

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda item 4

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

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PROPOSED DRAFT GUIDELINES ON RECOGNITION AND MAINTENANCE OF EQUIVALENCE OF NATIONAL FOOD CONTROL SYSTEMS (NFCS)

Prepared by an electronic working group¹ 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 2023/09/OCS-FICS](#) available on the Codex webpage/Circular Letters 2023:<http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

Introduction

1. During discussion at its 21st Session, in 2014, on emerging issues and the future direction of its work, the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS21) agreed to the development of a discussion paper, to be prepared by New Zealand, on the possible development of guidance on the use of systems equivalence/comparability², especially as a means to further facilitate safe trade while better utilizing and risk targeting inspection resources.
2. At CCFICS22 (2016), the discussion paper (CX/FICS 16/22/7) and a project document (CRD11) were considered, and it was agreed to establish an electronic working group (EWG), led by New Zealand with the United States of America and Chile acting as co-chairs, to revise the discussion paper and the project document. The Committee noted that while systems equivalence was a complex topic, it was important to expand the suite of tools that recognized the ability of a competent authority to provide assurances regarding the safety of food. This work would represent the next stage of evolution of existing CCFICS texts on equivalence. CCFICS22 further noted that the development of guidance in the area of system equivalence should address the dual mandate of Codex.³
3. At iCCFICS23 (2017), the discussion paper (CX/FICS 17/23/6) and project document (CRD17)⁴were considered. It was recalled that the proposed new work would complement the other three texts that explicitly mentioned equivalence, namely: the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CXG 26-1997), the *Guidelines of Equivalence Agreements regarding Food Import and Export Inspection and Certification Systems* (CXG 34-1999) and the *Guidelines on the Judgement of Equivalence of Sanitary Measures associated with Food Inspection and Certification Systems* (CXG 53-2003). Moreover, the proposed new guidance would also fit well with the *Guidelines for National Food Control Systems* (CXG 82-2013) and the *Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food* (CXG 89-2016).

¹ The 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, Sweden, Switzerland, Thailand, United States of America, United Kingdom, and Uruguay.

² REP15/FICS, Para. 63

³ REP16/FICS, Paras. 49-52

⁴ REP17/FICS, Paras. 31-44

4. It was noted that while both CXG 26-1997 and CXG 34-1999 covered the dual mandate of Codex and anticipated the potential for systems equivalence, neither provided practical guidance on processes and procedures that could assist countries in approaching systems equivalence considerations. Further, CXG 53-2003 had limited application to overarching systems-equivalence processes as its focus was on the equivalence of specific sanitary measures. The examination of CCFICS texts had clearly shown a gap in guidance on how to initiate and conduct a systems-equivalence assessment.⁵
5. CCFICS23 expressed broad support for developing additional guidance on the use of systems equivalence and noted (among other aspects) that the “guidance would assist countries in tackling this complex issue and may reduce unnecessary trade restrictions and save competent authority resources”⁶. Following revision of the project document, the Committee agreed to forward it for approval as new work by CAC40 and to establish an EWG, chaired by New Zealand and co-chaired by Chile and the United States of America.⁷ CAC40 approved the new work in July 2017.
6. A draft proposed guidance was prepared by New Zealand with the support of Chile and the United States of America and circulated, in English and Spanish, to the EWG in October 2017. A physical working group (PWG) was convened in Santiago, Chile in December 2017. The PWG was attended by delegations from 33 Codex Members and Observers⁸, the Chairperson of CCFICS and the Codex Secretariat, with several delegations participating virtually. The PWG considered all the written comments received from the EWG and further revised the draft proposed guidance.
7. A second draft guidance based on the written comments and the discussion at the Santiago PWG was prepared by New Zealand with the support of Chile and the United States of America and circulated to the EWG, in English and Spanish, in March 2018. A further PWG was convened in Edinburgh, Scotland in May 2018. The PWG was attended by delegations from 25 Codex Members and Observers⁹, the Chairperson of CCFICS and the Codex Secretariat, with several delegations participating virtually. The PWG considered all the written comments received and further revised the draft proposed guidance.
8. At CCFICS24 (2018), the draft proposed guidelines (*Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems*) and the report of the working group (CX/FICS 18/24/4) were considered. CCFICS24 revised the proposed draft guidance and agreed to re-establish the EWG chaired by New Zealand and co-chaired by Chile and the United States of America. The EWG was tasked to continue the development of the proposed guidelines, taking into account the comments made and/or submitted at CCFICS24, for circulation and consideration at CCFICS25 with the intention to advance the draft guidance for adoption in line with the timeframe in the original project document.¹⁰
9. The Chairperson and co-chairpersons of the EWG circulated a revised draft of the proposed guidelines to the EWG¹¹ in May 2019. A number of additional questions were also posed for consideration by the EWG, including:
 - inclusion of footnotes, some with a specific reference to another CCFICS text and some providing an illustrative example;
 - inclusion and/or wording of certain definitions and principles; and
 - the order / reorder of the process steps.

