CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



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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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PROPOSED DRAFT CONSOLIDATED CODEX GUIDELINES RELATED TO EQUIVALENCE (UPDATED)¹

Prepared by an electronic working group² led by New Zealand with the United States of America and Chile

(At Step 3)

Codex members and Observers wishing to submit comments at Step 3 on this draft should do so as instructed in CL 2021/18/OCS-FICS available on the Codex webpage/Circular Letters 2021: http://www.fao.org/fao-who-codexalimentarius/circular-letters/en/

INTRODUCTION

- 1. At its 24th Session (2018), CCFICS discussed the consolidation of Codex guidelines related to equivalence³.
- 2. This discussion arose during consideration of the draft proposed Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems (CX/FICS 18/24/4). New Zealand, as Chair of the electronic working group (EWG) responsible for this work, explained that it and its assisting co-chairs (the United States of America and Chile) were in agreement on working towards merging the current draft standard once finalized with the other two existing Codex guidelines related to equivalence (i.e. Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CXG 34-1999) and the Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CXG 53-2003)) and making any relevant consequential amendments.
- 3. There was an exchange of views among CCFICS24 delegates regarding the process and the next steps of the complex work related to consolidating Codex guidelines on equivalence. It was the view of the Codex Secretariat and some delegations that this consolidation work was captured under the project document for the system equivalence work already underway (job number N25-2917). However, several delegations emphasized the need for clarity and transparency, including for those countries not present at CCFICS24, and requested a new project document to address the consolidation part of the work that would take place following the adoption of the current draft guidelines on system equivalence.
- 4. A new work project document was developed by an in-session working group and following review by CCFICS24 was recommended for approval by CAC42 (REP19/FICS Appendix II). The committee also agreed that the re-established EWG, led by New Zealand with the United States of America and Chile acting as co-chairs, be tasked with commencing the consolidation work in parallel with completing the draft proposed Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems⁴.
- 5. The new work proposal underwent Critical review by CCEXEC77 and their report (CX/EXEC 19/77/2 Rev.1 Appendix 1) noted the consolidation of all Codex guidance on equivalence (existing guidance and the draft guidelines on recognition and maintenance of equivalence of NFCSs) will be helpful for national

¹ This Updated document takes into account the comments solicited, through CL 2020/03/OCS-FICS

²The electronic working group comprised representatives of Argentina, Australia, Brazil, Canada, Chile, Costa Rica, Dominican Republic, Ecuador, Egypt, El Salvador, European Commission, India, Indonesia, Jamaica, Japan, Kazakhstan, Republic of Korea, Mexico, Morocco, New Zealand, Nigeria, Norway, Peru, Singapore, Switzerland, Thailand, United States of America, United Kingdom, Uruguay, GFSI, SSAFE.

³ REP19/FICS, Paras. 26 - 31

⁴ REP19/FICS paras 16 – 32

authorities, including developing countries, and will also help ensuring fair practices in food trade. CCEXEC77 recommended approval of the new work by CAC42, which was received in July 2019⁵.

TERMS OF REFERENCE

- 6. The terms of reference for the EWG were to 'commence the consolidation work of all Codex guidance related to equivalence and prepare a proposal for circulation for comments at Step 3 and for consideration to CCFICS25⁶.
- 7. Of particular relevance is also the project document item '6 Information on the relation between the proposal and other existing Codex documents' as it specifically identified the relevant text and how it might be impacted:

The proposed work will take into consideration the results of the ongoing work being progressed by the Committee on the use of system equivalence; the Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CXG 34-1999); the Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems (CXG 53-2003); and the relevant parts of Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CXG 26-1997). The proposed work will also take into account aspects of the recently promulgated Guidelines for National Food Control Systems (CXG 82-2013); the Guidelines for Food Import Control Systems (CXG 47-2003); and the Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food (CXG 89-2016). Minor amendments to other Codex guidelines that mention equivalence may also be considered, if appropriate.

METHODOLOGY / APPROACH

- 8. Commencement of the consolidation work was broken into stages as it was the view of the EWG Chair (and Co-Chairs) 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 20/25/6) should be completed before drafting of a specific consolidation text is initiated.
- 9. The first stage had been to confirm which Codex text and what sections or paragraphs of each text need to be included and to provide an initial indication of what type of work needs to be undertaken, for example editorial amendment, review, deletion, or consideration within the consolidation. The results of this first stage, considered by the EWG in 2019, were presented in Appendix 1 to CX/FICS 20/25/7.
- 10. This initial assessment identifies there are three complete texts (CXG 34-1999, CXG 53-2003 and, when completed, Appendix I to CX/FICS 21/25/6) and specific parts of CXG 26-1997 (Section 5 and paragraph 55) that need to be considered in the consolidation work. In respect of the other CCFICS text these contain either a general statement relating to recognition of an exporting country food control system and are not specific to equivalence or have specific references to one or more of the CCFICS text that are to be considered in the consolidation work. A review relating to these texts is therefore appropriately undertaken once the consolidation work is completed and the need for any change to the references can be determined, this being dependent on what the consolidation work produces.
- 11. When considering the approach for the development of consolidated text related to equivalence, there are a range of potential options. The following, identified by the EWG, are the options that seem most appropriate for initial consideration:
 - Review and amend each text to remove all duplication but maintain each as a separate text with a single focus.
 - Take one text dealing with the dual mandate of Codex as the base and insert the content of the others either within the main text or as annexes.
 - Establish a framework or outline of the sections that need to be provided in a new single text and once agreed then insert the relevant content from the four identified text into those sections.
- 12. It is the view of the EWG that the third option is an appropriate starting point for development of a consolidated text related to equivalence. Recognising there are two key outcomes that need to be achieved from this consolidation work rationalisation and updating this approach also recognises that the various text relating to equivalence have been developed over a period of more than 20 years. Over

