



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**  
**CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION**  
**AND CERTIFICATION SYSTEMS**  
**Twenty-Fourth Session**  
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**PROPOSED DRAFT GUIDANCE ON USE OF SYSTEMS EQUIVALENCE**  
**(At Step 3)**

Prepared by an electronic working group<sup>1</sup> led by New Zealand with the United States and Chile

## Introduction

1. During discussion at its 21st session, in 2013, 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>2</sup>, especially as a means to further facilitate safe trade while better utilizing and risk targeting inspection resources.
2. At its 22nd session CCFICS considered the discussion paper (CX/FICS 16/22/7) and a project document (CRD11). 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. The Committee further noted that the development of guidance in the area of system equivalence should address the dual mandate of Codex.<sup>3</sup>
3. CCFICS 22 agreed to establish an electronic Working Group, 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.
4. At its 23rd session CCFICS considered the discussion paper (CX/FICS 17/23/6) and a further revised project document (CRD17). The Committee expressed broad support for developing additional guidance on the use of systems equivalence and noted the following aspects<sup>4</sup>:
  - i. There was a need for more-detailed guidance on the development of systems-equivalence agreements, including on information exchange, which was a critical factor in determining equivalence.
  - ii. Guidance would assist countries in tackling this complex issue and may reduce unnecessary trade restrictions and save competent authority resources.
  - iii. The guidance should provide clear recommendations for developing and implementing systems equivalence; facilitate the use of CAC/GL 34-1999; and focus on systems equivalence for food import and export.
  - iv. The guidance should be consistent and avoid overlapping with, existing Codex texts.
  - v. The guidance should serve as a foundational document for initiating discussions on systems equivalence between food exporting and importing countries, and should take into account countries' development status.

<sup>1</sup>The electronic working group comprised representatives of Argentina, Australia, Brazil, Canada, Chile, Colombia, Denmark, Dominican Republic, Egypt, European Commission, Finland, France, India, Indonesia, Ireland, Jamaica, Japan, Kenya, Republic of Lao, Malaysia, Mexico, New Zealand, Nicaragua, Norway, Papua New Guinea, Paraguay, Singapore, Switzerland, Thailand, United States of America, United Kingdom, FAO, OIE, INC, FIA, ICGMA, SSAFE, IAF, CGF

<sup>2</sup> Para. 63, REP15/FICS

<sup>3</sup> Paras. 49-52, REP16/FICS

<sup>4</sup> Para 38, REP17/FICS

- vi. The work should be conducted in such a way as not to become a barrier to trade, noting that the Codex Procedural Manual states that food-safety assurance should be achieved through a risk-analysis approach.
  - vii. The new work should describe factors that facilitate the appraisal of the experience, knowledge and confidence of the importing country regarding the exporting country's food-control system and criteria for evaluating systems equivalence.
5. The Committee revised the project document in detail and agreed to forward it for approval by CAC40. It was further agreed to establish an electronic working group, with the possibility of convening physical meetings, chaired by New Zealand and co-chaired by Chile and the United States of America, to prepare a proposal for circulation for comments and for consideration at CCFICS 24; and to consider whether the outcome of the new work would be a stand-alone document or an appendix to an existing text at a later stage of its development.<sup>5</sup> CAC40 approved the new work in July 2017.

### Approach

6. 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. Comments were received from 14 members of the eWG<sup>6</sup>. A physical working group was convened in Santiago, Chile in December 2017. The pWG was attended by delegations from 33 Codex members and observers<sup>7</sup>, the Chair 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.
7. A second draft 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. Comments were received from 15 members of the eWG<sup>8</sup>. A physical working group was convened in Edinburgh, Scotland in May 2018. The pWG was attended by delegations from 25 Codex members and observers<sup>9</sup>, the Chair 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. The draft proposed guidance has been prepared in the form of a standalone text. This approach has been taken to allow the focus of the work to remain on developing the areas of guidance that will assist Codex members in line with the project document agreed by the Committee and the conclusion of the discussion at CCFICS 23<sup>10</sup>. In preparing the draft guidance concepts and language from the existing CCFICS text have been drawn on and were referenced for transparency during the drafting process. A simplified flow chart of the process steps is also included in the current draft.
9. During the development of the draft proposed guidance members of the working group have discussed the use of examples to support the understanding of the concepts and processes. Some examples remain in the current draft text or in footnotes. The Committee is asked to consider if such examples remain useful and should be retained as the document progresses or if they have served their purpose in supporting the drafting process and can be removed.