⁵ REP17/FICS, Paras. 32-33

⁶ REP17/FICS, Para 38(ii)

⁷ REP17/FICS, Para 46

⁸ Australia, Argentina, Belgium, Bolivia, Canada, Chile, Colombia, Costa Rica, Denmark, Ecuador, European Union, Guyana, Guatemala, Honduras, India, Indonesia, Japan, Jamaica, Mexico, New Zealand, Nicaragua, Norway, Panama, Paraguay, Thailand, South Africa, United Kingdom, USA, Uruguay, FAO, CGF, ICGMA, and SSAFE

⁹ Australia, Argentina, Belgium, Canada, Chile, European Union, India, Ireland, Italy, Japan, Mexico, New Zealand, Netherlands, Norway, Peru, Philippines, Switzerland, Thailand, United Kingdom, USA, FAO, OIE, WTO, CGF, and SSAFE

¹⁰ REP19/FICS paras 16 – 32

¹¹ The electronic working group comprised representatives of Argentina, Australia, Brazil, Canada, Chile, Costa Rica, Dominican Republic, Ecuador, Egypt, El Salvador, European Commission, India, Indonesia, Jamaica, Japan, Kazakhstan, Republic of Korea, Mexico, Morocco, New Zealand, Nigeria, Norway, Peru, Singapore, Switzerland, Thailand, United States of America, United Kingdom, Uruguay, GFSI, and SSAFE.

