



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

Twenty-seventh Session

Cairns, Australia

16 – 20 September 2024

PROPOSED DRAFT CONSOLIDATED CODEX GUIDELINES RELATED TO EQUIVALENCE

(At Step 3/4)

(Prepared by an electronic working group¹ led by New Zealand with the United States of America and Kenya)

Codex Members and Observers wishing to submit comments, at Step 3/4, on this draft (Appendix) should do so as instructed in [CL 2024/70-FICS](#) available on the Codex webpage/Circular Letters 2024: <https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

INTRODUCTION

1. At its 24th Session (2018), CCFICS discussed the consolidation of Codex guidelines related to equivalence².
2. Following an exchange of views 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 initiating the consolidation work in parallel with completing the draft proposed *Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems*³.
3. 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 then draft guidelines on recognition and maintenance of equivalence of NFCSSs) will be helpful for national authorities, including developing countries, and also help ensuring fair practices in the food trade. CCEXEC77 recommended approval of the new work by CAC42, which was received in July 2019⁴.
4. 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 CCFICS25⁵, initially scheduled for 27 April – 1 May 2020.
5. Work was commenced in 2019 via the Codex e-Forum and was broken into stages as it was the view of the EWG Chair (and Co-Chairs) that the Codex step process related to the then draft Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems should be completed before drafting of a specific consolidation text was initiated.
6. The first stage was to confirm which Codex text and what sections or paragraphs of each text needed to be included and to provide an initial indication of what type of work should be undertaken, for example editorial amendment, review, deletion, or consideration within the consolidation. This initial assessment

¹The electronic working group comprised representatives of Argentina, Australia, Brazil, Canada, Chile, China, Costa Rica, Ecuador, European Commission, Ghana, Guatemala, Honduras, India, Indonesia, Japan, Kenya, Republic of Korea, Mexico, Morocco, New Zealand, Norway, Panama, Peru, Senegal, Singapore, Sweden, Tanzania, Thailand, United States of America, United Kingdom.

² REP19/FICS, Paras. 26 - 31

³ REP19/FICS paras 16 – 32

⁴ REP19/CAC – paragraph 96 & Appendix V

⁵ Para 32 (iii) (b), REP19/FICS

identified three complete texts, - *Guidelines for the Development of Equivalence Agreements Regarding Food Imports and Export Inspection and Certification Systems* (CXG 34-1999); *Guidelines on the Judgement of Equivalence of Sanitary Measures associated with Food Inspection and Certification Systems* (CXG 53-2003) and, when completed, the *guidelines on recognition and maintenance of equivalence of NFCS* and specific parts of *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CXG 26-1997) (Section 5 and paragraph 55), - that need to be considered in the consolidation work. In respect of the other CCFICS texts, 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 texts 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.

7. In October 2020, Codex Members and Observers were advised⁶ that as a result of the rescheduling of CCFICS25 to 2021 (due to the COVID-19 pandemic) the EWG was continuing its work.
8. CCFICS25 (2021) considered CX/FICS 21/25/7 (Appendix I and II) [REP21-FICS paras 85-90] and agreed to:
 - i. progress the work on the proposed draft consolidated Codex guidelines related to equivalence as outlined in CX/FICS 21/25/7; and
 - ii. establish an EWG chaired by New Zealand and co-chaired by the United States and Kenya, working in English only, to progress the work on the draft consolidated Codex guidelines on equivalence. The Report of the EWG should be submitted at least three months prior to CCFICS26.
9. Given the ongoing impact of the Global pandemic CCFICS26 was rescheduled to 1 – 5 May 2023. The EWG continued its work including development of an enhanced framework and then focused on the development of principles, drawing from existing CCFICS text. A virtual workshop on equivalence, open to all Codex Members and Observers was also held in September 2022.
10. Following further revisions and consideration of discussion at the workshop a full draft of a consolidated text on equivalence, was circulated as CX/FICS 23/26/5 with comments invited by circular letter (CL2023/10/OCS-FICS) and published as CX/FIC 23/26/5 Add 1. A physical working group (PWG) meeting was held on 30 April immediately prior to CCFICS26 and considered the comments received.
11. CCFICS26 (2023) agreed to consider the draft Consolidated text revised by the PWG and presented as CRD2 and proceeded to review the text paragraph by paragraph. At the conclusion of the discussion CCFICS26⁷ agreed:
 - i. The aim of the work was to produce a single consolidated text ensuring that all critical matters in the existing CCFICS texts were appropriately captured, with revocation of the existing texts to be confirmed at the time the consolidation was finalised by CCFICS.
 - ii. To hold at step 4 the text under “Section 1 Preamble”; “Section 2 Scope”, “Section 3 Purpose” and “Section 4 Principles” found in Appendix V, noting that these provisions remain open for comment.
 - iii. To return the rest of the draft principles and guidelines as presented in Appendix 1 of CX/FICS 23/26/5 to Step 2 for further drafting, taking into account the discussion at CCFICS26, and written comments received.
 - iv. To establish an EWG open to all Members and Observers, chaired by New Zealand, and co-chaired by the United States of America and Kenya working in English only, with the following terms of reference:
 - to prepare revised draft consolidated Codex guidelines related to equivalence taking into account written comments received and set out in CX/FICS 23/26/5 Add 1, CRDs 6, 13, 17, 21, 22, 26 and the comments made and discussed at CCFICS26, for circulation of the entire text for comments and for consideration at CCFICS27.
 - to submit the report of the EWG at least three months in advance of the next session.
 - v. To keep open the option to hold a physical working group session immediately prior to the next CCFICS session and/or a virtual intersessional meeting, to address any outstanding issues.
12. CCFICS26 (2023) also completed consideration of the draft Guidelines on the Recognition and Maintenance of Equivalence of NFCS and recommended its adoption at steps 5 and 8. The 46th Session of the Codex Alimentarius Commission (CAC46) adopted the guidelines as CXG 101-2023.

