

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda item 5

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

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PROPOSED DRAFT CONSOLIDATED CODEX GUIDELINES RELATED TO EQUIVALENCE

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

(At Step 3)

Codex Members and Observers wishing to submit comments, at Step 3, on Appendix 1 of this proposed draft should do so as instructed in CL 2023/10/OCS-FICS available on the Codex webpage/Circular Letters 2023: <https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

INTRODUCTION

1. At the 24th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS24, held in 2018), the Committee discussed the consolidation of Codex guidelines related to equivalence².
2. There was an exchange of views among CCFICS24 delegates regarding the process for, 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 National Food Control System (NFCS) 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 NFCS equivalence.
3. A new work project document was developed by an in-session working group (IWG) 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 Systems*³.
4. The new work proposal underwent Critical review by CCEXEC77 and its 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 NFCS) will be helpful for national authorities, including developing countries, and will also help ensuring fair practices in the food trade. CCEXEC77 recommended approval of the new work by CAC42, which was confirmed in July 2019⁴.

¹The electronic working group comprised representatives of Argentina, Australia, Brazil, Canada, Chile, Ecuador, Egypt, Estonia, European Commission, France, Iran, Jamaica, Japan, Kenya, Republic of Korea, Malaysia, Mexico, Morocco, New Zealand, Nigeria, Norway, Panama, Peru, Singapore, Spain, Sweden, Switzerland, Thailand, United States of America, United Kingdom, Uruguay.

² REP19/FICS, Paras. 26 - 31

³ REP19/FICS paras 16 – 32

⁴ REP 19/CAC – paragraph 96 & Appendix V

5. 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 CCFICS25”⁵.

METHODOLOGY / APPROACH

6. Commencement of the consolidation work was undertaken via the Codex e-Forum and was broken into stages.
7. 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 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.
8. This initial assessment identified there are three complete texts (CXG 34-1999, CXG 53-2003 and, when completed, the draft guidelines on recognition and maintenance of equivalence of NFCS) 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 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 and the need for any change to the references can be determined, this being dependent on what the consolidation work produces.
9. When considering the approach for the development of consolidated text related to equivalence, the EWG agreed there were a range of potential options. The EWG identified the most appropriate starting point to be: *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.*
10. The EWG recognised that there are two key outcomes that need to be achieved from this consolidation work – rationalisation and updating. 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, taking into account that the various texts relating to equivalence have been developed over a period of more than 20 years, thus supporting the rationalisation objective that will be worked on at the next stage of the consolidation work. It also ensures that the duplication and at times conflicting guidance that can be found in the current texts can be addressed.

FORMAL COUNTRY COMMENTS AND WORKING GROUP DISCUSSION

11. An initial proposal for a framework for a single consolidated text was presented in Appendix II to CX/FICS 20/25/7. Formal comments on CX/FICS 20/25/7 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 organisations⁶ and were published as CX/FICS 20/25/7 Add 1.
12. In October 2020 Codex Members and observers were advised (via CX/FICS 20/25/7 Add 1) that following the rescheduling of CCFICS25 to 2021 (due to the COVID-19 pandemic) the EWG was continuing its work including addressing the comments received. 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

⁵ Para 32 (iii) (b), REP 19/FICS

⁶ Brazil, Canada, Colombia, Ecuador, European Union, Honduras, Iraq, Mexico, Morocco, Nicaragua, New Zealand, Paraguay, Thailand, United States of America, FAO, and CCTA

- provided some useful comment and suggestions for the next steps of the consolidation work.
13. The EWG Chair and Co-Chairs agree that the formal comments received in 2020 were helpful and provided clarity for the approach and matters to be considered in the next steps. The comments were presented to CCFICS25, as CX/FICS 21/25/7 (Appendix I and II), along with a proposed approach for the next steps.
 14. CCFICS25 was asked to endorse the following step wise approach to further progress the development of a consolidated single text on equivalence:
 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.
 15. CCFICS25 considered CX/FICS 21/25/7 (Appendix I and II) [REP21/FICS paragraphs 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.
 16. In addition, Chile informed the Committee of their intention to step down as Co-Chairperson of this EWG, and Kenya was subsequently nominated as Co-Chairperson along with the United States of America.