10. Generally, the EWG supported the continued inclusion of footnote references to relevant CCFICS texts and the use of illustrative examples where these could facilitate understanding. The discussion at CCGP31¹² on the use of examples was also noted.
11. A further revised draft was circulated to the EWG in September 2019 for a second round of comments along with some further specific questions relating to changes to the revised text and noting the inclusion of additional guidance on the maintenance and review of recognitions of equivalence.
12. The responses and suggestions from the EWG were incorporated into the *Draft Guidelines on recognition and maintenance of equivalence of National Food Control Systems (NFCS)* attached to agenda paper (January 2020) as Appendix 1.
13. Formal comments on CX/FICS 20/25/6 were requested via a circular letter (CL 2020/02 FICS) with a closing date of 1 May 2020. Comments were received from 20 Codex Members and two observer organizations¹³ and were published as CX/FICS 20/25/6 Add 1, with an additional note advising that following the rescheduling of CCFICS25 to 2021 (due to the COVID-19 pandemic) the EWG was continuing its work including addressing the comments received.
14. In July 2020, a table of the CX/FICS 20/5/6 Add 1 comments, with a response to each, was circulated to the EWG along with an amended draft of the guidelines reflecting the comments received.
15. Responses were received from 11 Members of the EWG. Based on these comments and following further discussion between the Chairperson and co-chairpersons, and clarification of some country comments, a further refinement of the draft was developed and circulated in March 2021 as CX/FICS 21/25/6. Formal comments on were requested via circular letter (CL 2021/17/OCS-FICS) with a closing date of 30 April.
16. The EWG met virtually on 23 March 2021. 65 Codex Members and Observers, the Chairperson of CCFICS and the Codex CCFICS secretariat attended the meeting. The objectives of the meeting were to provide an opportunity for further discussion and any necessary clarifications prior to the closing date for comments in response to CL 2021/17/OCS-FICS. The report of the EWG informal virtual meeting was presented at CCFICS25 as CRD 02¹⁴.
17. Comments in response to CL 2021/17/OCS-FICS were received from 16 Codex Members and one Observer organization¹⁵ and were published as CX/FICS 21/25/6 Add.1. The EWG Chairperson and co-chairpersons reviewed the comments and prepared a revised draft of the guidelines presented at CCFICS25¹⁶ as CRD04.
18. At CCFICS25 (2021), it was agreed to use CRD04 as the basis for discussion. Following discussion and review of Section 1, 2 and 3 the Committee identified some outstanding issues that required further consideration and at the recommendation of the Chair of CCFICS agreed to convene an In-session Working Group (IWG). CCFICS25 considered the report of the IWG¹⁷ (CRD21) noting that while progress had been made some differences still existed. There were also mixed views on how to proceed. Several delegations noted that the IWG did not review the entire CRD0 4 text and that there had not been sufficient time for the Committee to fully review the IWG report (CRD21), to ensure all concerns had been addressed.
19. The Committee agreed to return the proposed draft guideline to Step 2/3 for redrafting and to clarify the issues raised. CCFICS25 re-established an EWG chaired by New Zealand and co-chaired by the United States and Kenya, and also that an extension of time should be requested.¹⁸ The extension of time was approved by CAC44 (November 2021).

Post CCFIC25 approach and working group discussion

20. Codex member and observers were invited to register (by 31 July 2021) to participate in the re-established EWG and in August 2021 members were invited to consider and provided comments on the revised draft guideline attached to CCFICS25 CRD21, including whether it had addressed the matters raised at CCFICS25. While the EWG was formally working in English only, CRD21 was available in English,

¹² REP19/GP, Para 27-39

¹³Canada, Colombia, Ecuador, Denmark, European Union, Honduras, Indonesia, India, Iraq, Japan, Mauritius, Mexico, Nicaragua, New Zealand, Norway, Paraguay, Switzerland, Thailand, United States of America, Zambia, FAO, and CCTA.

¹⁴ CCFICS25/CRD02

¹⁵Australia, Canada, Chile, Cook Islands, Ecuador, European Union, Honduras, Iran, Iraq, Japan, Mexico, New Zealand, Peru, Republic of Korea, Thailand, United States of America, and FAO.

¹⁶ CCFIC25/CRD04

¹⁷ CCFICS/CRD21

¹⁸ REP21-FICS, paragraph 84.

Spanish and French and EWG members were able to provide comments in any of these languages. By the closing date of 15 October 2021, comments from six members of the EWG were received.

21. Following the final scheduling of CCFICS26 to 2023, a revised draft of the guideline was circulated to the EWG in May 2022 along with a table setting out proposals prepared by the EWG Chairperson and co-Chairpersons to address the comments and concerns expressed by the EWG in respect of the IWG report as well as further edits to address the CCFICS25 discussion and report. The EWG was invited to provide comments by 10 June 2022 along with response to three specific questions.

Virtual workshop on Equivalence – September 2022

22. In August 2022 an invitation was issued to all Codex Members and Observers to attend a CCFICS workshop on equivalence, to be held virtually on 21 September 2022 in English and Spanish.

23. 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.

24. 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, with responses received on the April 2022 draft guideline, and the responses to the specific questions in the draft guideline. The paper also identified a number of issues for consideration at the workshop. These included:

- interface with the WTO SPS and TBT Agreements;
- how to best keep the guidance and the terms used broad enough to cover equivalence considerations across the full scope of NFCSs;
- definitions – getting the right balance of defined terms and further contextual explanations in the main text where necessary;
- the description of the initial discussions between parties and the right to make a request for consideration of equivalence; and
- the continued necessity for text in the guideline that highlighted the differences between the two WTO Agreements especially as these applied to decision criteria.

