

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
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World Health  
Organization

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Agenda item 6

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

Twenty-fifth Session

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### PROPOSED DRAFT GUIDELINES ON RECOGNITION AND MAINTENANCE OF EQUIVALENCE OF NATIONAL FOOD CONTROL SYSTEMS (NFCS) (UPDATED)<sup>1</sup>

Prepared by an electronic working group<sup>2</sup> led by New Zealand with the United States of America and Chile

(At Step 3)

Codex members and Observers wishing to submit comments at Step 3 on this draft should do so as instructed in CL 2021/17/OCS-FICS available on the Codex webpage/Circular Letters 2021:  
<http://www.fao.org/fao-who-codexalimentarius/circular-letters/en/>

#### Introduction

1. During discussion at its 21<sup>st</sup> 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 (CCFICS) 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/comparability<sup>3</sup>, especially as a means to further facilitate safe trade while better utilizing and risk targeting inspection resources.
2. At its 22<sup>nd</sup> Session (2016), CCFICS considered the discussion paper (CX/FICS 16/22/7) and a project document (CRD11) and 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.<sup>4</sup>
3. At its 23<sup>rd</sup> Session (2017), CCFICS considered the discussion paper (CX/FICS 17/23/6) and project document (CRD17)<sup>5</sup>. It was recalled that the 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).
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

<sup>1</sup> This Updated document takes into account the comments solicited through CL 2020/02/OCS-FICS

<sup>2</sup> 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, FAO, GFSI, SSAFE.

<sup>3</sup> REP15/FICS, Para. 63

<sup>4</sup> REP16/FICS, Paras. 49-52

<sup>5</sup> REP17/FICS, Paras. 31-33

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. 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”<sup>6</sup>. 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.<sup>7</sup> 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 observers<sup>8</sup>, the Chairperson of CCFICS and the Codex Secretariat, with several delegations participating via webinar technology. 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 observers<sup>9</sup>, the Chairperson of CCFICS and the Codex Secretariat, with several delegations participating via webinar technology. The PWG considered all the written comments received and further revised the draft proposed guidance.
8. At its 24<sup>th</sup> Session (2018), CCFICS considered 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). 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 CCFIC25 with the intention to advance the draft guidance to adoption in line with the timeframe in the original project document.<sup>10</sup>

#### **Post CCFIC24 approach and working group discussion**

9. The Chairperson and co-chairpersons of the EWG took into account the additional comments submitted to and made at CCFICS24 and circulated a revised draft of the proposed guidelines to the EWG<sup>11</sup> in May 2019.
10. A number of additional questions were also posed for consideration by the EWG, including:
  - acceptability of specific words or phrases to be used consistently throughout the text;
  - 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;
  - the order / reorder of the process steps; and
  - requesting suggestions for examples to illustrate the concept of ‘decision criteria’ and how variability and uncertainty estimates could influence the assessment process.

<sup>6</sup> REP17/FICS, Para 38

<sup>7</sup> REP17/FICS, Para 46

<sup>8</sup> 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, SSAFE

<sup>9</sup> 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, SSAFE

<sup>10</sup> REP19/FICS paras 16 – 32

<sup>11</sup> 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, SSAFE.