### Relationship of new work to existing guidance

10. Taking note of the discussion at CCFICS 23 as outlined above a key consideration in the comments and discussions of the working group has been to ensure appropriate consistency while avoiding unnecessary overlap with existing Codex texts.
11. As noted in the Project Document the original references to equivalence in both 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 the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999) incorporate a wider context for the concept and therefore can be said to explicitly contemplate the potential for systems equivalence determinations and agreements. However, neither document provides specific,

<sup>5</sup> REP17/FICS, Para 46, REP17/FICS

<sup>6</sup> Brazil, Canada, Colombia, Finland, India, Indonesia, Jamaica, Japan, Republic of Lao, Paraguay, Thailand, European Commission, FAO, INC

<sup>7</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>8</sup> Brazil, Canada, Chile, Colombia, Denmark, Egypt, India, Indonesia, Japan, Malaysia, Mexico, Thailand, USA, FAO, INC

<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> REP17/FICS, Para 46c,

practical guidance on how such evaluations should be made. The *Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003), was primarily developed to provide guidance on directly comparing the outcomes of a specified measure or set of sanitary measures rather than recognizing the equivalence of the system as a whole. It also does not provide specific, practical guidance on the recognition of those aspects of a national food control system (NFCS) relating to fair practices in the food trade. CAC/GL 53-2003 also introduces the term "Objective Basis of Comparison (OBC)" for comparing the effects of specific sanitary measures whereas the previous guidance focussed on the capability of different Food Inspection and Certification Systems to meet the same objectives.

12. The recently promulgated *Guidelines for National Food Control Systems* (CAC/GL 82-2013) now provide a basis for a more common understanding of the generic components of NFCSs among countries and introduces a wider basis for potential comparison than that described in previous documents which solely focused on Food Inspection and Certification Systems. CAC/GL 82-2013 describes the key principles and core elements of an efficient and effective NFCS covering both the protection of the health of consumers and facilitating fair practices in the food trade. It provides useful recommendations on the characteristics of a NFCS which when applied may form a useful basis for importing countries to have confidence in the design and functioning of an exporting country's NFCS or parts thereof.
13. *Principles and Guidelines on the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food* (CAC/GL 89-2016) provides guidance to assist the competent authority of the importing and exporting countries to identify when the exchange of information may be necessary and what information is essential for the assessment of the relevant component(s) of the NFCS. It also provides guidance to simplify and harmonize the information and the process of the exchange.
14. The proposed new guidance provides a chronological sequence of the process steps for assessment, broadens the application to a wider NFCS consideration of equivalence and refocuses such considerations to how the system or relevant part is designed and functions.

#### **Working group discussions on relationship with existing text**

15. The pWG in Edinburgh discussed the broad options for where this new guidance may sit in relation to the existing CCFICS text, in particular the two current expansions of the CAC/GL 26-1997 text on equivalence: *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999); and *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* (CAC/GL 53-2003). Members expressed the following views:
  - a. the new guidance does not appear to fit as an annex to either of these existing CCFICS texts that expand on CAC/GL 26-1997;
  - b. the new guidance should continue to progress as a standalone text so as to ensure that the overarching purpose of this work is achieved. That is to provide practical guidance to competent authorities of importing and exporting countries on the use of systems equivalence recognition as a means to further facilitate protecting the health of consumers and ensuring fair practices in the food trade; and
  - c. the new guidance and the existing texts need to fit together in an appropriate way without undue overlap and ensuring each has an appropriate core focus.
16. The pWG recalled that the project document for this new work identified that modification of existing text may be required as a consequence of the new guidance.
17. To achieve the desired objective of providing practical guidance for Codex members to support the appropriate use of equivalence that includes the new guidance currently under development and the two existing texts that expand on CAC/GL 26-1997 (CAC/GL 34-1999 and CAC/GL 53-2003) two main options for potential additional work were identified by the pWG:
  - A. Consider amendments to the existing guidance to remove areas where there is duplication and ensure the language across all the guidance is consistent and reflects current usage and understanding; or
  - B. Consider the development of new work to merge and rewrite the new and existing equivalence guidance.
18. Arguments both in favour and against each of these options can be made. However it is the view of the Chair and co-chairs of the working group that further analysis of what would be involved in each option should be undertaken by the existing working group before CCFICS is asked to endorse one of these

