



## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

#### Twenty-fifth Session

*Virtual, 31 May – 8 June 2021*

### PROPOSED DRAFT CONSOLIDATED CODEX GUIDELINES RELATED TO EQUIVALENCE

#### Comments at Step 3 (in reply to CL 2021/18/OCS-FICS)

Comments of Australia, Cuba, Ecuador, European Union, Indonesia, Iraq, Malaysia, New Zealand, Peru, Thailand, United States of America, and FAO

Comment	Author
<p>Indonesia would like to express appreciation to New Zealand as a Chair of the Electronic Working Group and Co-Chair (US and Chili) for their efforts to prepare proposed draft Consolidated Codex Guidelines related to Equivalence (Updated).</p> <p>Indonesia has 2 (two) comments to be considered in the 25th Meeting of CCFICS, that is:</p> <ol style="list-style-type: none"> <li>1. This proposed draft needs two-way equivalence in both exporting countries and important countries to make it efficient and to facilitate the fair trade.</li> <li>2. If the objective of this draft to consolidate the equivalent provisions in all Codex standards, it would be better if the draft equivalence of NFCS and other related standards of equivalence be replaced with the Draft Consolidated Guidelines related to Equivalence. The object could be NFCS, standard product or other horizontal standards.</li> </ol>	<b>Indonesia</b>
Australia has no comments on this circular letter.	<b>Australia</b>
Peru supports the proposals of the above-mentioned document on the methodology for progressing the review, rationalisation and updating of Codex guidance on equivalence and the development of a single consolidated text. Therefore no comments have been made on the document under examination.	<b>Peru</b>
<p>Malaysia thanks New Zealand, United States of America and Chile and the rest of the EWG members for the effort and in preparing the revised text.</p> <p>Malaysia supports the methodology proposed for progressing the consolidation of Codex guidance relating to equivalence and development of a single consolidating text as recommended in para 22 of CX/FICS 21/25/7. This includes the list of identified CCFICS text, the review of these texts and development of new text based on agreed outline.</p>	<b>Malaysia</b>
<p>New Zealand thanks the working group for their on-going engagement with this work.</p> <p>New Zealand endorses the proposals set out in CX/FICS 21/25/7 relating to the methodology proposed for progressing the review, rationalisation and updating of the Codex guidelines relating to equivalence, and the development of a single consolidated text. We note and support the additions make to Appendix I identifying relevant CCFICS text for consideration during the development of a single consolidated text. We also support the amended initial outline / framework provided in Appendix II.</p> <p>New Zealand supports the recommendations that the current Working Group continue and be tasked to undertake the Next Steps as set out in paragraph 20 of CX/FICS 21/25/7 and to report back to CCFICS26 on progress. New Zealand is prepared to continue as Chair of the Working Group.</p> <p>New Zealand agrees that the first task for the Working Group is to prepare an annotated outline briefly summarising the potential source of content for the sections in a single</p>	<b>New Zealand</b>