⁶ CX/FICS 20/25/7 Add 1 – Explanatory note 3

⁷ REP23/FICS paragraph 68

METHODOLOGY / APPROACH

13. The EWG recognised there are two key outcomes that need to be achieved from the consolidation work – rationalisation and updating. It identified the most appropriate starting point as: *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.* This approach, with its initial focus on structure and concepts rather than specific wording takes into account that the various text relating to equivalence have been developed over a period of more than 20 years thus facilitating the rationalisation objective. It also ensures that the duplication and at times conflicting guidance that can be found in the current texts can be addressed.
14. An initial proposal for a framework for a single consolidated text was presented in Appendix II to CX/FICS 20/25/7. Formal comments were requested via circular letter (CL 2020/03 FICS) with a closing date of 1 May 2020.
15. In October 2020, Codex members and observers were advised⁸ that as a result of the rescheduling of CCFICS25 to 2021 (due to the COVID-19 pandemic) the EWG was continuing its work including addressing the comments received and published as CX/FICS 20/25/7 Add 1⁹.
16. The EWG chair and co-chairs agree that the formal comments received in 2020 were helpful and provide clarity for the approach and matters to be considered in the next steps. The comments were re-presented to CCFICS25, as CX/FICS 21/25/7 (Appendix I and II), along with a proposed approach for the next steps.
17. CCFICS25 (2021) agreed to progress the consolidation as proposed and re-established the EWG chaired by New Zealand and co-chaired by the USA and Kenya.
18. In November 2021, an expanded annotated outline drawing on the comments received and discussion at CCFICS25 was prepared and circulated to the EWG as step 1 of the agreed process. The outline included a list of potential topics for the development of principles common to all equivalence considerations. The comments received from the EWG confirmed support for the framework and the list of potential common principles.
19. In April 2022, following the rescheduling of CCFICS26 to May 2023 and advice that the EWG was to continue its work, the EWG Chairperson and Co-Chairpersons provided an update and a revised timetable. This included a proposal to approach the analysis of the work for the development of a single consolidated guidance document (step two of the agreed overall approach) by working in stages. The EWG Chairperson and Co-Chairpersons further proposed commencing with the Principles section, as these are a key part of the consolidated guidance.
20. In June 2022, the EWG considered proposals for consolidated principles drawn from existing text (both those identified as such and the sentences / paragraphs that state a principle).
21. On 21 September 2022, over 100 Codex Members and Observers, the Chairperson of CCFICS and the Codex and Australia CCFICS secretariates participated in a virtual workshop on equivalence working in English and Spanish. New Zealand, as chair of the EWG, lead the discussion supported by the USA and Kenya as co-chairs. The background document shared prior to the workshop was a table of the comments and responses to the specific questions relating to each of the proposed consolidated principles. The discussion on the Consolidation work focused on the draft principles and greatly assisted the revision.
22. Drawing on the expanded annotated outline and the draft principles developed by the EWG, along with the discussion at the virtual workshop, an initial full draft of a consolidated guidance on equivalence was developed and circulated to the EWG in February 2023. The draft included explanatory notes at the beginning of most sections, intended to assist the drafting process with the expectation these are removed prior to the finalisation of the guideline.
23. The revised draft, taking into account the initial EWG comments received, was circulated as Appendix 1 to CX/FICS 23/26/5. Appendix 1 also includes a number of specific questions related to the form and content of the draft consolidated Codex guidance on equivalence.
24. Immediately prior to CCFICS26, the working group held a physical meeting and considered the comments received¹⁰. The report of the working group was presented as CRD2 and included updated text for Sections 1 (Preamble), Section 2 (Purpose), Section 3 (Scope) and Section 4 (Principles), there having been insufficient time to review the entire draft.

⁸ CX/FICS 20/25/7 Add 1 – Explanatory note 3

⁹ Comments received from: Brazil, Canada, Colombia, Ecuador, European Union, Honduras, Iraq, Mexico, Morocco, Nicaragua, New Zealand, Paraguay, Thailand, United States of America, FAO, and CCTA

¹⁰ CX/FIC 23/26/5 Add 1

25. CCFICS26 reviewed and amended Sections 1-4 and provided general comments and suggestions on the remaining Sections – Refer paragraphs 47 – 67 of REP23/FICS. The EWG was reestablished with terms of reference as set out in paragraph 11 (iv) above.