options. This further analysis could be undertaken in parallel with the progress of the draft proposed guidance.

19. While some level of consequential amendments to existing guidance is within the scope of the project document for the current work, more substantive revisions may require approval as new work by the CAC. The Committee should seek advice from the Codex Secretariat as to what the formal approval process should be if this option is pursued.
20. Undertaking this parallel work while continuing to progress the draft proposed guidelines supports the achievement of the overarching objective of the new work approved by CAC40. That is to provide practical guidance for Codex members to support the appropriate use of systems equivalence to reduce unnecessary restrictions on trade and the duplication of controls while protecting the health of consumers and ensuring fair practices in the food trade.

### Recommendations

21. Attached for the consideration of the Committee (Appendix 1) is the proposed *Draft Guidelines on recognition and maintenance of equivalence of National Food Control Systems (NFCSS)*.
22. The Committee is invited to:
  - i. consider the proposed draft presented in Appendix 1, at Step 3, including the following specific matters:
    - a. the retention of full references to other existing CCFICS text in the draft or the use of footnotes as and where appropriate;
    - b. if some examples within the document should be retained as the document progresses or if they have served their purpose as part of the development of the draft and can now be removed; and
    - c. if some examples are useful, where should they be provided and should such examples be within the main body of text, or in footnotes, or in an annex to the text?
  - ii. consider as appropriate advancement of the proposed draft in the Codex step process;
  - iii. note that to achieve the desired objective of providing practical guidance for Codex members to support the appropriate use of equivalence that includes the new guidance currently under development and the two existing texts that expand on CAC/GL 26-1997 (CAC/GL 34-1999 and CAC/GL 53-2003) two main options for potential additional work were identified by the physical working group:
    - A. Consider amendments to the existing guidance to remove areas where there is duplication and ensure the language across all the guidance is consistent and reflects current usage and understanding; or
    - B. Consider the development of new work to merge and rewrite the new and existing equivalence guidance;
  - iv. endorse the undertaking by the working group established by CCFICS23 of further analysis on these options;
  - v. request the working group to report back to CCFICS 25 with a recommendation that EITHER:  
**Option A** is achievable and present revised text for consideration by the Committee; OR  
**Option B** should be considered, including presenting a revised project document for consideration by the Committee with timelines to merge the new proposed guidance with the existing equivalence guidance.

## APPENDIX 1

**Draft Guidelines on Recognition and maintenance of Equivalence of National Food Control Systems (NFCS)**

(Step 3)

**Section 1 – PREAMBLE / INTRODUCTION**

1 A large majority of trade in food occurs without exporting countries being required to undergo a detailed assessment of their National Food Control System (NFCS) or having to replicate all or parts of an importing country's NFCS. However, where additional assurance is required, several mechanisms as outlined in various existing Codex guidelines may be available to facilitate this. For example CAC/GL 89-2016<sup>1</sup> provides guidance on the exchange of NFCS information between importing and exporting countries to support trade in food and CAC/GL 26-1997<sup>2</sup> provides guidance on the assessment of a Food Inspection and Certification System.

2 While countries have a right to set their own level of protection<sup>3</sup> recognition of the equivalence of the whole or a part of an exporting country's NFCS as relevant to the foods of interest can provide an effective means for protecting the health of consumers and ensuring fair practices in the food trade while minimizing unnecessary duplication of controls.