11. 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 CCGP31<sup>12</sup> on the use of examples was also noted.
12. The inclusion of a specific definition for 'National Food Control Systems' and the wording of a definition for 'Decision Criteria' generated a range of views. There was consensus that a specific definition of 'National Food Control System' was not needed.
13. The reorder of the process steps and the reworking of section 5 were generally supported with helpful editorial suggestions also being provided.
14. When commenting on the definition for NFCS Objective, there was a suggestion to replace the word 'objectives' with 'outcomes' throughout the text. This was not accepted as a wholesale change and was explained to the EWG noting the definition was drafted to align with existing text (CAC/GL 82-2013) recognising it uses 'objective' and 'goal' interchangeable in sections 3 and 4.1 but also gives a hierarchy by stating in section 2 that the objective of a NFCS is protection of health of consumers and ensuring fair practices in food trade. Section 4.2 (System Design) then links the ability to achieve the system objectives with elements of the system as described in that section. Objectives is therefore at the higher level and is the starting point in assessing equivalence as one needs to know the objective to be able to judge if a particular outcome is actually contributing to achieving the objective.
15. All of the comments received along with a response to each and a further revised draft was again circulated to the EWG in September 2019 for a second round of comment along with some further specific questions relating to changes to the revised text including the:
  - wording of the definition for 'Decision criteria';
  - refinement of illustrative examples in specific footnotes; and
  - inclusion of additional guidance on the maintenance and review of recognitions of equivalence.
16. 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 CX/FICS 20/25/6 (January 2020) as Appendix 1. The agenda paper noted that the draft guidelines had been refined and:
  - continued to address the dual mandate of Codex;
  - included definitions proposed as necessary for this guidelines;
  - the explanation of the process steps included a limited number of illustrative examples, sufficient to provide practical assistance to Codex members without placing an undue burden on either party;
  - avoided duplication of guidance in other existing Codex texts on equivalence to the maximum extent possible; and
  - removed text in square brackets (i.e., [ ]) except for one instance (paragraph 10 2nd bullet – referring to international standards) which was drawn to the committees attention for consideration.
17. 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 organizations<sup>13</sup> 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.
18. In July 2020, a table of the CX/FICS 20/25/6 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. The EWG was asked to consider if further examples of decision criteria should be included and if so to make a suggestion.
19. 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 has been developed. This refined draft includes:
  - a revised Preamble/Introduction to improve clarity and provide (as requested) some examples of the potential benefits of equivalence;

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<sup>12</sup> REP19/GP, Para 27-39

<sup>13</sup>Canada, 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

- further clarification of the possible matters that may arise or be addressed in Step 1 of the process (Initial discussions, scope and decision to commence);
- more neutral language regarding which trading partner may suggest holding an initial discussion;
- some additional clarification regarding how existing experiences, knowledge and confidence, and requests for additional information exchanges could be handled in step 4 (Description of exporting country NFCS);
- further guidance on the decision process outcome.

20. The updated draft is attached as Appendix 1

21. A virtual working group meeting will be held on 23 / 24 March 2021 for 3 hours in accordance with the specific time zones set out in the invitation issued by the Codex Secretariat. This virtual meeting will provide an opportunity for discussion and any necessary clarifications prior to the closing date for formal country comments on the draft presented as Appendix 1.

22. The EWG Chairpersons acknowledges and thanks 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. It therefore remains the view of the eWG Chair 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 consider recommending accelerated progress within the step process.

### **Recommendations**

23. The Committee is invited to:

- i. consider the revisions to the draft guidelines following the EWG review of the formal country comments submitted in 2020 and indicate their views on these;
- ii. note the extensive work undertaken to date and the level of support for completing this guidelines; and
- iii. consider the appropriateness of recommending the accelerated advancement of the proposed *Draft Guidelines on recognition and maintenance of equivalence of National Food Control Systems (NFCSs)* as contained in Appendix 1.

## APPENDIX 1

**DRAFT GUIDELINES ON RECOGNITION AND MAINTENANCE OF EQUIVALENCE OF NATIONAL FOOD CONTROL SYSTEMS (NFCS)****(STEP 3)****SECTION 1 – PREAMBLE / INTRODUCTION**

1 Most trade in food occurs without exporting countries being required to undergo a detailed assessment of their National Food Control System (NFCS)<sup>1</sup> or assessments of product specific Inspection and Certification systems. However, some importing countries do require exchange of information, assessment and or assurances from the exporting country's competent authority to support the trade in certain foods. Such processes may relate to both the protection of the health of consumers and ensuring fair practices in the food trade.