POST CCFICS26 & EWG DISCUSSION

26. An invitation to register for the EWG to be hosted on the Codex E-forum was posted by the New Zealand Codex Contact Point with replies requested by 28 July 2023. An initial message and timetable was posted to the EWG on 18 August 2023. The EWG chairperson and co-chairpersons recalled that CCFICS26 had reviewed Section 1 Preamble, Section 2 Scope, Section 3 Purpose, Section 4 Principles and agreed to hold these at step 4 thus indicating a level of satisfaction with the current drafting. They advised that it was therefore their intention to focus the first round of EWG comments on the other sections of the draft consolidated text.
27. On 16 November 2023, a request for comments was posted to the EWG. The paper presented for review and comment was the text presented to CCFICS26 as Agenda paper 5 (CX/FICS 23/26/5) with revisions taking into account the comments received by CCFICS26 as well as the plenary discussion. The specific sections for review and comments were: Definitions (Section 4); Initial Discussions (Section 5); Process steps (Section 6); Documenting the Agreement and Implementing the Decision (Section 7); Maintenance of Equivalence Recognitions (Section 8); and Appendix 1 and 2. The draft included explanatory notes and a number of specific questions and requests. Also provided in a separate document was a table of all the comments on these sections presented to CCFICS26 in CX/FICS 23/26/5/Add 1, and in several CRDs. A response to each comment was provided and an indication of changes to the draft presented to CCFICS26.
28. The EWG was requested to provide comments and responses by 22 December 2023. Comments were subsequently received from 10 members of the EWG and included both general comments, responses to the questions and suggestions for amendments to the draft text. In summary the following were addressed:
- The definition of 'Equivalence' – whether it should be updated to take account of the various forms of equivalence or if more than one definition was necessary.
 - The inclusion of definitions from other existing CCFICS text – whether these should be updated, and the inclusion of new definitions. While there had been proposals to CCFICS26 to include several further definitions, it was the majority view of the EWG that most were not necessary.
 - The expansion of the definition for 'Sanitary Measure' to that in CXG 53-2003 – which is the full definition from the WTO SPS Agreement – rather than the proposal from the EWG chair and co-chairs to limit the definition to those classes of hazard that can result in risks in food, and not include how the hazard gets into a food. There was a clear preference from the EWG not to include additional text in the proposed definition.
 - The retention of passages of text from other existing CCFICS guidelines without amendment or if updating of text and concepts to take account of the passage of time is appropriate for a consolidation.
 - Whether or not it is necessary to include separate sections on the assessment of system equivalence and assessment of the equivalence of measures. There were mixed views from the EWG on the need for separate Assessment process sections. It remains the view of the EWG Chair and co-Chairs that separate sections are not necessary. Any specific guidance related to a difference in the assessment process should be included as additional or amended text in the current Section 5.
29. The EWG Chairperson and Co-Chairpersons revised the draft text taking the comments and suggested amendments into consideration. A table of the comments, responses and suggested text including a response to each was provided to the EWG for their information and to acknowledge their contribution. Unfortunately, it was not possible to circulate a revised draft to the EWG for comment as originally intended.

CCFICS27 QUESTIONS FOR DISCUSSION

30. A draft of the Consolidated text on Equivalence, drawing on the contributions of the EWG is attached to this agenda paper. The changes of note from the previous draft considered by CCFICS include the following:
- The phrase 'conditions of trade' is replaced with 'requirements for trade', with a slightly amended version of the CXG 34-1999 definition of "requirement" being included in the list of definitions.
 - Using to the extent practical and reasonable text from the recently adopted *Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems (NFCS)* – (CXG 101-2023)-.

- Including definitions from other existing CCFICS text with some minor amendment to reflect current Codex language.
- Including a new principle on 'demonstration of equivalence'.
- Some reordering and clarification of the guidance provided in the section and steps on 'Process' to ensure the flow is clear and logical. Some repetition of guidance remains in acknowledgement that future readers of the Consolidation may be seeking guidance on a specific step in the process and may not read the document in sequential order.
- Inclusion of a separate section on Maintenance of Equivalence Recognition.

31. Codex Members and Observers are invited to comment on the draft text set out in the **Appendix** and to give specific consideration to the questions, which highlight where there was a mix of views in the EWG comments and responses.

NEXT STEPS

32. A physical working group will be convened on 15 September in Cairns to consider the comments and responses to questions received on **Appendix**, with the intention to prepare a revised draft for consideration at CCFICS26.

RECOMMENDATIONS

33. The Committee is invited to:

- i. consider the proposed draft Consolidation of guidance relating to equivalence presented at **Appendix** and to provide responses to the specific questions as highlighted in the boxes (in yellow) under the different provisions;
- ii. note a physical working group will be held **15 September 2024** to consider the comments and responses to the specific questions in Appendix ; and
- iii. note the working group will report to CCFICS27 on the outcome of the discussion via a CRD.

34. The Committee is requested to confirm the continuation of 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.

APPENDIX

Please note that the boxed comments are provided only as an explanation to assist drafting and will be removed prior to finalization.