3 Existing guidelines address equivalence in terms of food import and export inspection and certification systems as opposed to how the operation of a NFCS in whole or in part can provide assurances. Current guidance primarily focuses on the development of equivalence agreements and the judgement of the equivalence of specified sanitary measures within a Food Inspection and Certification System.

4 This guideline focuses on the processes that should be applied by countries prior to and when assessing whether one NFCS in whole or in part can reliably achieve the same objectives as another NFCS as relevant to the trade in food types and issues under consideration. The guidance can be applied to system equivalence considerations covering both the protection of the health of consumers and ensuring fair practices in the food trade.

5 These guidelines further elaborate the guidance contained within the foundation guidance on FICS and NFCS and complements the existing Codex guidelines on the exchange of information to support trade in food as well as those that focus primarily on the development of equivalence agreements<sup>4</sup> and the judgement of the equivalence of specified sanitary measures<sup>5</sup>.

**SECTION 2 – SCOPE / PURPOSE**

6 This document provides practical guidance for competent authorities prior to formal requests for consultations on the recognition of equivalence; and then on the process for undertaking considerations, assessments, recognitions and maintenance of the equivalence of the whole or a relevant part of the NFCS.

7 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 and be associated with an entire NFCS or only to that part of a NFCS relevant to the particular products that are traded or are intended to be traded and that are covered by the request<sup>6</sup>.

8 [The consideration, assessment and recognition of the equivalence of one country's NFCS in whole or the relevant part is independent of any reciprocal process occurring. Where appropriate, countries may choose to undertake reciprocal consideration of the other country's NFCS in parallel with the original request. Reciprocal considerations may have different scopes and may arrive at different conclusions.]

**SECTION 3 – DEFINITIONS**

[National Food Control System: [as defined / described by CAC/GL 82/2013 and noting that import and export inspection and certification systems are part of a NFCS.]

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<sup>1</sup> Principles and guidelines on the Exchange of Information between Importing and exporting Countries to Support Trade in Food (CAC/GL 89-2016)

<sup>2</sup> Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems (CAC/GL 26-1997)

<sup>3</sup> In accordance with the obligations contained within the SPS and TBT Agreements.

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

<sup>5</sup> Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (CAC/GL 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 major processing type such as canned seafood. A request for equivalence recognition could cover a horizontal process for providing assurances such as laboratory controls.

**Alternative:**

[National Food Control System: consists of the policy settings, system design, implementation and monitoring and review of the production, packing, storage, transport, handling and sale of foods within national borders, including import and export control systems, as established and maintained by national governments and their competent authority for the protection of the health consumers and ensuring fair practices in the food trade.]

Equivalence: the capability of different inspection and certification systems to meet the same objectives.

System Equivalence: 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 these contribute to the overarching goals of the NFCS to protect the health of consumers and ensure fair practice 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>7</sup>

Decision Criteria: those factors used to determine whether the exporting country's NFCS or relevant part is capable of reliably meeting the objectives of the importing country's NFCS or the relevant part for the products under consideration.

**SECTION 4 – PRINCIPLES**

9 Consideration of the equivalence of systems should be based on the application of the following principles:

***Equivalence of Systems***

- a. Countries should recognize that NFCS's, or the relevant parts thereof, of importing and exporting countries, although designed and structured differently, are capable of meeting the same 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 existing experience, knowledge and confidence and may consider where appropriate relevant assessments by other countries or international organizations.

***Alignment with International Standards***

- c. The use of Codex or other relevant international standards, guidelines or recommendations can facilitate the consideration, assessment and recognition of the equivalence of systems.

***Decision Criteria***

- e. The decision criteria used for assessing system equivalence should reflect the objectives of the importing country's own NFCS, or the relevant part, and focus on whether the exporting country's NFCS, or relevant part, is [likely to / will] reliably achieve the same objectives.