2 Several mechanisms already outlined in existing Codex guidelines may facilitate the exchange and assessment of additional information between competent authorities where required. For example, CXG 89-2016<sup>2</sup> provides guidance on the exchange of information on the whole or parts of NFCS between importing and exporting countries to support trade in food, CXG 26-1997<sup>3</sup> provides guidance on, the assessment of a Food Inspection and Certification System, and CXG34-1999 on the development of equivalence agreements<sup>4</sup>. Countries may also use CXG 53-2003<sup>5</sup> where a more specific evaluation of a single sanitary or group of sanitary measures associated with Food Inspection and Certification Systems is justified.

3 Recognition of the equivalence of the whole or a part of an exporting country's NFCS as relevant to the trade in foods under consideration can also provide an effective means for protecting the health of consumers and ensuring fair practices in the food trade while minimizing unnecessary duplication of controls. The recognition of equivalence, where it occurs, should result in both positive changes to the conditions of trade and should 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 reduced rates of port of entry inspection).

4 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 / SCOPE**

5 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 part of the NFCS at the system level.

6 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 and include the entire NFCS or a part of a NFCS as relevant to the trade in foods and the conditions of trade covered by the request.<sup>6</sup>

**SECTION 3 – DEFINITIONS**

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

NFCS Objectives: The intent or purpose of the core elements of the NFCS or the relevant part including how

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<sup>1</sup> Principles and guidelines for National Food Control Systems (CXG 82-2013)

<sup>2</sup> Principles and guidelines on the Exchange of Information between Importing and exporting Countries to Support Trade in Food (CXG 89-2016)

<sup>3</sup> Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems (CXG 26-1997)

<sup>4</sup> Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CXG 34-1999)

<sup>5</sup> Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (CXG 53-2003)

<sup>6</sup> 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.

these contribute to the overarching goals of the NFCS to protect the health of consumers<sup>7</sup> and ensure fair practices in the food trade.

**Outcome:** Intended effects or results that contribute to achieving the NFCS objectives. Outcomes may be categorized at different levels, such as ultimate, high-level, intermediate, preliminary, or initial.<sup>8</sup>

**Decision Criteria:** Those factors used to determine whether the exporting country's NFCS or relevant part meet the objectives of the importing country's NFCS or the relevant part for the products under consideration.

## **SECTION 4 – PRINCIPLES**

7 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 meeting the same NFCS objectives 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.

### ***Alignment with International Standards***

c. The use of or reference to Codex standards, guidelines, and/or codes of practice 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 NFCS objectives of the importing country are met and the process should be documented; transparent; evidence-based; outcome-focused; efficient; and be conducted in a cooperative and timely manner.

### ***Formalisation and Maintenance of Recognition***

e. The importing and exporting countries should document and formalise 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**

8 The following process steps relate to consideration, assessment, recognition and maintenance of the equivalence of NFCSs.<sup>9</sup>

**Step 1: Initial discussions, scope and decision to commence**

**Step 2: Description of the importing country's NFCS 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: Formalization and maintenance of the recognition**

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<sup>7</sup> The World Trade Organisation Sanitary and Phytosanitary Agreement refers to this as the country's appropriate level of sanitary protection where the conditions of trade fall within its scope of application.

<sup>8</sup> CXG 91-2017

<sup>9</sup> The principles and processes described in CXG 89-2016 are also useful in informing the exchange of information.

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

### Initial discussions

9 Prior to a country formally requesting consultations on the recognition of the equivalence of its NFCS or the relevant part, initial discussions should take place between the relevant competent authorities of both countries. These discussions should identify if commencing an assessment of the equivalence of the exporting country's NFCS is the most appropriate approach or whether some other mechanism<sup>10</sup> would be better to address the matters under discussion.

- 10 Relevant matters for the initial discussions may include<sup>11</sup>:
- the bilateral justification and appropriateness of the identified conditions of trade considered by the exporting country to be unnecessarily impeding trade;
  - 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 general trading history;<sup>12</sup>
  - the different level<sup>13</sup> of development between the countries<sup>13</sup>;
  - the similarity of design of each country's NFCS in whole or the relevant part including the legislative framework and NFCS objectives;
  - the similarity to or harmonisation of the whole of parts of the NFCS with the relevant international standards;
  - 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; 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

11 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 trade in foods and conditions of trade to be covered by the request.