25. The Chairperson and co-chairs were very appreciative of the comments received and the discussion at the workshop which they noted had greatly assisted in the preparation of the revised *Draft Guidelines on Recognition and Maintenance of Equivalence of NFCS*, circulated on 30 September 2022 with a request for comments by 31 October 2022. It was noted that the following aspects were now included in the revised draft:

- The paragraph numbers have been updated to now run consecutively throughout the draft (please note that this means the paragraph numbering is different to that in the comments table).
- The word *achieve / achieving* is now used in place of *meet / meeting* in relation to objectives and is used consistently throughout the document.
- The definitions have been kept short on the understanding that any necessary additional explanation is provided later in the text.
- Consistent with the above and as discussed at the workshop, while the definitions and some of the higher-level statements continue to refer to *achieving the objectives*, where the intent of the subsequent paragraphs is to explain how this may be more fully described or achieved the expanded format of *objectives, and related outcome or level of protection*, is then used. Noting also that level of protection is a way to express the desired or intended outcome thus the use of the word “OR”.
- As relevant to the context of the specific paragraph the phrase *NFCS in whole or the relevant part* is used when referencing the NFCS.
- Section 5.1 (Step 1 Initial Discussions, Scope and Decision to Commence) includes a footnote to the opening sentence *Noting that countries may formalise a request at any point* in recognition that this

should be clear at the beginning of this section rather than at the end. Consistent with the wider discussion that the guidance should not directly reference or contradict anything in one of the WTO agreements.

- Similarly, Section 5.3 (Step 3 The Decision Criteria for Comparison) has been edited so that the reference to the WTO SPS and TBT Agreements are not required. Noting that the objective of the protection of the health of consumers and the concept of level of protection are common to both.
- The draft contains two potential question that could be taken forward to CCFICS 26 if that is the recommendation of the EWG. Both questions relate to whether or not the referred list of examples should be retained.

26. Based on the EWG comments received the final draft of the guideline is attached as Appendix 1 for consideration by CCFICS26.

Conclusion

27. The EWG Chairperson and co-chairpersons acknowledge and thank the Codex Members and Observer organisations for their ongoing and continued engagement during the long development process and multiple rounds of comment on these guidelines. This has provided opportunity for members to ask questions and seek clarifications on the often complex matter of equivalence recognition. Most members have now expressed support for progressing and completing these guidelines.

28. It is the view of the EWG Chairperson and co-chairpersons that given the extensive work undertaken by working groups and by previous sessions of CCFICS the tasking given to it by the CCFICS and the CAC has been fulfilled and the draft has reached a stage where it is now appropriate for CCFICS to recommend accelerated progress within the step process to steps 5/8.

Recommendations

29. The Committee is invited to:

- i. note the extensive work undertaken to date and the level of support for completing this guideline; and
- ii. consider recommending the accelerated advancement to steps 5/8 of the proposed *Draft Guidelines on recognition and maintenance of equivalence of National Food Control Systems (NFCSs)* as contained in Appendix 1.

APPENDIX 1

Proposed Draft Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems (NFCS)**(Step 3)****SECTION 1 – PREAMBLE**

1 Recognition of the equivalence of the whole or a part of an exporting country's National Food Control System (NFCS)¹, as relevant to the trade in foods under consideration, can provide an effective means for minimizing unnecessary duplication of controls, while protecting the health of consumers and ensuring fair practices in the food trade. The recognition of equivalence, where 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 (for example: recognition of lists of eligible export establishments; alternative processing and inspection procedures; or a reduced intensity and frequency of routine port of entry inspection).

2 These guidelines are intended to 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* (CAC/GL 26-1997), and the *Guidelines for Food Import Control Systems* (CAC/GL 47-2003).