***Assessment and decision***

- f. The processes and decisions relating to the assessment of systems equivalence should focus on objectives; be documented and transparent; evidence-based; efficient; and conducted in a cooperative [and timely] manner; and should not introduce an objective, outcome, standard or process in excess of what is being applied within the importing country without justification.

***Recognition Documentation***

- g. Recognitions of system equivalence should be documented including how the recognition of equivalence impacts the conditions of trade between the two countries.

***Maintenance and Review***

- h. Recognitions of systems equivalence should include provisions for the maintenance and review of the recognition arrangement.

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<sup>7</sup> CAC/GL 91-2017

## SECTION 5 – PROCESS STEPS

10 The process steps related to consideration, assessment, recognition and maintenance of the equivalence of NFCSs include the following<sup>8</sup> and are expanded in the following subsections and illustrated as a simplified flow chart at Figure 1:

### **Step 1: Initial discussions and decision to commence:**

Prior to countries formally requesting consultations, initial discussions should occur to determine whether to commence a system equivalence assessment and whether any preliminary considerations are met. The countries should then agree the potential scope of the assessment and identify the gaps in existing experience, knowledge and confidence relating to that scope. Once the decision to commence and the associated scope has been discussed the exporting country should formalise its request.

### **Step 2: The decision criteria for comparison**

The importing country provides the decision criteria for determining whether the exporting country's NFCS or the relevant part is capable of reliably meeting the objectives of the importing country's NFCS for the products under consideration.

### **Step 3: Description of the importing country's NFCS objectives**

The Importing country provides its NFCS objectives and describes, with relevant references and evidence, how its own system meets these objectives.

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

Exporting country provides a description of its NFCS in whole or the relevant part, including relevant references and evidence as to how its NFCS or relevant part meets the objectives of the importing country's NFCS for the products under consideration.

### **Step 5: Assessment**

The assessment process 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.

### **Step 6: Decision process**

The decision process should be transparent and the result of the assessment documented with the results discussed with the exporting country prior to finalisation.

### **Step 7: Formalization and maintenance of the recognition**

Recognitions of system equivalence should be documented and subject to regular review.

## **5.1 STEP 1: INITIAL DISCUSSIONS AND DECISION TO COMMENCE**

11 Initial discussions including identification of the relevant competent authorities should occur before an exporting country formally requests the importing country enter into consultations on recognition of equivalence of systems.

12 These discussions should identify if commencing an equivalence of systems assessment is appropriate and if so identify the scope of the assessment to be undertaken. The discussions are also useful to identify where experience, knowledge and confidence relating to that scope already exists and or where there are potential gaps.

### **Preliminary considerations**

13 The initial discussions should reflect on whether an equivalence of systems recognition is the most appropriate approach to reduced impediments to trade and duplication of control activities while protecting the health of consumers and ensuring fair practices in the food trade, or whether some other mechanism is more appropriate for the circumstances. The discussions should cover any matters that the importing country considers are a prerequisite for a successful system equivalence recognition. The initial discussion should also address the potential scope of any equivalence of systems assessment.

14 Relevant matters relating to preliminary considerations and the likelihood of success may include:

- experience, knowledge and confidence derived from, for example: the history, level and importance of trade between the countries and the history of compliance with the importing

<sup>8</sup> The principles and processes described in CAC/GL 89-2016 are useful in informing the exchange of information.

countries requirements; the level of familiarization and or cooperation between the competent authorities; and the exporting country's general trading history<sup>9</sup>:

- similarity of design and or consistency of each country's NFCS in whole or the relevant part with international standards, including the legislative foundations and objectives underpinning the NFCS;
- whether an equivalence of systems recognition will likely result in reducing duplication of control activities and impediments to trade, while protecting the health of consumers and ensuring fair practices in the food trade;
- information exchanges and assessments that may have already occurred (e.g. in accordance with CAC/GL 89-2016) or the existence of other relevant equivalence determinations or recognitions between the two countries or with third countries.

### Scope Considerations

15 It is important that countries engage in preliminary discussions on the potential scope of any equivalence of systems assessment. The scope may relate to an entire NFCS or only to that part of a NFCS relevant to the products that are currently or intended to be traded between the two countries.