⁵ REP 19/CAC – paragraph 96 & Appendix V

⁶ Para 32 (iii) (b), REP 19/FICS

this time ideas about the form and content of Codex guidance have changed and the importance of ensuring that the guidance is up to date and does not include conflicting advice is recognised.

- 13. An initial proposal for a framework for a single consolidated text was presented in Appendix II to CX/FICS 20/25/7.
- 14. The proposed approach with its initial focus on structure and concepts rather than specific wording supports the development of consolidated practical guidance for Codex members along with facilitating the rationalisation objective that will be worked on at the next stage of the consolidation work. It can also ensure that the duplication and at times conflicting guidance that can be found in the current texts can be addressed.
- 15. The recommendations in CX/FICS 20/25/7 invited the Committee to consider the proposals relating to the methodology for progressing the consolidation of Codex guidance relating to equivalence and indicate their views regarding:
 - i. The list of CCFICS text and proposed actions as set out in Appendix I to CX/FICS 20/25/7.
 - ii. The approach for the development of consolidated guidance set out in paragraphs 8 11 above and the proposal to progress with the third option set out in paragraph 11.
 - iii. The framework proposed for the content of a single consolidated guidance text as set out in Appendix II.

FORMAL COUNTRY COMMENTS AND WORKING GROUP DISCUSSION

- 16. Formal comments on CX/FICS 20/5/7 were requested via circular letter (CL 2020/03 FICS) with a closing date of 1 May 2020. Comments were received from 14 Codex Members and two observer organisations⁷ and were published as CX/FICS 20/5/7 Add 1, with an additional note advising that following the rescheduling of CCFICS25 to 2021 (due to the COVID-19 pandemic) the EWG was continuing.
- 17. The comments:
 - indicated general support for the proposed methodology and approach;
 - indicated general agreement on the existing Codex texts identified for consideration in developing a consolidation and those that will likely require some amendment once the preparation of a single consolidated text is completed;
 - suggested additional existing Codex text that may also need to be considered for the consolidation or for amendment as a consequence of the consolidation (Appendix I has been amended to include CXG 60-2006 Principles for Traceability/Product Tracing as a Tool Within a Food Inspection and Certification System; the annex to CXG26-1997; and CXG91-2017 Principles and guidelines for Monitoring the Performance of NFCS);
 - indicated general support for the proposed framework for a single consolidated text, with some suggestions for changes, (Appendix II has been amended to add, combine, and reorder the proposed sections); and
 - provided some useful comment and suggestions for the next steps of the consolidation work.
- 18. The EWG chair and co-chairs agree that the formal comments received in 2020 and now captured in Appendix I and II are helpful and provide clarity for the approach and matters to be considered in the next steps.
- 19. It is with regret that the chair and co-chairs of the EWG must advise the Committee that it has not been able to further progress the development of a consolidated single text on equivalence. This is due to the impact of the COVID19 pandemic on progressing the work on the draft Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems, which is also to be consolidated with other relevant Codex documents on equivalence guidance.

NEXT STEPS

20. Taking into account the comments received and included in Appendix I & II and further consideration by CCFICS25, the review, rationalisation and updating of the Codex guidelines relating to equivalence should follow a step wise approach as follows:

⁷ Brazil, Canada, Colombia, Ecuador, European Union, Honduras, Iraq, Mexico, Morocco, Nicaragua, New Zealand, Paraguay, Thailand, United States of America, FAO, and CCTA

- 1. Preparation of an annotated outline briefly summarising the potential source of content for the sections in a single consolidated text on equivalence (Appendix II);
- 2. using as necessary a more detailed side by side analysis of all relevant text identified for consideration (Appendix I) identify the specific areas of duplication or conflict;
- 3. undertake a rationalisation process and development of a first draft of the consolidated guidance;
- 4. confirm and recommend as necessary any consequential amendments required for other existing Codex text that make reference to text specifically dealing with equivalence.
- 21. It is suggested that this work continue to be undertaken by an EWG with the possibility of a physical working group with progress to be reported to CCFICS26.