<p>consolidated text on equivalence in line with the framework proposed in Appendix II of CX/FICS 21/25/7.</p> <p>New Zealand notes that substantial progress on rationalisation of the content of existing CCFICS texts to support the drafting of a single consolidated text is dependent on completion of the separate but associated work on the Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems being considered by CCFICS25 under Agenda Item 6 (CX/FICS 21/25/6).</p>	
<p>The European Union and its Member States (EUMS) would like to thank New Zealand, the United States and Chile for leading the electronic working group developing proposals to consolidate Codex guidelines on equivalence.</p> <p>The EUMS support the recommendations in paragraph 22 of CX/FICS 21/25/7 on the methodology for progressing the review, rationalisation and updating of the Codex guidelines relating to equivalence and development of a single consolidated text on the consolidation of the guidance on equivalence and the continuation of the current EWG as proposed in paragraph 23.</p>	<p><b>European Union</b> Mixed Competence  European Union Vote</p>
<p>Para 22 of CX/FICS 21/25/7</p> <p>i. The approach for the development of consolidated guidance set out in paragraphs 8-12 of CX/FICS 21/25/7</p> <p>Thailand's response: We can agree in principal with the proposed approach for the development of guideline.</p> <p>ii. The initial list of identified CCFICS text and proposed actions as set out in Appendix 1 of CX/FICS 21/25/7</p> <p>Thailand's response: On the initial list of identified CCFICS text as proposed in the Appendix I, we note that the three main documents i.e. (i) CXG 34-1999, (ii) CXG 53-2003 and (iii) the Guideline on Recognition and maintenance of equivalence of NFCS (once endorsed by CAC) need to be assessed in the first place, while the remaining identified CCFICS texts will be subsequently assessed, in particular on the contents related to Equivalence.</p> <p>In relation to this, we view that any further works upon the above assessments should be carefully conducted and will not cause any substantive changes to the existing CCFICS texts.</p> <p>iii. The initial outline / framework proposed for the content of a single consolidated guidance text as set out in Appendix II (noting the combination or division of sections will be clarified as the drafting progresses)</p> <p>Thailand's response: We have no objection to the draft initial outline. However, we also can be flexible with CCFICS to consider any appropriate adjustments to the draft outline, as needed, in the future.</p> <p>Para 23 of CX/FICS 21/25/7</p> <p>i. progress the development of draft consolidated guidance relating to equivalence in line with the sequence set out in next steps (paragraph 20 above) and</p> <p>ii. report to CCFICS26 on the preparation of draft text for considered in the Codex step process.</p> <p>Thailand's response: We can agree in principal with the stepwise approach for the next steps to be reported to CCFICS26. Moreover, with regard to the proposed Step 4, any consequential amendments required for other existing Codex texts should not lead to any substantive changes to the existing texts.</p>	<p><b>Thailand</b></p>
<p>Peru supports the proposals of the above-mentioned document on the methodology for progressing the review, rationalisation and updating of Codex guidance on equivalence and the development of a single consolidated text. Therefore no comments have been made on the document under examination.</p>	<p><b>Peru</b></p>
<p>Ecuador appreciates the work done on the document "Proposed draft consolidated Codex guidelines related to equivalence", this country does not submit comments on this occasion and agrees to progress in the elaboration of a preliminary text of consolidated guidelines related to equivalence.</p>	<p><b>Ecuador</b></p>

Agree	<b>Iraq</b>
<p>Cuba expresses in principle its comments on CL 2021/18/OCS-FICS. Comments on the proposed draft consolidated Codex guidelines related to equivalence and therefore considers the following:</p> <p>With regard to Document CX/FICS 21/25/7 Para 22. (i)</p> <p>It is considered appropriate to develop a consolidated text on equivalence, considering the purpose of rationalisation and updating, recognizing that the various texts on equivalence were developed over a period of more than 20 years and require updating to ensure up-to-date and non-contradictory recommendations.</p> <p>With regard to Document CX/FICS 21/25/7 Para 22. (ii)</p> <p>It is considered that in addition to the list of texts identified in Appendix 1, account should be taken of the WTO SPS Committee guidelines on equivalence, and of other relevant documents developed by the World Organisation for Animal Health (OIE) and the International Plant Protection Convention (IPPC).</p> <p>With regard to Document CX/FICS 21/25/7 Para 22. (iii)</p> <p>It is considered that the initial outline proposal for a single consolidated guidance text related to equivalence as presented in Appendix II of the document is adequate.</p>	<b>Cuba</b>
<p>The United States appreciates the opportunity to review the updated Proposed draft consolidated Codex guidelines related to equivalence. We acknowledge the challenges related to the impact of the COVID19 pandemic to progressing the development of consolidated Codex text related to equivalence.</p> <p>The United States notes the view expressed in paragraph 8 that the Codex step process related to the draft Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems (currently before CCFICS as Appendix I of CX/FICS 21/25/6) should be completed before drafting of a consolidated text is initiated. There is no reason to continue postponing the work on consolidation of Codex texts on equivalence pending completion of the draft Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems. As outlined in paragraph 7 in CX/FICS 21/25/7, the consolidation of Codex texts on equivalence will include the on-going work being progressed by the Committee on the use of systems equivalence, as well as appropriate sections of existing Codex guidance (CXG 34-1999, CXG 53-2003, CXG 26-1997, CXG 82-2013, CXG 47-2003, CXG 89-2016 and any other relevant guidelines). This is consistent with the purpose and scope of the project document approved by CAC42 (2019). The United States supports commencing the work on Consolidated Codex Guidance on Equivalence, regardless of the outcome of the draft Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems in the step process. The United States notes that while the initial identification and assessment of Codex texts outlined in Appendix 1 to CX/FICS/21/25/7 will provide guidance for the information that can be considered in consolidating existing Codex texts, Appendix 1 does not take into account the draft Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems. Further, the United States cautions against deleting operative or significant requirements without substantive discussion by Member Countries. Sufficient time should be provided for this review in the EWG as the development of the consolidated Codex Guidelines document progresses. Therefore, the United States cannot support a recommendation to use only the CCFICS texts and proposed actions outlined in Appendix I, without recognition that this analysis may be used as a guide but does not restrict consideration of any relevant section or paragraph in other existing or pending Codex texts relevant to equivalence that may have been overlooked. The United States suggests adding a statement to table in Annex 1 that will ensure other relevant texts as identified by the EWG will be included. The United States supports the recommendation of the EWG to develop a new single text consolidating Codex texts relevant to equivalence that will provide clear, comprehensive, and up to date guidance. Specific to the steps outlined in Paragraph 20, the United States supports an expedited approach for the EWG to develop draft consolidated Codex guidelines related to equivalence, without awaiting completion of other work. The United States recognizes the initial outline provided in Appendix II is a framework that will be clarified as the drafting progresses. We have attached for review by members a more detailed outline indicating the types of information that may be included.</p>	<b>USA</b>