3 The consideration, assessment, recognition, and maintenance of the equivalence of one country's NFCS in whole or the relevant part is independent of any reciprocal process occurring. Reciprocal considerations, where requested, may have different scopes and durations and may also arrive at different conclusions.

SECTION 2 – PURPOSE

4 These guidelines provide practical guidance, information and recommendations for importing and exporting countries to use when considering the appropriateness and/or scope of, as well as the process for assessing, recognising and maintaining the equivalence of the whole or a part² of the NFCS at the system level.

5 A request for a recognition of equivalence may 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

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

Outcome: Intended effects or results that contribute to achieving the relevant NFCS objectives.

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.

SECTION 4 – PRINCIPLES

6 Consideration of the recognition of the equivalence of a NFCS should be based on the application of the following principles:

Equivalence of National Food Control Systems (NFCS)

a. Countries should recognize that NFCS's, or the relevant parts thereof, of importing and exporting countries, although designed and structured differently, may be capable of achieving the same objectives, and related outcomes or level of protection, with respect to protecting the health of consumers and ensuring fair practices in the food trade and can therefore be found to be equivalent.

Experience, Knowledge and Confidence

b. Countries should consider relevant experience, knowledge and confidence and may consider appropriate assessments by other countries or international organizations.

¹ Principles and guidelines for National Food Control Systems (CXG 82-2013)

² For example, an equivalence request could be limited to assurances associated with a specified sector such as seafood, or further refined to a subsector such as aquaculture or a processing type such as canned seafood. A request for equivalence recognition could cover a horizontal process for providing assurances such as the recognition of regulatory controls for sampling protocols and/or laboratory or specific methodology approvals.

Alignment with International Standards

c. 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 NFCS, or the relevant part.

Assessment

d. The assessment process should evaluate whether the relevant objectives, and related outcomes or level of protection, of the importing country's NFCS are achieved and the process should be documented; transparent; evidence-based; outcome-focused; efficient; and be conducted in a cooperative and timely manner.

Final documentation

e. The importing and exporting countries should document any recognition reached, including how the recognition of equivalence will be implemented and maintained for the trade in food between the countries.

SECTION 5 – PROCESS STEPS

7 The following process steps relate to the consideration, assessment, recognition and maintenance of the equivalence of NFCSs.³

Step 1: Initial discussions, scope and decision to commence

Step 2: Description of the importing country's NFCS and the relevant objectives

Step 3: The decision criteria for comparison

Step 4: Description of exporting country's NFCS or relevant part

Step 5: Assessment process

Step 6: Decision process

Step 7: Final documentation

5.1 STEP 1: INITIAL DISCUSSIONS, SCOPE AND DECISION TO COMMENCE

Initial discussions

8 Prior to a country requesting consultations on the recognition of the equivalence of its NFCS or the relevant part, it is recommended that initial discussions take place between the relevant competent authorities of both countries⁴. These discussions can help identify if commencing an assessment of the equivalence of the exporting country's NFCS is the most appropriate approach or whether some other mechanism⁵ would be better to address the matters under discussion.

9 Relevant matters for the initial discussions may include⁶:

- whether recognition of the equivalence of the NFCS or the relevant part will likely result in cost and resource savings, reduced duplication of control activities and/or removal of unnecessary impediments to trade, while protecting the health of consumers and ensuring fair practices in the food trade;
- the potential scope of an equivalence request;
- experience, knowledge and confidence derived from, for example: the history and level of trade between the countries; the history of compliance with the importing country's requirements; the level of familiarization and/or cooperation between the competent authorities; and the exporting country's trade in the same or similar products with other countries⁷;

³ The principles and processes described in CXG 89-2016 are also useful in informing the exchange of information.

⁴ Noting that countries may make a request for consultations on equivalence at any point during the initial discussions.

⁵ Examples of other mechanisms include but are not limited to: The exchange of information to support trade; equivalence of a specific sanitary measure or group of measures; compliance with importing county requirements; harmonisation of requirements; mutual recognition; memoranda of understanding; or assurances based on some other means acceptable to both countries.