RECOMMENDATIONS

- 22. The Committee is invited to endorse the proposals set out in this document relating to the methodology proposed for progressing the review, rationalisation and updating of the Codex guidelines relating to equivalence and development of a single consolidated text including:
 - i. The approach for the development of consolidated guidance set out in paragraphs 8 12 above.
 - ii. The initial list of identified CCFICS text and proposed actions as set out in Appendix I.
 - 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).

23. The Committee is requested to confirm the continuation of the current EWG to:

- 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
- ii. report to CCFICS26 on the preparation of draft text for considered in the Codex step process.

Initial Identification and assessment of Codex text relevant to Equivalence

Document	Section or paragraph	Proposed Action	Rationale
Principles for Food Import and Export Inspection and Certification (CXG 20-1995)	Section 3 – Principles paragraph 12 Equivalence	Editorial amendment 1 st sentence – <i>inspection/certification systems</i> to 'inspection <u>and</u> certification systems'	This formulation is not used in any other CCFICS text and should be amended to ensure consistency
Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CXG 26- 1997)	Section 5 Equivalence (paragraphs 9 to 16) Paragraph 55 is specific to demonstration of equivalence	Whole of Section 5 to be considered in development of consolidation and then consequential amendment to ensure text appropriate to a revised CXG 26- 1997 Retention or deletion of Paragraph 55 to be considered following completion of consolidation work	Section 5 contains a mix of principle like statements, statements on the purpose of or reason for undertaking equivalence, some process statements and statements on the content of agreements. Paragraph 55 is essentially a statement of a principle or process specific to equivalence
Principles and Guidelines for the Conduct of Assessments of Foreign Official Inspection and Certification Systems (Annex to CXG 26-1997)		Consider if aspects of the annex need to be captured or referenced in the consolidation and /or is any consequential amendment appropriate	To ensure consistency and avoid any conflicts in guidance
Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CXG 34- 1999)	Whole document	Consideration in development of consolidation	This entire document deals with equivalence
Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems (CXG 53-2003)	Whole document	Consideration in development of consolidation	This entire document deals with equivalence
Guidelines for Food Import Control Systems (CXG 47-2003)	Paragraphs 13 and 32 provide generally for the recognition of an exporting country food control system.	Consequential amendment following completion of consolidation work, particularly in respect of the cross	The identified paragraphs are general in nature and not specific to equivalence

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	Paragraph 32 contains a cross reference to Section 5 of CXG 26-1997	reference in paragraph 32 and footnote in paragraph 33	therefore a review at the conclusion of the consolidation work is appropriate.
	Paragraph 33 has a footnote reference to CXG 34-1999		The cross references should also be reviewed at that time to determine if any amendment is necessary.
Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems (currently before CCFICS as Appendix I of CX/FICS 21/25/6)	Whole document	Consideration in development of consolidation	This entire document deals with equivalence
Guidelines for National Food Control Systems (CXG 82-2013)	Section 3, Principle 10 (Paragraph 21) contains a footnote reference to CXG 34-1999 and CXG 53-2003	Consequential amendment following completion of consolidation work if footnote references need amendment.	Cross references are appropriate to review at conclusion of the consolidation work
	Paragraph 43 bullet 3 contains a footnote reference to CXG 53-2003		
CXG 60-2006, Principles for Traceability/Product Tracing as a Tool Within a Food Inspection and Certification System		Consider if aspects of this text need to be captured or referenced in the consolidation and /or is any consequential amendment appropriate	To ensure consistency and avoid any conflicts in guidance
Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food (CXG 89-2016)	1. Introduction includes specific reference to CXG 53-2003 and to paragraph 55 of CXG 26-1997	Consequential amendment following completion of consolidation work to references and footnote if needed.	Cross references are appropriate to review at conclusion of the consolidation work
	5. Principles e) has a footnote that includes reference to the annex to CXG 53-2003		
CXG91-2017 Principles and guidelines for Monitoring the Performance of NFCS)		Consider if aspects of this text need to be captured or referenced in the consolidation and /or is any consequential amendment appropriate	To ensure consistency and avoid any conflicts in guidance

Appendix II

Initial outline proposal for a single Consolidated Guidance on Equivalence				
Title:	To be agreed			
Section 1	Introduction / Preamble			
Section 2	Purpose / Scope / Objectives (of guideline)			
Section 3	Definitions			
Section 4	Principles			
Section 5	Considerations before entering formal equivalence process (including initial competent authority discussions)			
Section 6	Process steps for consideration of equivalence			
	Determination of scope (System or relevant part; measure by measure; SPS; TBT)			
	Description of importing country NFCS or relevant part			
	Decision Criteria for assessment of equivalence			
	Description of exporting country's NFCS or relevant part			
	Assessment process			
	Decision process and final determination			
Section 7	Formalization of Equivalence Agreement (including content)			
Section 8	Maintenance of recognition			
Section 9	Other matters			

Note: the above is an initial outline or framework only – the combination or division of sections will be clarified as the drafting progresses