- 12 Relevant considerations in determining the scope may include:
- the range of products currently being traded between the countries and/or products proposed for future trade<sup>14</sup>;
  - those requirements (conditions of trade) considered by the exporting country to be unnecessarily impeding trade;
  - the range of assurances to be addressed (e.g. food safety, qualitative claims, labelling, or other matters relating to NFCS objectives);
  - 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

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<sup>10</sup> Examples of other mechanisms include, but are not limited to: The exchange of information to support trade; equivalence of a 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.

<sup>11</sup> Paragraphs 9 and 11 of CXG 34-1999 and paragraph 3 of the Appendix of CXG 53-2003 provide additional guidance.

<sup>12</sup> 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.

<sup>13</sup> See also paragraph 16

<sup>14</sup> Paragraph 5 of CXG 34-1999

trade; and

- the availability of resources likely to be necessary to undertake the process as it relates to the whole or a relevant part of the NFCS proposed to be considered and the possible benefits.

13 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 required<sup>15</sup>.

### **Decision whether to commence**

14 At the conclusion of the initial discussions between the exporting and importing countries and where it is considered that:

- an assessment of the equivalence of the NFCS is an appropriate mechanism;
- there is a likelihood of success; and
- the potential benefits and resource savings that can be achieved justify the cost and resource implications of the process;

the request for a recognition of equivalence should be formalised and include a description of the scope of products and conditions of trade to be covered.

15 The two countries should then agree on a plan for undertaking the assessment which may include for example, timeframes and if necessary, priorities. <sup>16</sup>

16 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 arrangement to help facilitate the trade. Alternative mechanisms to address the matters discussed could be considered, as noted in footnote 10. CXG 34/1999 (paragraph 11) also identifies that amongst other things, information exchange, joint training, technical cooperation, and the development of infrastructure and food control systems can serve as building blocks for a future request for recognition of the equivalence of systems.

## **5.2 STEP 2: DESCRIPTION OF THE IMPORTING COUNTRY'S NFCS AND ASSOCIATED OBJECTIVES**

17 The importing country should identify those elements of its NFCS and their associated objectives relevant to the scope of the request that are to be part of the assessment for example:<sup>17</sup>

- regulatory and legislative framework;
- control and approval programs (for example establishment, process and product programs);
- verification 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
- any other elements directly relevant to the specific products or programs under consideration.

### **Description and evidence on how the importing country's NFCS meets the objectives**

18 To facilitate the exporting country in describing its own systems, the importing country should describe, with appropriate references, how the elements of its NFCS relevant to the scope of the request achieve each of the identified objectives.

19 In describing its own NFCS or the relevant part, the importing country may include reference to

<sup>15</sup> Paragraphs 11 and 12 of CXG 53-2003 provide some additional useful guidance.

<sup>16</sup> Paragraph 4(d) of Appendix to CACGL/53-2003 and Paragraph 8 and 9 of CXG 34/1999 refers.

<sup>17</sup> ref: CXG 34-1999, Section 7; CXG 82-2013, paragraph 43 and CXG 89-2016 Section 7



relevant international standards (e.g. Codex, OIE, IPPC).

### 5.3 STEP 3: THE DECISION CRITERIA FOR COMPARISON

20 Once the request for a recognition of equivalence of a NFCS or the relevant part has been formalized, the importing country should document the decision criteria to be used to evaluate the exporting country's NFCS associated with the scope of the request. The criteria should reference the NFCS objectives and any related outcomes that must be demonstrated for recognition of equivalence. The decision criteria document should be provided to and discussed with the exporting country in a cooperative manner.

21 The decision criteria should facilitate the assessment process being able to determine whether the exporting country's system design and implementation meets the importing country's NFCS objectives and any related outcomes associated with the scope of the request.<sup>18</sup>

22 The decision criteria should describe:

- the level of qualitative or quantitative evidence that is expected; and
- the indicators<sup>19</sup> of outcomes if these are to be used to facilitate comparisons.
- how experience, knowledge and confidence is to be used;

23 The decision criteria should focus on the performance of the system as a whole as opposed to individual procedures or measures. As such decision criteria relating to a NFCS or its relevant part will often be more qualitative than quantitative.