⁶ Paragraphs 9 and 11 of CXG 34-1999 and paragraph 3 of the Appendix of CXG 53-2003 provide additional guidance.

⁷ Paragraph 10 of the Appendix to CXG 53-2003 provides some further possible examples which may or may not be relevant depending on the circumstance.

- the different level of development between the countries NFCS⁸;
- the similarity of design of each country's NFCS in whole or the relevant part including the legislative framework and the relevant objectives, and related outcomes or level of protection;
- the similarity to or harmonisation of the whole or the relevant part of the NFCS with standards, guidelines, and/or codes of practice from Codex or other recognized relevant international standard setting bodies; and
- the information exchanges and assessments that may have already occurred (e.g. in accordance with CXG 89-2016) or the existence of other relevant recognitions of equivalence between the two countries or with third countries.

Scope Considerations

10 During the initial discussions exporting and importing countries should determine the appropriate scope for the assessment. The scope may relate to an entire NFCS or only to that part of a NFCS relevant to the foods and conditions of trade to be covered by the request.

11 Relevant considerations in determining the scope may include:

- the range of products currently being traded between the countries and/or products proposed for future trade⁹;
- identification of 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;
- the range of NFCS assurances to be addressed (e.g. food safety, qualitative claims, labelling, or other matters relating to technical regulations, conformity assessment procedures or standards);
- the level of trust and confidence in the performance of the exporting country's NFCS in whole or the relevant part relating to those products already being traded or those proposed for future trade; and
- the availability of resources likely to be necessary to undertake the process as it relates to the whole or the relevant part of the NFCS proposed to be considered and the possible benefits.

12 Discussions on scope should identify those areas where there may already be sufficient existing experience, knowledge and confidence versus those areas where additional information exchanges are likely to be required¹⁰.

Decision whether to commence

13 Where the conclusion of the initial discussions between the exporting and importing countries is that a recognition of equivalence is the appropriate mechanism, the request for consultations should be made and submitted in writing including a description of the scope of products and conditions of trade to be covered.

14 The two countries may then agree on a plan for undertaking the assessment which may include for example, timeframes and if necessary, priorities.¹¹

15 Where the initial discussions between the two countries conclude that an assessment of the equivalence of the exporting country's NFCS is not the most appropriate mechanism, the countries may wish to consider working jointly towards some other mechanisms to help facilitate the trade. Alternative mechanisms to address the matters discussed could be considered. CXG 34/1999 (paragraph 11) also identifies that amongst other things, information exchange, joint training, technical cooperation and support, and the development of infrastructure and strengthening of the food control systems can serve as building blocks for a future request for recognition of the equivalence of systems.

⁸ See also paragraph 15.

⁹ Paragraph 5 of CXG 34-1999.

¹⁰ See CXG 53-2003 paragraphs 11 and 12 and paragraphs 9-13 of the Appendix for additional guidance.

¹¹ Paragraph 4(d) of Appendix to CXG 53-2003 and Paragraph 8 and 9 of CXG 34/1999 refers.

5.2 STEP 2: DESCRIPTION OF THE IMPORTING COUNTRY'S NFCS AND THE RELEVANT OBJECTIVES

16 As relevant to the scope of the request and to facilitate the exporting country in describing its own systems, the importing country should provide information to describe, with appropriate references, the related elements with the objectives, and relevant outcomes or level of protection, of its NFCS that are to be part of the assessment for example:¹²

- regulatory and legislative framework;
- control and approval requirements (for example establishment, process and product programs);
- verification or conformity assessment, and audit programs;
- monitoring, surveillance, investigation and food safety incident response programs;
- enforcement and compliance programs;
- stakeholder engagement, communication and rapid alert systems;
- system overview monitoring and evaluation programs, or existing conformity assessment procedures; or
- any other elements directly relevant to the specific products or programs under consideration.