POST CCFICS25 & EWG DISCUSSION

17. An expanded annotated outline drawing on the comments received and discussion at CCFICS25 was prepared and circulate to the EWG in November 2021 with comments due 15 December 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.
18. Following the rescheduling of CCFICS26 to May 2023 and advice that the EWG was to continue its work, in April 2022 the EWG Chairperson and Co-Chairpersons provided an update and revised timetable. This included a proposal to approach the analysis work for the development of a single consolidated guidance document (step two of the agreed overall approach) by working in stages. Considering separate sections, rather than trying to do the analysis of all the existing text for all sections of the consolidated text at the same time, will enable progress while ensuring the EWG has the opportunity for focused engagement in the analysis. The EWG Chairperson and Co-Chairpersons further proposed commencing with the Principles section, as these are a key part of the consolidated guidance. Consideration of the principles also provides the opportunity to discuss some key concepts and will support reaching agreed understandings.
19. A table summarizing the Principles in existing texts (both those identified as such and the sentences / paragraphs that state a principle) with an initial analysis and a proposal for a consolidated principle was posted to the e-Forum on 1 June 2022 for consideration and review by the EWG. A set of objectives to guide the development of the principles section were presented and a number of specific questions related to each proposed principle were included to assist consideration of the draft. Comments were requested by 15 July 2022 and were receive from 11 members of the EWG.

Virtual workshop on Equivalence – September 2022

20. In August 2022 an invitation was issued to all Codex Members and Observers to attend a CCFICS workshop on Equivalence, which was held virtually, on 21 September 2022 working in English and Spanish.

21. The objectives of the workshop were to:

- Hold a focussed discussion on outstanding issues based on the last round of comments received on Workstream 1 (Draft guidelines on recognition and maintenance of equivalence of national food control systems), with the view to facilitating completion of the work at CCFICS26.
- Hold a focussed discussion on the comments received on Workstream 2 (Draft consolidated Codex guidelines related to equivalence) and consider how to proceed with further consolidation ahead of CCFICS26.

22. Over 100 Codex Members and Observers, the Chairperson of CCFICS and the Codex and Australia CCFICS secretariats participated in the workshop. 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 focused on the draft principles and greatly assisted their revision.

23. In November 2022 a revised draft of the principles for the consolidation was circulated to the EWG for review, with comments requested by 2 December 2022. Comments were received from six Members of the EWG.

First full draft of Consolidated Guidance on Equivalence

24. Drawing on the expanded annotated outline and the draft principles developed by the EWG, along with the discussion at the virtual workshop, the EWG Chairperson prepared an initial full draft of a consolidated guidance on Equivalence. This draft was circulated to the EWG in February 2023. The EWG Chairperson and Co-Chairpersons noted that the pressure of other CCFICS work, including the EWG's work on the guidance for Equivalence of NFCSSs, has significantly impacted the timeframes for further EWG contributions to the development of the first full draft. While a very short timeframe was available for EWG initial comments, the Chairperson and Co-Chairpersons were mindful that formal country comments will be requested by circular letter (CL) prior to CCFICS26 and a physical working group will be held on 30 April 2023 to consider the responses.

25. The revised draft taking into account the initial comments received, is attached as Appendix 1. The draft includes explanatory notes at the beginning of most sections to assist with the drafting process with the expectation these notes are removed prior to the finalisation of the guideline. Appendix 1 also includes a number of specific questions related to the form and content of the draft consolidated Codex guidance on equivalence.

NEXT STEPS

26. A physical working group will be convened on 30 April 2023 in Hobart to consider the comments and responses to questions received on Appendix 1, with the intention to prepare a revised draft for consideration at CCFICS26 (1-5 May 2023).

RECOMMENDATIONS

27. The Committee is invited to:

- i. consider the proposed draft consolidation of guidance relating to equivalence presented at Appendix 1 and to provide responses to the specific questions;
- ii. note that a physical meeting of the working group will be held 30 April 2023 to consider the comments and responses to the specific questions in Appendix 1; and
- iii. note that the working group will report to CCFICS26 on the outcome of the discussion via a CRD.

28. 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 CCFICS27 with a revised draft text for progression in the Codex step process.

DRAFT

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

**PROPOSED CONSOLIDATED TEXT ON THE:
PRINCIPLES AND GUIDELINES FOR THE RECOGNITION OF THE EQUIVALENCE OF SPECIFIED
MEASURES OR THE WHOLE OR A PART OF NATIONAL FOOD CONTROL SYSTEMS**

(At Step 3)

SECTION 1: PREAMBLE

Please note that this section will remain under review until the rest of the sections have completed at least one round of comments at step 3.