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

(AT STEP 3/4)

SECTION 1: PREAMBLE (AT STEP 4)

1. The recognition of equivalence is not generally required for most trade. However, where applied it can provide an effective means for further ensuring the requirements for trade between two countries are the least trade restrictive to ensure the importing country's relevant objectives, and related outcomes or level of protection are achieved. The recognition of equivalence, when it occurs, should result in positive changes to the conditions of trade, and facilitate the more efficient and effective use of resources in the importing and exporting countries.
2. Requests for the recognition of equivalence can cover those requirements for trade that relate to both the protection of the health of consumers and fair practices in the food trade and can cover a specified measure, or the whole or a part of an exporting country's National Food Control System (NFCS). Requests for the recognition of equivalence normally relate to changes that would improve the requirements for trade or proposed trade.
3. The recognition of equivalence may facilitate trade through reducing the need for exporting countries to implement additional controls over and above those already effectively being delivered by its NFCS and may also result in resource savings for importing countries. The recognition of equivalence may lead to efficiencies in approval, audit, inspection, and certification processes especially as these may relate to food control systems, establishments, products, and processes.
4. These guidelines consolidate and update [and replace] the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CXG 34-1999), *Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CXG 53-2003) and *Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems* (CXG 101-2023).
5. These guidelines are intended to also be read in conjunction with other existing Codex text including *Principles and Guidelines for National Food Control Systems* (CXG 82-2013) the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CXG 26-1997), 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).

SECTION 2: PURPOSE (AT STEP 4)

6. This consolidated text provides practical guidance for importing and exporting countries on the process that may be applied for the assessment, recognition and maintenance of equivalence of a specified measure, or the whole or part of a NFCS, as well as what should be covered in any resulting agreement/arrangement and associated documentation¹.

SECTION 3: SCOPE (AT STEP 4)

7. The guidance covers the assessment, recognition and maintenance of equivalence that relate to either the protection of the health of consumers or ensuring fair practices in the food trade, or both, as relevant to the trade in foods and the requirements for trade covered by the request.

¹ Documentation of a recognition of equivalence may take the form of an "international agreement" under the Vienna Convention on the Law of Treaties or may be a less formal arrangement such as an exchange of letters or a memoranda of understanding between the parties.

SECTION 4: DEFINITIONS

Definitions for the following terms are proposed – the source of each is indicated. The notes on source will be deleted prior to finalization of the text.

Note: There was a mix of WG views on including the full phrase “objectives, and related outcomes or level of protection” as used in CXG 101-2023 in some but not all definitions.

Question 1: Is the current approach and wording supported?

Note: There was a mix of WG views on the wording for ‘Measure’ and for ‘Requirements’. The current proposed wording draws a distinction between ‘measure’ which can refer to either the importing or exporting country and ‘requirements’ which are the importing country’s conditions for trade.

Question 2: Is the current proposed wording supported?

Equivalence: The capability of different NFCS, in whole or in part, or different specified measures, to achieve the same objectives. [New Definition adapted from CXG 26-1997 and CXG 101-2023 to capture the range of equivalence approaches].

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 [Adapted from CXG 101-2023].

Measure: 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. [New definition drawn from existing Codex and WTO texts]

NFCS Objective means a legitimate policy goal for the NFCS or the relevant part with respect to the protection of the health of consumers or ensuring fair practices in the food trade including how the relevant part or specific measure contributes to the policy goal. [New Definition derived from CXG 82-2013]

Outcomes: Intended effects or results that contribute to achieving the relevant NFCS objectives [From CCFICS26 NFCS Equivalence guidance and CXG 91-2017].

Requirements: are the conditions 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. [Adapted from CAC/GL 34-1999]

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

Technical measure: means any measure other than a sanitary or phytosanitary measure to ensure the protection of the health of consumers or fair practices in the food trade². [Derived from the WTO TBT Agreement]

SECTION 4: PRINCIPLES (AT STEP 4)

8. The consideration, assessment, recognition, and maintenance of equivalence should be based on the following principles.

A: Equivalence

Countries should recognize that different measures, NFCS, or relevant parts of NFCS although designed and structured differently, may achieve the same objectives, and can therefore be recognized as equivalent.

B: Experience, Knowledge and Confidence

Importing countries should consider relevant experience, knowledge and confidence in the exporting country’s NFCS, or relevant part, including appropriate assessments by other countries or international organizations.

C: Scope of the request and assessment

The scope of any request or any subsequent assessment should focus on those products and conditions affecting trade where the exporting country considers the specific measure, its NFCS, or relevant part of NFCS

² Includes those technical regulations standards and conformity assessment procedures that are applied to the trade in food between an importing and exporting country.

already achieves the same objectives, and related outcomes or level of protection as achieved by the importing country.

D: Alignment with International Standards

The use of or reference to Codex standards, guidelines and/or codes of practice, or other relevant international standards by importing and exporting countries can facilitate the consideration, assessment and recognition of the equivalence of a specific measure, NFCS, or the relevant part.

E: Transparency and co-operation

Importing and exporting countries should work through the process in good faith, in a reasonable timeframe and in a transparent, evidence-based and outcome-focused manner.

F: Demonstration of Equivalence

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

Note: CCFICS26 discussed the inclusion of a Principle on Demonstration of Equivalence noting that the draft text was not as yet written as a principle. The text has been revised by the EWG co-Chairs drawing on WTO/SPS Article 4 and WTO/ TBT Article 2.7.

Question 3: Is the now revised proposed wording supported?

G: Documentation and maintenance

Importing and exporting countries should document any recognition reached, including specifying the food products and measures covered or excluded, and how the recognition of equivalence will be implemented and maintained for the trade in products between the countries.

H: Technical assistance / Regulatory co-operation

Importing countries should, upon request and where feasible, consider providing technical assistance to an exporting developing and in particular least developed countries, to facilitate the assessment and recognition of equivalence.