17 In describing its own NFCS or the relevant part, the importing country may include reference to relevant standards, guidelines, and/or codes of practice from Codex or other recognised international standard setting bodies.

5.3 STEP 3: THE DECISION CRITERIA FOR COMPARISON

18 Once the request for consultations on a recognition of equivalence of a NFCS or the relevant part has been made, the importing country should document the decision criteria to be used to evaluate the exporting country's NFCS or relevant part associated with the scope of the request. The criteria should reference the relevant objectives, and related outcomes or level of protection, that must be shown to be achieved for recognition of equivalence. The decision criteria document should be provided to and discussed with the exporting country in a cooperative manner.

19 The decision criteria should facilitate the importing country's assessment process being able to determine 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.¹³

20 The decision criteria may be qualitative or quantitative and may include for example:

- the level of qualitative or quantitative evidence that is expected;
- the indicators¹⁴ of outcomes if these are to be used to facilitate comparisons;
- the level of protection achieved by the importing country's NFCS or relevant part, and
- how experience, knowledge and confidence are to be used.

21 The decision criteria should focus on the performance of the NFCS in whole or the relevant part as opposed to individual procedures or measures.

22 Where the objectives of any part of the NFCS under consideration relate to the protection of the health of consumers the decision criteria should focus on whether the exporting country NFCS in whole or the relevant part achieves the level of protection as set by the importing country.

23 Where the objectives of any part of the NFCS under consideration relate to matters set out in technical regulations, conformity assessment procedures, or standards, the decision criteria should focus on whether the exporting country's NFCS in whole or the relevant part adequately achieves the relevant outcomes associated with the objectives of the importing country's NFCS.

24 The decision criteria should not apply a standard or level of performance in excess of that which the

¹² ref: CXG 34-1999, Section 7; CXG 82-2013, paragraph 43 and CXG 89-2016 Section 7

¹³ 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).

¹⁴ See Appendix B of CXG 91-2017 for some illustrative examples of outcomes and examples of potential indicators for those selected outcomes.

importing country's NFCS or relevant part achieves as it relates to the protection of the health of consumers and ensuring fair practices in the food trade.

5.4 STEP 4: DESCRIPTION OF EXPORTING COUNTRY'S NFCS OR RELEVANT PART

25 The exporting country should make available appropriate information, including relevant references and evidence that describes the exporting country's NFCS or the relevant part and demonstrates how it achieves the objectives, and related outcomes or level of protection, of the importing country's NFCS or relevant part for the foods and conditions of trade covered by the request.

26 As far as practical, and especially where consistent with the relevant Codex guidance, importing countries should allow flexibility in the format of the information submitted by the exporting country.¹⁵

27 Taking into consideration the scope of the request for recognition of equivalence and existing experience, knowledge and confidence, additional information exchanges may be required for those matters or elements of the exporting country NFCS which need to be subjected to a more detailed assessment.

5.5 STEP 5: ASSESSMENT PROCESS

28 Once the relevant information and evidence are available the assessment process can proceed. The methodology used in the assessment process by the importing country should be transparent and evidence-based. The importing country should focus its assessment on determining whether the exporting country's NFCS in whole or the relevant part meets the decision criteria. There should be an effective communication mechanism between both countries, for providing feedback.

29 The assessment process will normally comprise a number of steps. The exact process may vary depending on: the type of foods in the scope of the request and the complexity of controls; any pre-existing experience, knowledge and confidence; and the particular modification to existing trade conditions being sought. In general, the importing country should:

- consider whether the information submitted by the exporting country or otherwise available is sufficient to enable an appropriate assessment;
- proceed with an assessment applying the decision criteria and requesting additional information if deemed necessary;
- consider any additional information submitted by the exporting country at the request of the importing country that could facilitate the assessment process;
- where appropriate, convey to the exporting country any information for the addition of one or more specific controls to their NFCS that could facilitate the assessment process;
- consider any additional controls proposed by the exporting country to facilitate a positive determination.