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 conditions of 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.
2. Requests for the recognition of equivalence can cover those conditions of 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 just those conditions of trade an exporting country considers are unnecessarily restricting their existing or proposed trade.
3. The recognition of equivalence may facilitate trade through reducing the need for exporting countries to implement unnecessary 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 bring together the guidance on equivalence set out in *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 *Draft Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems* (CX/FICS 23/26/4) [reference to be updated when finalized].
5. These guidelines are intended to also be read in conjunction with other existing Codex text including 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/SCOPE (of guideline)

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

6. This consolidated text provides practical guidance, information and recommendations for importing and exporting countries on the process that may be applied for the assessment of requests for the recognition of the equivalence of a specified measure, or the whole or part of a NFCS, as well as what should be covered in any resulting agreement.
7. The guidance covers requests for recognition 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 conditions of trade covered by the request.

SECTION 3: 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.

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

Equivalence: The capability of different NFCS, in whole or in part, or different specified measures, to achieve the same objectives, and related outcomes or level of protection. [*New Definition adapted from CXG 26-1997 and the NFCS Equivalence draft guidance paper to capture the range of equivalence approaches*].

Equivalence of specified sanitary measures: The capability of an alternative sanitary measure or measures as applied by the exporting country to achieve the same level of protection, as achieved by the specified importing country's measure or measures. [*New definition drawn from existing Codex and WTO texts to capture the difference between equivalence of NFCS or the relevant part and equivalence of a specified measure or measures*].

Equivalence of specified technical measures: The capability of an alternative technical regulations, standards or conformity assessment processes as applied by the exporting country to achieve the same objective as achieved by the specified importing country's technical regulations, standards or conformity assessment processes. [*New definition drawn from existing Codex and WTO texts*]

Decision Criteria: Those factors used to objectively determine whether the exporting country's NFCS or the relevant part achieve the objectives of the importing country's NFCS or the relevant part for the products under consideration [*From NFCS Equivalence draft guidance*].

Measure: A type of control required for trade that is necessary to ensure the exporting party meets the importing country's relevant NFCS objectives. [*New definition drawn from existing Codex and WTO texts*].

NFCS Objective: 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 NFCS Equivalence draft guidance and CXG 91-2017*]

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

Technical measure: Any measure other than a sanitary or phytosanitary measure as required by the importing country for the trade in food to ensure the protection of the health of consumers or fair practices in the food trade⁷. [*Derived from the WTO TBT Agreement*]

SECTION 4: PRINCIPLES

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

Equivalence

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

Experience, Knowledge and Confidence

b. Importing countries should take into account relevant experience, knowledge and confidence in the exporting country's NFCS, or relevant part, including appropriate assessments by other countries or international organizations.

Scope

c. The scope of any request and subsequent assessment should focus on those conditions of trade the exporting country considers to be unnecessarily affecting trade in the specified products.

Timeliness

d. Requests for recognition of equivalence should be made in writing by the exporting country and should be addressed in a timely manner.

Alignment with International Standards

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

Transparency and co-operation

⁷ Includes those technical regulations standards and conformity assessment procedures that are applied to the trade in food between an importing and exporting country.

f. Importing and exporting countries should cooperate in working through the process in a transparent, evidence-based and outcome-focused manner.

Demonstration of Equivalence

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

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

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

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

Documentation and maintenance

g. Importing and exporting countries should document in an agreement 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.

Technical assistance / Regulatory co-operation

h. Importing countries should, upon request, consider providing technical assistance to an exporting developing / less developed country, 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, noting that such a request may be made at any point during these discussions.

10. The initial discussions should review the nature and relevance of the conditions of trade that the exporting country considers to be unnecessarily restricting. The discussions should identify whether the measures of concern are sanitary or technical, or a potential combination of both. Both countries should consider whether there may be potential solutions or processes other than an assessment of equivalence to address these concerns.

11. The discussions should be used to refine both the scope of any consideration as well as to identify what additional information and / or objective evidence may be required for an assessment process. The discussions should identify how existing knowledge, experience and confidence, or previously exchanged information or assessments may be used, including to simplify any process.