16 Relevant considerations in determining the scope may include:

- the range of products currently being traded between the countries and or which are subject to similar controls in the exporting country;
- the range of assurances to be addressed (e.g. [food safety, qualitative claims, labelling, or other matters relating to fair practices in the food trade]);
- the level of confidence in the performance of the exporting country's NFCS in whole or the relevant part relating to those products already being traded; 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.

17 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.

### Decision whether to commence

18 The decision to commence an equivalence of systems assessment may involve a determination that:

- an equivalence of systems assessment is an appropriate mechanism;
- the preliminary considerations are sufficiently met;
- the potential benefits and resource savings that can be achieved justifies the cost and resource implications of the process.

19 Once the decision to commence and the associated scope has been discussed the exporting country should formalise its request to the importing country for an equivalence of systems recognition. The two countries should then agree on a plan for progressing the assessment which may include for example milestones, timeframes and if necessary priorities.

20 Where the preliminary considerations are not sufficiently met countries may wish to consider working jointly toward identifying possible technical assistance that could support a future arrangement to reduced impediments to trade and duplication of control activities. 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 equivalence of systems recognition.

## 5.2 STEP 2: THE DECISION CRITERIA FOR COMPARISON

21 Once the exporting country has formalized its request for an equivalence of systems recognition, the importing country in consultation with the exporting country should establish and document the decision criteria for determining whether the exporting country's NFCS or the relevant part is capable of reliably delivering outcomes that meet the objectives of the importing country's NFCS or the relevant part for the products under consideration.

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<sup>9</sup> Paragraphs 10 of the Appendix to CAC/GL 53-2003 provides some further possible examples which may or may not be relevant depending on the circumstance.



22 The decision criteria should allow an assessment as to whether the two systems are likely to reliably achieve the same objectives. In addition the assessment should consider how any difference in the exporting country's NFCS could impact on achieving the overarching goals of the importing country's NFCS as opposed to whether specific procedures or functions (and who undertakes these) in the importing country are replicated.

23 The decision criteria should describe:

- how experience, knowledge and confidence is to be used;
- the level of qualitative or quantitative evidence that expected; and
- possible examples of indicators<sup>10</sup> of high level outcomes that could be useful to facilitate comparisons.

24 The decision criteria should acknowledge and take into account the level of variability and uncertainty inherent to the estimates of what the importing country's NFCS actually achieves.

25 Experience, knowledge and confidence can assist in reducing the number of elements within the scope that need detailed assessment and therefore reduce the resources required to complete an assessment.<sup>11</sup>

### 5.3 STEP 3: DESCRIPTION OF IMPORTING COUNTRY NFCS OBJECTIVES

26 The importing country should make available its NFCS objectives as well as describing, with relevant references and evidence, how its own system meets these objectives. The information should ideally be set out in a way that facilitates the exporting country describing its own system, for example under similar headings or objectives, so as to facilitate subsequent comparisons.

#### NFCS Objectives

27 In general, a description of the objectives of the importing country's NFCS or the relevant part as it relates to the products under consideration should include the following elements:<sup>12</sup>

- regulatory and legislative framework;
- control and approval programs;
- verification and audit programs;
- monitoring, surveillance, investigation and response programs;
- enforcement and compliance programs;
- stakeholder engagement, communication and rapid alert systems;
- system overview monitoring and evaluation programs, [periodic review and continuous improvement]; and
- any other elements directly relevant to the specific products under consideration.

28 Other factors relevant to consideration of objectives include: the transparency of decision making; freedom from conflict of interest; and adequacy of resourcing.

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

29 To facilitate the exporting country describing its own systems, the importing country should describe how the elements of its NFCS or relevant part achieves the associated objective and how they contribute to the overarching goals of the NFCS or the relevant part. Specific references should be provided to documents evidencing the implementation of the policy, system design, operation, monitoring and review elements (e.g. regulations, standards, directives and specifications). In addition, where appropriate, evidence of how the actual results of the above support the effectiveness of the elements in achieving the stated objective should be provided.