30 The importing country's assessment process should:

- focus on whether the exporting country's NFCS in whole or the relevant part achieves the objectives, and related outcomes or level of protection, of the importing country's NFCS or the relevant part in accordance with the decision criteria (as opposed to whether specific procedures or functions, undertaken by certain parties in the importing country, are replicated);
- allow for indicators of outcomes different to the importing country's to be used by the exporting country to demonstrate the performance of its NFCS in whole or the relevant part to achieve the importing country's objectives, and related outcomes or level of protection;
- weigh the outcome of the various elements of the exporting country's NFCS relative to their impact on achieving the objectives and or overarching goals of the importing country's NFCS or relevant part;
- be conducted in a cooperative and timely manner and may include the review of documents, and the use of in-country assessments / audits¹⁶ where justified as necessary;
- allow for regular discussion / consultations between the countries and the provision of clarifications and / or supplementary information as required; and
- appropriately protect commercially sensitive and confidential information.

¹⁵ See Paragraph 6 d) of CXG 89-2016

¹⁶ See the Annex to CXG 26/1997 for further guidance on the conduct of assessments

31 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 improvement¹⁷; and
- the availability of resources and infrastructure to continue to implement the NFCS or the relevant part.

32 Meetings between the importing country assessors and the exporting country's competent authority may assist the assessment process and their potential use should be included in the planning for the equivalence of systems assessment, as appropriate. Countries are encouraged to communicate and conduct meetings electronically, where practicable. Where relevant, the provision of technical assistance may also be used to support the assessment process.¹⁸

5.6 STEP 6: DECISION PROCESS

33 The decision process should:

- be transparent and conducted in a timely manner; and
- 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.

34 The importing country should document the draft assessment conclusion and the rationale and the exporting country should be given the opportunity to comment on the draft conclusions. In the case of an initial finding that the exporting country's NFCS or the relevant part is assessed as not equivalent, the exporting country should have the opportunity to provide additional information for consideration by the importing country prior to the finalization of the decision.

35 In the case where the exporting country's NFCS or the relevant part is 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. Subsequent additional information should be reviewed by the importing country without requiring all aspects of the assessment process to be repeated. The importing country should document the final assessment conclusions and the associated rationale.

5.7. STEP 7: FORMALIZATION AND MAINTENANCE OF THE RECOGNITION

36 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 done for example, through an exchange of letters or through the negotiation of a more comprehensive equivalence agreement or arrangement¹⁹.

37 The documentation of the recognition of the equivalence of systems should include provisions on maintenance and review of the recognition. Maintenance of recognition arrangements should allow regulatory frameworks, programs and oversight to evolve over time. The documentation should include what level of change to the exporting country's NFCS or other changes in circumstance requires notification to the importing country and when a review of the recognition of equivalence may be required.

38 The countries should document their expectations with respect to ongoing communication and cooperation.

39 Maintenance and review of recognitions of the equivalence of NFCS may include activities such as:

¹⁷ Paragraph 36, CXG 82-2013

¹⁸ Examples could include technical exchanges to help facilitate better understanding of each country's systems, or assistance with making changes to those parts of the NFCS that are identified during the assessment process as needing further development.

¹⁹ Although this guideline refers to "countries" and "agreements," in many cases the relevant competent authorities will enter into agreements or other arrangements. CXG 34-1999 Appendix A provides a list of information that could, as appropriate, be included in an equivalence agreement.

- regular provision of summary information on the performance of the NFCS or the relevant part;
- advice of and potential review of 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;
- regular technical discussions between relevant experts; and
- intermittent country visits or technical exchanges so as to maintain the currency of experience, knowledge and confidence.²⁰

²⁰ See Section 1(2) of the Annex to CXG 26-1997 (*Principles and Guidelines for the Conduct of Assessments of Foreign Official Inspection and Certification Systems*)

Figure 1: Equivalence of National Food Control Systems Process

Simplified flow chart for recognition and maintenance of equivalence of NFCS
(individual steps may be iterative)