<p>FAO support the approach proposed. As part of the future work, FAO considers very important that a review and consolidation of terminology for consistency is performed. We note that there are different terms that essentially have similar meanings (eg: decision criteria - objective basis of comparison; equivalence of sanitary measures - equivalence of systems) and in describing parts of a NFCS different terms are used (e.g., objectives, outcomes, parts, elements) An emphasis on consistency in terminology would be important as the documents advance.</p>	<p><b>FAO</b></p>
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**PROPOSED DRAFT CONSOLIDATED CODEX GUIDELINES RELATED TO EQUIVALENCE (UPDATED)**

**Initial outline proposal for a single Consolidated Guidance on Equivalence**

<p>Proposed Title</p> <p>Proposed Draft Principles and Guidelines for the Conduct and Maintenance of Equivalence Determinations of National Food Control Systems</p> <p>[to include guidance for equivalence determinations involving Sanitary and Phyto-Sanitary (SPS) single measures, groups of measures, or systems [1] as well as equivalence of technical regulations and conformity assessment procedures[2] ]</p> <p>Guidance consolidates equivalence guidance contained in:</p> <p>Guidelines for Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CXG 34-1999);</p> <p>Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CXG 53-2003);</p> <p>Proposed Draft Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems. (CX/FICS 21/25/6, in development by CCFICS, currently at Step 3).</p> <p>The guidance also includes information contained in:</p> <p>Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CXG 26-1997);</p> <p>Principles and Guidelines for National Food Control Systems (CXG 82-2013);</p> <p>Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food (CXG 89-2016).</p> <p>The guidance will include newly developed text to cover certain aspects of equivalence determinations not previously contained in existing Codex texts, including TBT equivalence determinations of technical regulations, conformity assessment procedures, and use of International Standardizing Bodies.</p> <p>Proposed Section by Section Outline</p> <p>The following are the proposed sections for the document. As appropriate, brief descriptive information on the content of each section is given.</p> <p><b>SECTION 1: PREAMBLE</b></p> <p>To be developed from preambular information contained in CXG 53-2003 and CX/FICS 21/25/6.</p> <p><b>SECTION 2: PURPOSE/SCOPE</b></p> <p>The section will indicate that a request for an equivalence determination can relate either to the protection of the health of consumers or ensuring fair practices in the food trade, consistent with the scope and mandate of Codex.</p> <p>It will be developed from information contained in CXG 34-1999, CXG 53-2003 and CX/FICS-21/25/6 and other relevant texts identified by the Committee. The section will indicate that the guidance contains information for a government wishing to undertake equivalence determinations, either for SPS measures (i.e., a single measure, for a group of measures, or for a food control system), for TBT technical regulations and conformity assessments, and for establishing bilateral or multilateral equivalence agreements.</p> <p><b>SECTION 3: DEFINITIONS</b></p> <p>Definitions need to reflect both SPS measures and TBT technical regulations and conformity assessments.</p>	<p><b>USA</b></p>
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Definitions contained in CXG 34-1999, CXG 53-2003 and CX/FICS-21/25/6 will be reviewed, and if appropriate, used as they are written. Other definitions may also be considered.