SECTION 5: INITIAL DISCUSSIONS

The section provides guidance on how countries should:

- *Review the nature and relevance of any potentially trade constraining requirements (e.g. sanitary versus technical matters or a combination) and the potential existence of solutions or processes, other than an assessment of equivalence to address these.*
- *Identify the purpose and Review what the scope of a consideration of equivalence could be if this is the most appropriate process to address the matters under discussion.*
- *Identify and then consider how existing knowledge, experience and confidence, or previously exchanged information or assessment may be used, including to simplify any process.*

9. It is recommended that the competent authorities of importing and exporting countries have initial discussions prior to formalizing a request for a recognition of equivalence, such a request may be made at any point during these discussions.
10. The initial discussions should review the nature and relevance of the requirements for trade that the exporting country considers to be unnecessarily restricting. The requirements for trade may relate to one or more additional controls that the exporting country may be required to implement but may also include any additional processes (e.g. audits, approvals or border inspections) applied by the importing country.
11. Both countries should consider whether there may be potential solutions or processes other than an assessment of equivalence to facilitate trade.

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;
 - the importing country's relevant NFCS objectives, and the related outcomes or level of protection;

- what flexibility the importing country currently has within the existing requirements for trade and what other mechanisms may be available;
- what evidence the exporting country may have that its NFCS or specified measures achieve the importing country's NFCS objectives, and the related outcomes or level of protection; and
- whether a recognition of equivalence will likely further facilitate trade, for example by resulting in cost and resource savings, reduced duplication of control activities and/or removal of unnecessary impediments, while still ensuring the importing country's relevant NFCS objectives, and the related outcomes or level of protection are met.

Initial scope discussions

13. The initial discussions should be used to refine both the scope of any consideration as well as to identify and clarify what additional information and / or evidence may be required for an assessment process. These discussions should:
 - identify the range of products for which the exporting country is seeking a recognition of the equivalence of its control measures,
 - identify those requirements where recognition of the equivalence of the NFCS or the relevant part will allow better use of resources, including resolution of issues affecting trade;
 - identify whether the relevant requirements are sanitary or technical measures, or a combination of both;
 - consider the resources likely to be necessary to undertake the assessment process relative to the possible benefits;
 - identify how existing experience, knowledge and confidence, or previously exchanged information or assessments may be used, and
 - consider any ways to simplify the assessment process to make it more efficient and less burdensome on both countries.

Experience Knowledge and Confidence

14. The use of or reference to existing experience, knowledge and confidence can reduce the amount of information and evidence the exporting country needs to provide. It can also reduce the resources and timelines for the assessment and decision-making processes.
15. Existing experience, knowledge and confidence may take the form of, for example:
 - existing arrangements / agreements;
 - previous assessments, audits, study tours, technical visits or other related interactions;
 - the prior history in food trade between the importing and exporting countries;
 - the level of compliance of the exporting country's food products with the importing country's requirements;
 - the level of cooperation that exists between the NFCS competent authorities of the importing and exporting countries;
 - the similarity in design, laws, regulations and operational principles and practices between the importing and exporting country's NFCS;
 - the similarity in design and operational principles and practices of the exporting country's measures or NFCS or relevant part with the relevant Codex standard, guidelines or codes of practice;
 - the alignment with relevant international standards, guidelines, recommendations, and conformity assessment practices; and
 - relevant assessments performed by the importing country, by recognized conformity assessment bodies, by other countries, or by international organizations.
16. Importing and exporting countries should develop a clear understanding of what role and to what extent existing experience, knowledge and confidence will be used in any consideration or assessment of equivalence. This understanding needs to cover how existing experience, knowledge and confidence will affect:
 - the assessment and decision-making processes applied to aspects within the scope of the request;

and

- the amount, nature and scope of evidence and information the exporting country should provide.

Outcome of initial discussions

17. Where the conclusion of the initial discussions between the exporting and importing countries is that an equivalence process is the appropriate mechanism for facilitating trade, the exporting country should submit a written request for consultations with the aim of achieving agreement on the recognition of equivalence.
18. Where the initial discussions identify that an equivalence process may not be the most appropriate mechanism, the countries may wish to consider working jointly towards some other mechanisms to help facilitate the trade. Alternative mechanisms may, for example, include:
 - the importing country may decide to provide some further flexibility or options within its specified requirements for trade on how its objectives, and related outcomes or level of protection, may be met;
 - the exporting country may decide to adopt additional controls which more closely align with or better achieve the importing country's objectives, and related outcomes or level of protection; or
 - the two countries may decide to engage in further cooperation and/or capacity building between them so as to better understand and address the relevant challenges negatively impacting trade between them.

SECTION 6: PROCESS STEPS

The section provides the logical flow of steps that can be followed when carrying out consideration of a request for a recognition of equivalence once a request has been formalized. A brief explanation of each step is included.

The section explores any differences in process relating to whether a request solely relates to parts of the NFCS which are sanitary in nature compared to those which may be solely technical in nature, or where the request covers a combination of both. The section also explores whether any differences in process are required for the consideration of requests, or components of requests, which relate to the consideration of the effects of discrete procedures, as opposed to whether the wider NFCS or relevant part is delivering the outcome required.

19. Where the initial discussions identify that an equivalence process is an appropriate mechanism for facilitating trade, the two countries should then agree on a plan for the exporting country to provide the appropriate submission and for the importing country to work through its assessment and decision-making process. This plan may also include anticipated timeframes and if necessary, priorities. A simplified flow diagram of the process steps is included at **Annex 1**.

