) should be in the main text as a component of the assessment process.

**ii) is there also a need for a balancing statement / principle re the importing party’s obligation to ensure their measure is only applied to the extent necessary to achieve their level of protection relative to the bilateral risks?**

There is no need for balancing statement/principle of the importing party’s obligation to ensure their measure is only applied to the extent necessary to achieve their level of protection relative to the bilateral risks,

#### **SECTION 6: PROCESS STEPS**

##### **Step 5a: Assessment process – System equivalence**

##### **Question to CCFICS26: Do we need something different here?**

The sections should provide specific assessment process for each text (CXG 34, CXG 53, and CX/FICS 23/26/4), as they have different processes.

##### **Step 5b: Assessment process – Equivalence of measures**

##### **Question to CCFICS26 : Do we need something different here?**

The sections should provide specific assessment process for each text (CXG 34, CXG 53, and CX/FICS 23/26/4), as they have different processes.

#### **SECTION 7: DOCUMENTING THE AGREEMENT AND IMPLEMENTING THE DECISION**

**Question to CCFICS26 : Does the information relating to maintenance of an equivalence recognition currently in Section 7 provide sufficient guidance OR should it be set out in a separate section as initially suggested?**

1. Information related to maintenance of an equivalence recognition should not be set out in a separate section.

2. Information on “Maintenance and review of recognitions of the equivalence” should be added into this section as it is stated in CX/FICS 23/26/4, paragraph 39.

#### **APPENDIX 1**

##### **Question to CCFICS26 :**

**If so are additional flow diagrams for different types of equivalence assessment required?**

To be clear, the additional flow diagrams for different types of equivalence assessment are required.

## Uganda

**Comment:** Uganda appreciates the work done by the EWG chaired by New Zealand and its co-chairs USA and Kenya.

Uganda supports the adoption of the guidelines to step 5/8, and recommends taking into consideration the comments raised below.

### Section 2 (Purpose/Scope)

**Comment:** Uganda proposes splitting the Purpose and Scope into two separate sections with paragraph 6 as the Purpose and paragraph 7 as the Scope.

**Justification:** The separation of Scope and Purpose will serve to provide clarity.

### Section 3

**Comment:** Uganda proposes revision of the definition for sanitary measure to read as follows: Any measure applied to protect human life or health within the territory of the country from risks arising from additives, contaminants, toxins or disease-causing organisms in food or feedstuffs, or from risks arising from diseases carried by foods obtained from animals and plants or from risks arising from any other hazards in foods (Adapted from CXG 53:2003).

**Justification:** The definition provided in the draft consolidated guidelines is limiting and excludes other key elements of a Food Control System. In addition, inclusion of foods obtained from animal and plants will align the guideline to the One Health Approach that calls for collaborative efforts to ensure optimal health for people, animals and the environment.

Uganda proposes that reference is made to relevant international standards/guidelines/recommendations instead of referring to only ISO guidelines.

### Section 4

#### Principles – Demonstration of equivalence

**Comment:** Uganda proposes retention of Demonstration of Equivalence as a separate principle, and proposes realignment of the principles so that all principles related to equivalence are close together. Therefore, “Demonstration of Equivalence” should be the 2nd principle. In addition, the realignment will improve coherence and sequential flow of related information.

To provide a balancing statement/principle in obligations for both the importing and exporting countries.

**Justification:** To provide a balancing statement/principle in obligations for both the importing and exporting countries.

### Section 5

**Comment:** Uganda proposes that reference is made to relevant international standards/guidelines/recommendations instead of referring to only ISO guidelines, to read:

- the alignment with relevant international standards, guidelines, recommendations, and conformity assessment practices;

**Justification:** This is to ensure consistency with the WTO SPS Agreement and to not limit the applicable “standards/guidelines” to ISO guidelines.

### Section 6 Step 1 Para24

**Comment:** Rearrange the statement for clarity as the word trade has been repeated unnecessary.

**Justification:** To read as ‘The conditions of trade considered to be unnecessarily restrictive;

### Section 7

**Comment:** Uganda supports the proposal to add a separate section relating to maintenance of equivalence recognition. CXG 34:1999, Para 23 in addition to the text provided in section 7 can offer guidance.

**Justification:** To provide guidance on how countries can maintain established equivalence agreements.

### Appendix 1

**Comment:** Uganda supports the provision of a flow diagram for the stages of the equivalence recognition process.

**Justification:** A flow diagram provides an easy-to-understand overview of the different stages of the equivalence recognition process.

**Additional Information on the course of Action when the decision for establishment of equivalence is negative.**

**Comment:** Absence of a text on the course of action when the final decision for establishment of equivalence is negative. Uganda would like some guidance on the next steps when the final equivalence decision is negative and recommends addition of a text guiding the course of action in the event that the final equivalence decision is negative under step 6.

**Justification:** To guide both the importing and exporting countries on the course of action in the event that the final decision is negative.

**53 Step 5 a and Step 5b**

More clarification is required on the questions.

**Section 7 Para 61**

**Comment:** Include the duration (timeline /grace period) for reassessment and implementation of the substantive change.

**Justification:** To read as 'The exporting and importing countries will agree on the reasonable duration (timeline /grace period) for reassessment and implementation of the substantive change'.