[Note: Specific to SPS, the definition for equivalence contained in the CXG 53-2003 which relates to appropriate level of protection (ALOP) should be considered, rather than that contained in CXG 34-1999 which relates to outcomes. Outcomes is broader than ALOP, does not relate specifically to the concept of equivalence contained in the SPS Agreement, and could refer to end-points of mechanisms to provide assurances other than equivalence (i.e., systems recognition) which could create confusion.]

#### SECTION 4: PRINCIPLES

Principles need to reflect both SPS measures and TBT technical regulations and conformity assessments.

To be developed from principles contained in CXG 53-2003 and CX/FICS-21/25/6, including:

- right to establish an ALOP (with respect to sanitary measures); right to establish an objective (with respect to technical regulations)
- equivalence of NFCS
- transparency of the equivalence process
- objectivity of the assessment process
- timeliness of the equivalence process
- taking into account experience/knowledge/confidence
- accessibility of information
- alignment with international standards (with respect to SPS and TBT)
- formalization of a positive determination
- maintenance of recognition
- consideration of technical assistance when a positive determination is not reached

#### SECTION 5: FUNDAMENTAL CONSIDERATIONS

This will be a new section intended to provide clearer guidance on certain fundamentals relating to undertaking an equivalence determination. The section will draw from information contained in CXG 34-1999, CXG 53-2003 and CX/FICS-21/25/6 but will also contain newly developed text.

- Review of nature of sanitary measures vs. technical regulations and the importance of differentiating with respect to undertaking an equivalence determination
- Decision to request/undertake an equivalence determination, including discussion of alternative approaches to market access, if any, and the relative benefits of each approach
- Scoping an equivalence determination
- How to take knowledge/experience and confidence into account
- The concept of decision criteria
- Making judgements on of equivalence employing decision criteria

#### SECTION 6: PROCESS STEPS

Process Steps need to reflect both SPS measures and TBT technical regulations and conformity assessments.

To be developed from information contained in CXG 34-1999, CXG 53-2003 and CX/FICS-21/25/6 and will also contain new text. The section will provide the logical flow of steps in carrying out an equivalence determination. The section will not duplicate information provided in Section 5 (Basic Considerations) but will include steps that relate to and reference Section 5, as appropriate (e.g., decision to undertake, use of Experience, Knowledge and Confidence (EKC), and decision making/judgement). The section will distinguish what aspects that apply to measure-for-measure equivalence, equivalence for groups of measures, and equivalence of systems.

The section will also indicate how to approach resolution of differences when the focus of the equivalence determination is on sanitary measures as opposed to when the focus is on technical

<p>regulations. The process steps will include:</p> <p>Step 1: Initial discussions, selection of market access approach, scope and decision to commence</p> <p>Step 2: Description of the importing country's NFCS or relevant parts</p> <p>Step 3: The decision criteria for comparing relevant measures of each NFCS</p> <p>Step 4: Description of exporting country's NFCS or relevant part</p> <p>Step 5: Assessment process</p> <p>Step 6: Decision process and final determination</p> <p>Step 7: Formalization a positive determination and maintenance of the recognition</p> <p>(Note: reference to equivalence agreements will be made in this step but will refer to the detailed information for agreements in Section 7.)</p> <p>The flow diagram contained in CX/FICS-20/25/6 will be included as an Appendix to this document.</p> <p><b>SECTION 7: EQUIVALENCE AGREEMENTS</b></p> <p>To be developed from information contained in CXG 34-1999. This section will contain information on:</p> <ul style="list-style-type: none"> <li>- The purpose/use of an equivalence agreement</li> <li>- The forms of an equivalence agreement</li> <li>- The standard content/provisions of an agreement; Appendix A of CXG 34-1999 will be included as an Appendix to this document.</li> </ul> <p>[1] Article 4, SPS Agreement</p> <p>[2] Article 2.7 and 6.1, TBT Agreement</p>	
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