24 Where the goal of any part of the NFCS under consideration relates to managing risks to human health<sup>20</sup> the decision criteria should relate to whether the NFCS of the exporting country achieves the appropriate level of protection as set<sup>21</sup> by the importing country.

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

26 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 meets the objectives of the importing country's NFCS or relevant part for the trade in foods and conditions of trade covered by the request.

27 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 countries.<sup>22</sup>

28 Taking into consideration the scope of the request for recognition of equivalence and existing experience, knowledge and confidence, additional information exchanges should only 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

29 Once the scope of the request is clear and 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, evidence-based and focus on assessing whether the exporting country's NFCS in whole or the relevant part as described meets the decision criteria. Where significant differences are identified the assessment should evaluate whether the objectives and any related outcomes of the importing country's NFCS can be achieved using the exporting country's alternative approach. There should be an effective communication mechanism between both countries, for providing feedback.

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<sup>18</sup> 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).

<sup>19</sup> See Appendix B of CXG 91-2017 for some illustrative examples of outcomes and examples of potential indicators for those selected outcomes.

<sup>20</sup> See Annex A, definition of sanitary measure (as it relates to food safety) of the WTO SPS Agreement.

<sup>21</sup> See Article 5 of the WTO SPS Agreement: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

<sup>22</sup> See Paragraph 6 d) CXG 89-2016

30 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 what sort of modification to existing trade conditions is being sought. In general, the importing country should:

- determine which elements of the exporting country's NFCS need to be assessed for the type of foods and the modification to existing trade conditions being sought and, when relevant, identify which aspects of existing trade are excluded from the assessment;
- clearly set out the importing country's own NFCS objectives for each of the elements being assessed along with how they relate to the decision criteria;
- consider whether the information submitted by the exporting country or otherwise available is sufficient to enable an appropriate analysis;
- proceed with in-depth assessment applying the decision criteria and requesting additional information if deemed necessary;
- consider any additional information submitted at the request of the importing country,
- consider any additional controls proposed by the exporting country to facilitate a positive determination.

31 The importing country's assessment process should:

- focus on whether the exporting country's NFCS or the relevant part meets the objectives 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 or the relevant part to achieve the importing country's objective;
- weigh the outcome of the various elements 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 / audits<sup>23</sup> where justified as necessary<sup>24</sup>;
- 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.

32 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 improvement<sup>25</sup>; and
- the ability of infrastructure and resources to continue to implement the NFCS or the relevant part as described and implemented by the exporting country.

33 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

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<sup>23</sup> See the Annex to CXG 26/1997 for further guidance on the conduct of assessments

<sup>24</sup> See the Appendix to CXG53-2003 paragraph 34 (Use of on-site visits) for examples of when on-site visits may be justified.

<sup>25</sup> Paragraph 36, CXG 82-2013

used to support the assessment process.<sup>26</sup>

## 5.6 STEP 6: DECISION PROCESS

34 The decision process should be transparent. 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 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. In the case where the exporting country NFCS or the relevant part is assessed as not equivalent the two countries may, if they wish, agree a plan and timeframe for the exporting country to resolve the identified deficiency. 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 rationale for them.

35 The decision process should:

- be conducted in a timely manner; and
- focus on whether the exporting country's NFCS 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.

## 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 port of entry requirements). Such documentation may be done for example, through an exchange of letters or through the negotiation of a more comprehensive equivalence agreement or arrangement<sup>27</sup>.

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.

38 The countries should document their expectations with respect to ongoing communication and cooperation. This should include what level of change to their NFCSs or other changes in circumstance requires notification to the other country and when a review of the recognition of equivalence may be required.

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

- 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;
- intermittent country visits or technical exchanges so as to maintain the currency of experience, knowledge and confidence.<sup>28</sup>

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<sup>26</sup> 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.

<sup>27</sup> 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.

<sup>28</sup> 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)