30 Information should only be required for those areas subject to a more detailed assessment (that is not for those areas covered by existing experiences, knowledge and confidence).

31 As an alternative to describing its own NFCS or the relevant part, importing countries may reference the relevant international standards as a way to be certain its objectives can be met.

<sup>10</sup> Definition of Indicator CAC/GL 91-2017

<sup>11</sup> [Ref Para 11 of CAC/GL 53-2003 and Para 13 of the Appendix]

<sup>12</sup> [ref: CAC/GL 34-1999, Section 7; CAC/GL 82-2013, para 43 and CAC/GL 89-2016 Section 7]

#### 5.4 STEP 4: DESCRIPTION OF EXPORTING COUNTRY'S NFCS

32 The exporting country should make available appropriate information, including relevant references and evidence that describes its NFCS or the relevant part and how it reliably meets the objectives of the importing country's NFCS or relevant part for the products under consideration. The information made available should also address the adequacy of resources, and how the exporting country ensures the transparency of decision making and freedom from conflicts of interest.

33 As far as practical, importing countries should allow flexibility in the format of the information submitted by the exporting countries.

34 Where substantial information has already been exchanged between countries and or where it has been identified during the initial discussions (step 1) that there is significant existing experience, knowledge and confidence, importing countries should only require that exporting countries submit the additional information necessary to demonstrate that the objectives of the importing country related to the products within the scope of the request can be reliably achieved.

#### 5.5 STEP 5: ASSESSMENT PROCESS

35 Having robust NFCSs as described by Codex text provides a good starting point for any comparison. The use of pre-existing experience, knowledge and confidence can support the assessment process. For example by reducing the areas where a more detailed assessment is required.

36 The assessment process may be assisted by in country visits, teleconferences or meetings. Where relevant, the provision of technical assistance may also support the assessment process. The use of such approaches should be included in the planning for the equivalence of systems assessment, as appropriate.

37 The assessment process should:

- focus on whether the exporting country's NFCS meets the objectives of the importing country's NFCS or the relevant part in accordance the decision criteria as opposed to whether specific procedures or functions, undertaken by certain parties in the importing country, are replicated;
- allow for different indicators of outcomes to be used by the exporting country (including by parties other than government as appropriate) to demonstrate the performance of its NFCS or the relevant part;
- weight the comparison of the objectives of the various elements relative to their impact on achieving the overarching goals of the NFCS or relevant part;
- be conducted in a cooperative and timely manner and include the use of on-site assessments as necessary;
- allow for regular consultations and the provision of clarifications and or supplementary information as required; and
- appropriately protect commercially sensitive and confidential information.

38 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>13</sup>; and
- the sufficiency, appropriateness and stability of infrastructure and resources to maintain an appropriate NFCS or the relevant part.

#### 5.6 STEP 6: DECISION PROCESS

39 The decision process should be transparent, document the assessment outcome and the rationale behind the outcome. The exporting country should be given the opportunity to comment on the draft conclusions and provide additional information prior to its finalization.

40 The decision process should:

- focus on whether the exporting country's NFCS meets the decision criteria;

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<sup>13</sup> Reference para 36 CAC/GL 82-2013

- be conducted in a timely manner; 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**

41 The importing and exporting countries should document any recognition reached and its effects on future trade between the countries. This may be done for example, through an exchange of letters or through the negotiation of a more comprehensive equivalence agreement<sup>14</sup>.

42 The documentation of the recognition of the equivalence of systems should include provisions on maintenance of the recognition. Maintenance of recognition arrangements should allow regulatory frameworks, programs and oversight to evolve over time.

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

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<sup>14</sup> Although this guideline refers to “countries” and “agreements,” in many cases the relevant competent authorities will enter into agreements or other arrangements. CAC/GL 34-1999 Appendix A provides a list of information that could, as appropriate, be included in an equivalence agreement.

**Figure 1: Systems Equivalence Process**

Simplified flow chart for the determination of systems equivalence (individual steps may be iterated)