The process steps are:

- Step 1: Scope of request discussed and documented
- Step 2: Importing country describes the basis of its requirements for trade
- Step 3: Importing country discusses and documents the decision criteria
- Step 4: Exporting country documents its case for equivalence
- Step 5: Assessment process
- Step 6: Decision process and final decision
- Step 7: Documenting the agreement and implementing the decision

Step 1: Scope of request discussed and documented

20. The exporting country requesting consultations with the aim of achieving agreement on the recognition of equivalence should discuss and document the scope of the request. The description of the scope of the request should include for example:
 - the specific foods or group of foods, including any types of secondary processing;
 - the requirements for trade for which the exporting country is seeking a recognition of equivalence; and
 - a brief description of the exporting country's specified alternative measures, NFCS or relevant part for which the exporting country is seeking an equivalence determination.

21. The request for consultations should also ask the importing country to describe in writing the basis for its requirements for trade and / or measures as relevant to the scope of the request.

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

22. The importing country should discuss and document the requirements for trade, for the scope of products covered by the request. This should include as appropriate:
- the scientific or policy basis justifying the necessity for the requirements for trade under consideration, including risk assessment where appropriate;
 - how the specified requirements for trade contribute to achieving the NFCS objectives, related outcomes or level of protection³;
 - where appropriate, an expression of the level of control of the hazard in a specific food or group of foods that is achieved by the sanitary measure;
 - the identification of the specific risks and level of control required as it relates to the protection of the health of consumers or ensuring fair practices in the food trade that the specified requirements are intended to address;
 - the justification for the requirements for trade and / or measures as relevant to the bilateral circumstances existing between the two countries; and
 - any additional information that may assist the exporting country in presenting an objective demonstration of equivalence.
23. For further context and to help the exporting country better tailor its case for recognition of equivalence, the importing country should also describe⁴, with appropriate references, how its own measures, NFCS or relevant part, achieves its specified NFCS objectives, and related outcomes or levels or protection.

Step 3: Discussing and documenting the decision criteria

24. 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, NFCS or relevant part, achieves the importing country's relevant NFCS objectives, and related outcomes or level of protection.
25. 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.
26. The decision criteria should facilitate the determination by 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.⁵
27. The decision criteria may be qualitative or quantitative and should include for example:
- the relevant importing country NFCS objectives, and related outcomes or level of protection;
 - the type of evidence expected;
 - an indication of the amount or level of qualitative or quantitative evidence that is expected;
 - any indicators⁶ of outcomes required if these are to be used to facilitate comparisons; and
 - how existing experience, knowledge and confidence are to be used.
28. The decision criteria should not apply a standard or level of performance that exceeds the achieved by the importing country's specified measures, NFCS or relevant part.

³ Including the quantitative or proportionate effect of their contribution.

⁴ ref: CXG 34-1999, Section 7; CXG 82-2013, paragraph 43 and CXG 89-2016 Section 7

⁵ One example of a possible decision criteria could be: Regulatory decisions are based on sound scientific analysis and evidence, involving a thorough review of all relevant information (e.g. historical regulatory decisions, published risk assessments, or compliance actions).

⁶ See Appendix B of CXG 91-2017 for some illustrative examples of outcomes and examples of potential indicators for those selected outcomes.

Step 4: Exporting country documents its case for equivalence

29. The exporting country should submit or make available appropriate information and evidence, including relevant references that demonstrates how its specified measures, 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.
30. The submission should as far as possible be tailored to appropriately cover all aspects of the decision criteria and objectively demonstrate that the exporting country's specified measures, NFCS or relevant part, meets those criteria.
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.
32. As far as practical, importing countries should allow flexibility in the format of the information submitted by the exporting country, and where appropriate allow reference to relevant international standards, guidelines, or codes of practice.
33. Subject to the scope of any request for recognition, additional information exchanges may be required where a more detailed assessment is considered necessary.

Step 5: Assessment process

34. The aim of the assessment process is for the importing country to evaluate the information and evidence submitted by the exporting country so that the summary findings can be considered against the decision criteria. The importing country and its assessment process should appropriately protect any commercially sensitive or confidential information as supplied by the exporting country.
35. Prior to initiating the full assessment process the importing country should assess whether the information submitted or otherwise available is likely to be sufficient to address the matters specified in the decision criteria.
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.
37. If the importing country has any concerns with the submission as presented, it should notify the exporting country at the earliest opportunity and should detail the reasons for concern. If possible, the importing country should suggest how the concerns might be addressed.
38. The assessment process should then proceed in a timely and cooperative manner, including where any further clarifications or supplementary information is required. The assessment process will normally comprise a number of steps which may vary depending on:
 - the scope of the request including the range of foods and the requirements for trade for which equivalence is sought;
 - the scope of assessment, e.g., whether it is restricted to certain specified measures or potentially requires a wider assessment of the NFCS or relevant part;
 - the complexity of the exporting country's controls to be assessed;
 - whether additional evidence, information or clarifications are needed; and / or
 - whether an in-country visit will likely be necessary.
39. The assessment process should normally start with a desktop review of the documents submitted, taking into account any existing knowledge, experience and confidence. The importing country should contact the exporting country where it requires any clarifications or further information during this phase.
40. An in-country visit may be justified and required as part of an assessment, for example in situations where:
 - existing knowledge, experience and confidence in the exporting country's NFCS is not sufficient to be able to conclude that the information and evidence submitted is sufficient to make a decision; or
 - the complexity of the consideration justifies additional verification as part of the assessment; or
 - sufficient confidence may not be able to be ascertained through the analytical data itself, or through conformity assessment processes undertaken in accordance with international accreditation arrangements, or through cross reference to other relevant assessments.