Appropriateness of an equivalence process

12. Relevant matters for considerations as to whether an equivalence process may be the most appropriate for the conditions of trade under review may include discussions on:

- the nature and impact of the conditions of 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 conditions of trade and what other mechanisms may be available;
- what level and type of objective 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 while still ensuring the importing country's relevant NFCS objectives, and the related outcomes or level of protection are met.

Initial scope discussions

13. Initial discussions on scope should focus on both the nature of the conditions of trade and why the exporting country considers these are unnecessarily restrictive.

14. The conditions of 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 applied by the importing country. For example, they may relate to specific additional processes and inspections required to be applied by the exporting country prior to export or additional product, process or establishment approval processes, or the frequency or type of import inspection as applied by the importing country.

15. The discussions should also identify the range of products for which the exporting country is seeking equivalence. When considering scope, both countries should also discuss the resources likely to be necessary to undertake the process relative to the possible benefits.

Experience Knowledge and Confidence

16. The use of or reference to existing experience, knowledge and confidence can reduce the amount of additional information and evidence that needs to be provided by the exporting country. It can also substantially reduce the scope and associated resources and timelines for the importing country assessment and decision-making processes.

17. Initial discussions should consider how existing experience, knowledge and confidence may be used to refine the process so as to make it more efficient and less burdensome on both countries.

18. Existing experience, knowledge and confidence may take the form of, for example:

- 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, legislative underpinning 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 ISO guidelines and conformity assessment practices; and/or
- relevant assessments performed by the importing country, by recognized conformity assessment bodies, by other countries, or by international organizations.

19. 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 process applied to aspects within the scope of the request;
- the amount, nature and scope of any additional information needing to be supplied; and
- the assessment and decision-making processes.

Outcome of initial discussions

20. Where the conclusion of the initial discussions between the exporting and importing countries is that an equivalence process is the appropriate mechanism, the request for consultations with the aim of achieving an agreement on the recognition of equivalence should be submitted in writing.

21. 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 conditions of 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.

22. Where the initial discussions identify that an equivalence process is an appropriate mechanism 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.

The process steps are:

Step 1: Scope of request discussed and documented

Step 2: Importing country describes the basis of its measures

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

23. The exporting country requesting consultations with the aim of achieving an agreement on the recognition of equivalence should discuss and document both the range of products and the conditions of trade that the request covers.

24. 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 conditions of trade considered to be unnecessarily restricting trade;
- the reasons the exporting country considers the conditions of trade to be unnecessarily restrictive; and
- a brief description of the exporting country's specified alternative measures, NFCS or relevant part that the exporting country is requesting a consideration of.

25. The request for consultations should also ask the importing country to describe in writing the basis for its measures as relevant to the scope of the request.

Step 2: Importing country describes the basis of its measures

26. The importing country should discuss and document the relevant NFCS objectives, and related outcomes or level of protection, for the conditions of trade and scope of products covered by the request. This should include as appropriate:

- the scientific or policy basis justifying the necessity for the specified measures under consideration, including risk assessment where appropriate;

- how the specified measures contribute to achieving the NFCS objectives, related outcomes or level of protection⁸;
- 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 as relative to the protection of the health of consumers or ensuring fair practices in the food trade that the specified measures are intended to address;
- the justification for the specified 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.

27. For further context and to help the exporting country better tailor its case for recognition of equivalence, the importing country should also describe⁹, 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

28. The decision criteria provides 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.

29. Discussions should occur between the exporting and importing country to assist the development and better understanding of the decision criteria to be applied, which where possible should be agreed between both countries.

30. The development of the decision criteria should also involve the assessment of a relative weighting of how important each will be regarded when coming to a final conclusion.

31. Following the discussions, the importing country should document the decision criteria to be used to evaluate the request and provide these to the exporting country.

32. 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;
- how existing experience, knowledge and confidence are to be used;
- an indication of the amount or level of qualitative or quantitative evidence that is expected; and
- any indicators¹⁰ of outcomes required if these are to be used to facilitate comparisons.

33. The decision criteria should not apply a standard or level of performance that exceeds the performance the importing country's specified measures, NFCS or relevant part achieves.

Step 4: Exporting country documents its case for equivalence

34. The exporting country should submit or make available appropriate information, including relevant references and evidence 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.

35. The detailed information provided in the submission should just cover those foods and conditions of trade covered by the request for a recognition of equivalence.

36. 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.

37. 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.

⁸ Including the quantitative or proportionate effect of their contribution.