41. Where an initial assessment identifies the lack of a specific control considered necessary to achieve the relevant importing country objectives, the importing country should, where appropriate, provide the exporting country an opportunity to remedy the deficiency.
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.

Note: There were mixed views on the need for separate Assessment process sections for systems equivalence and for equivalence of measures. It remains the view of the EWG Chair and co-Chairs that separate sections are not necessary. Any specific guidance related to a difference in the assessment process should be included as additional or amended text in the current Section 5.

Question 4: Do you agree with this assessment that separate sections are not needed?

Question 4a: If not, what additional text do you proposed needs to be included?

Question 5: In which paragraph or sub-section should additional text be provided?

Step 6: Decision process and final decision

43. The importing country should consider its summarised assessment findings against the documented decision criteria with a view to producing a decision document.
44. The importing country's decision process should:
 - be transparent, documented and conducted in a timely manner;
 - focus on whether the exporting country's NFCS or the relevant part meets the decision criteria; and
 - not, without justification, introduce an objective, or outcome, standard or process in excess of what is being applied within the importing country.
45. This decision document should highlight whether and, where relevant, the degree to which, each of the decision criteria have been met along with the relative weighting each has had on the draft final decision. Where the importing country considers one or more of the decision criteria have not been met the importing country should clearly document why it has reached this conclusion.
46. 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 NFCS or the 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.
47. The importing country should review the exporting country's additional information without requiring all aspects of the assessment process to be repeated, so long as the exporting country provides the additional information in a timely manner.
48. The importing country should document the final assessment conclusions and the associated rationale.
49. Where the importing country recognises the equivalence of the specified measures, NFCS or relevant part, both countries should then discuss how this recognition will affect the requirements for trade between the countries.

⁷ Paragraph 36, [CXG 82-2013](#)

SECTION 7: DOCUMENTING THE AGREEMENT AND IMPLEMENTING THE DECISION

This section had been developed largely based on information contained in CXG 34-1999 and a review of the other text, updated as appropriate. This section contains information on:

- *The purpose/use of an equivalence recognition*
- *The form in which an equivalence recognition could be documented*
- *The standard content/provisions for a document, included as an Appendix.*

50. The importing and exporting countries should document any recognition reached including how the recognition of equivalence will be implemented for the trade in food between the countries (e.g. recognition of lists of establishments; or modification to point of entry, or additional in-country process prescriptive requirements). Such documentation may be completed, for example, through an exchange of letters or through the negotiation of a more comprehensive equivalence agreement or arrangement.
51. Suggested content headings for a recognition agreement / arrangement document are provided in **Annex 2**.
52. Where both parties agree the scope of an equivalence recognition may be amended at a later time to cover additional products or processes. In such a case, the level and extent of the assessment required would be agreed between the parties, should an extension of scope be proposed.

SECTION 8: MAINTENANCE OF EQUIVALENCE RECOGNITIONS

This section provides some guidance (for inclusion in the documentation) on how countries can maintain the ongoing currency of equivalence recognitions through:

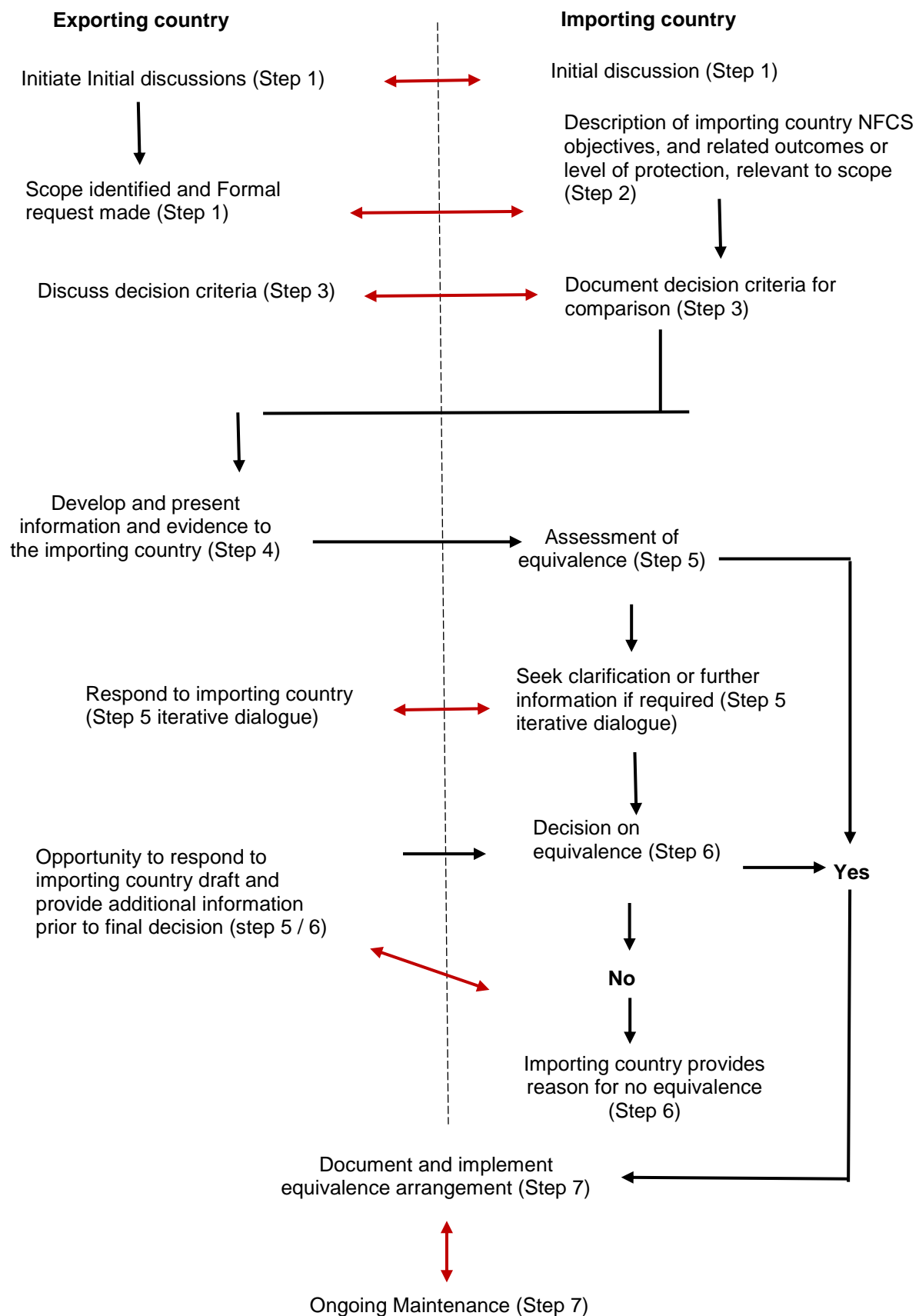
- *The use of regular information exchanges*
- *Agreeing criteria for when some level of reassessment may be appropriate*
- *How recognitions may affect in-country audits etc*

53. Equivalence recognition agreements / arrangements typically include expectations with respect to ongoing exchanges of information consistent with the maintenance of an appropriate level of experience, knowledge and confidence, including regular technical discussion between experts where relevant.
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 change to the importing country's level of protection; and / or
 - a drop in the 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 or performance measures underpinning the components of either country's NFCS covered by the recognition of equivalence arrangement.
55. The agreement / arrangement should also address situations where more urgent actions may be justified.
56. Where appropriate, the agreement / arrangement may also cover expectations with respect to the type and frequency of any ongoing audits. Generally, such audits should be mutually agreed and jointly undertaken and reflect the principles and guidelines developed by CCFICS⁸.
57. These audits should focus on how the exporting country's NFCS is continuing to assure the specified measures, NFCS or relevant part, as recognized as equivalent are continuing to be effectively applied.

⁸ Annex to CXG 26-1997; CXG102-2023

ANNEX 1: Flow Diagram**Figure 1: Equivalence of National Food Control Systems Process**

Simplified flow chart for recognition and maintenance of equivalence of the whole or a part of NFCS
(individual steps may be iterative)



ANNEX 2: CONTENT OF AN EQUIVALENCE RECOGNITION DOCUMENT

[Adapted from Appendix A of CXG 34-1999]

Note: the specific language used will depend on whether the equivalence recognition is a cooperative arrangement between the relevant competent authorities or a treaty level agreement between the governments of the two countries.

The following information may be included, as appropriate:

- (a) **Title:** The name given to the agreement/arrangement may vary, depending on the preferences and legal requirements of the parties.
- (b) **Parties / Participants:** The name of the entities entering into the agreement/arrangement.
- (c) **Purpose:** A brief statement of the specific purpose of the agreement/arrangement.
- (d) **Scope:** Identification of the products and measures that are the subject of the agreement/arrangement.
- (e) **Definitions:** Definitions of terms used in the agreement/arrangement, as needed. Where possible, definitions in WTO and Codex documents should be used.
- (f) **Principles:** The collectively agreed principles that will apply to the administration of the agreement/arrangement.
- (g) **Equivalence finding:** A statement of the specified measures, NFCS or relevant part that have been found to be equivalent and the effect this has on the requirements for trade for the exporting country for products / measures within the scope of the agreement/arrangement.
- (h) **Administrative Provisions / Intentions:** A comprehensive description of each participant's intentions and specific responsibilities with respect to the ongoing implementation and maintenance of the agreement/arrangement. These may include, for example:
 - i. **Liaison channels**
 - ii. **Information exchange**
 - iii. **Meeting and consultation provisions**
 - iv. **Audit and verification**
 - v. **Notification provisions**
 - vi. **Reassessment criteria**
- (i) **Emergency measures:** The notification, cooperation and cooperation provisions that will apply should one Party / Participant need to adopt an emergency measure.
- (j) **Review, modification and termination:** The methods for the review, modification and termination of the agreement/arrangement.
- (k) **Entry into effect:** The date on which the provisions of the agreement/arrangement enter into effect.
- (l) **Signature panel:** Dates, signatures, names, titles and country / competent authority committing the respect governments or competent authorities to the agreement/arrangement.