⁹ Ref: CXG 34-1999, Section 7; CXG 82-2013, paragraph 43 and CXG 89-2016 Section 7.

¹⁰ See Appendix B of CXG 91-2017 for some illustrative examples of outcomes and examples of potential indicators for those selected outcomes.

38. 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.

39. The exporting country may provide qualitative data in summary form or in a full data package, as appropriate to demonstrate performance of the exporting country's NFCS or relevant part.

40. Any quantitative supporting data referenced by the exporting country should be appropriately summarized with relevant statistical analyses provided as appropriate. Fuller data packages should be made available on request where appropriate.

41. Subject to the nature and scope of any request for recognition, additional information exchanges may be required where a more detailed assessment is considered necessary.

Step 5: Assessment process

42. 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.

43. The importing country and its assessment process should appropriately protect any commercially sensitive or confidential information as supplied by the exporting country.

44. 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.

45. Prior to initiating the 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.

46. 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.

47. The assessment process should then proceed in a timely and cooperative manner, including where any further clarifications or supplementary information is required.

48. 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 conditions of 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 alternative controls needing to be assessed;
- whether additional information or clarifications are needed; and / or
- whether an in-country visit will likely be necessary.

49. The assessment process should normally start with a desktop review of the documents submitted, taking into account any existing knowledge, experience and confidence.

50. The importing country should contact the exporting country where it requires any clarifications or further information during this phase.

51. 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 conclusion;
- the complexity of the consideration justifies additional verification as part of the assessment;
- where 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.

52. 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 an opportunity to remedy the deficiency.

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

Step 5a: Assessment process – System equivalence

Question to CCFICS26

Do we need something different here?

Step 5b: Assessment process – Equivalence of measures

Question to CCFICS26

Do we need something different here?

Step 6: Decision process and final decision

54. The importing country should consider its summarised assessment findings against the documented decision criteria with a view to producing a decision document.

55. 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 introduce an objective, outcome, standard or process in excess of what is being applied within the importing country without justification.

56. The 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 have 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.

57. The draft decision document should be consulted with the exporting country. The importing country should allow the exporting country to correct any error in fact, and in the case of a draft negative overall decision, the importing country should allow the exporting country to propose a remedy to any identified deficiency. The importing country should take any additional information provided by the exporting country into account when finalizing the decision document.

58. 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 conditions of trade between the countries. The recognition of equivalence and how it affects the conditions of trade between the two countries should then be documented in an equivalence agreement / arrangement.

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.*

59. The importing and exporting countries should document any recognition reached. This agreement / arrangement should stipulate both the scope of recognition as well as how it changes the conditions of trade in the affected commodities or products exported to the importing country.

60. The agreement / arrangement should document expectations with respect to the future maintenance of the recognition. Such 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.

61. 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;
- 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.

62. The agreement / arrangement should also address situations where more urgent actions may be justified, such as associated with individual exporter performance failures or new or emerging issues threatening the safety of the foods traded.

63. 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. These audits should focus on how the exporting country's NFCS is continuing to ensure the specified measures, NFCS or relevant part, as recognized as equivalent are continuing to be effectively applied.

Note: *The Annotated outline previously circulated contained a proposed Section 8: Maintenance of Equivalence Recognitions with the following note:*

It is suggested that this is a new section which 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*

Question to CCFICS26

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

APPENDIX 1:*To be determined:***Question to CCFICS26***Is a flow diagram useful?**If so are additional flow diagrams for different types of equivalence assessment required?***APPENDIX 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 agreement is a cooperative arrangement between the relevant competent authorities or a treaty level agreement between the governments of the two countries.

- (a) **Title:** The name given to the agreement may vary, depending on the preferences and legal requirements of the parties to the agreement/arrangement.
- (b) **Parties / Participants:** The name of the entities entering into the agreement.
- (c) **Purpose:** A brief statement of the specific purpose of the agreement.
- (d) **Scope:** Identification of the products and measures that are the subject of the agreement.
- (e) **Definitions:** Definitions of terms used in the agreement, as needed.
- (f) **Principles:** The collectively agreed principles that will apply to the administration of the agreement.
- (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 conditions of trade for the exporting country for products / measures within the scope of the agreement.
- (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. 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.
- (k) **Entry into effect:** The date on which the provisions of the agreement enter into effect.
- (l) **Signature panel:** Dates, signatures, names, titles and country / competent authority committing the respect governments or competent authorities to the agreement.