



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

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

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CCFICS25 commenced discussion of CRD4 in Plenary and reviewed Sections 1, 2 and 3 and made some amendments. In moving into a discussion on Section 5 the plenary made some amendments but also identified some outstanding issues that required further consideration. Following a recommendation by the Chair an informal intersessional was proposed to focus on the identified outstanding issues, identifying in particular paragraphs 14 and also paragraphs 24 and 24 bis.

The informal intersessional was held with translation available in English, French and Spanish and open to all CCFICS25 participants.

The intersessional helped in making some adjustments to the text to improve its clarity and consistency, as well as identifying and correcting some of the references in text and the footnotes.

Below is a list identifying the paragraphs and changes that have been reviewed and agreed during the plenary discussion. Also below are the paragraphs that were amended with provisional consensus at the informal intersessional. One paragraph (14) was placed in square brackets for further discussion by the plenary. The minor proposed changes in paragraphs 32, 34, 36 and a small change to Figure 1 were not able to be reviewed.

Section 1 – Introduction

Paragraphs 1 and 2 – Deleted by Plenary

Paragraph 3 bis – revised by Plenary and edits checked by Intersessional

Para 3 bis bis – inserted by Plenary

Section 3 – Definitions

NFCS Objectives – the Plenary deleted the definition and inserted the text as a foot note to Principle 7. a (Equivalence of NFCS)

Section 5.1

Paragraph 10 – the Plenary deleted Bullet 1 and moved Bullet 6 to position 1

Paragraph 10 Bullet 5 – reviewed and amended by the Intersessional

Paragraph 12 Bullet 2 – reviewed and amended by the Intersessional

Paragraph 14 – discussed and placed in square bracket [] by the Intersessional for further consideration.

Section 5.2

Paragraphs 18 and 19 – reviewed and amended by the Intersessional with the sub-title also amended.

Section 5.3

Paragraph 24 and 24bis – reviewed and amended by the Intersessional.

The revised draft as outlined above but without tracked changes is attached for consideration by the Plenary.

NOTE: Changes from **CRD4** are identified with underline

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

SECTION 1 – PREAMBLE

1 Deleted

2 Deleted

3 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 also 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, reduce impediments and also 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).

3bis. A NFCS addresses aspects that are covered by both the WTO-SPS Agreement and the WTO-TBT Agreement which both include the concept of equivalence. While there are some similarities there are also some differences in the concepts of equivalence and how it is considered under these two agreements. This guideline provides an approach that countries can use to review different sanitary measures², technical regulations, conformity assessment, or standards³ in the realm of a systems equivalence evaluation. It is not intended to override any of the rights and obligations within any of the WTO Agreements.

3bis bis. The proposed guidelines are intended to be read in conjunction with 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).

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

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, as relevant to the trade in foods and the conditions of trade covered by the request.⁴

SECTION 3 – DEFINITIONS

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

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.⁵

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.

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

² The meaning of Sanitary Measure is defined in Annex A of the WTO Sanitary and Phytosanitary (SPS) Agreement.

³ The meaning of Technical Regulations, Conformity Assessment and Standards are defined in Annex 1 of the WTO Technical Barriers to Trade (TBT) Agreement: Terms and their Definitions for the Purpose of this Agreement.

⁴ 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.

⁵ Principles and Guidelines for Monitoring the Performance of National Food Control Systems (CXG 91-2017)

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 objectives⁶ 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, 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 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.⁷

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

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 mechanism⁸ would be better to address the matters under discussion.

⁶ The intent or purpose of the core elements of the NFCS or the relevant part including how these contribute to achieving the overarching goal of the NFCS to protect the health of consumers and ensure fair practices in the food trade

⁷ The principles and processes described in CXG 89-2016 are also useful in informing the exchange of information.

⁸ 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 country requirements; harmonisation of requirements; mutual recognition; memoranda of understanding; or assurances based on some other means acceptable to both countries.

10 Relevant matters for the initial discussions may include ⁹:

- 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;
- 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;¹⁰
- the different level of development between the countries¹¹;
- 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 or the relevant parts of the NFCS with for example standards, guidelines, and/or codes of practice from Codex or other recognized relevant international standardization 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

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 trade¹²;
- identification of those requirements where recognition of the equivalence of NFCS or the relevant part will allow better use of resources, including resolution of issues affecting 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 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 required¹³.

Decision whether to commence

Original CRD Text

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

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

¹⁰ 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.

¹¹ See also paragraph 16

¹² Paragraph 5 of CXG 34-1999

¹³ Paragraphs 11 and 12 of CXG 53-2003 provide some additional useful guidance.

- an assessment of the equivalence of the NFCS is an appropriate mechanism rather than some other mechanism (see Footnote 11);
- 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.]

With amendments suggested at informal intersessional

[14 At the conclusion of the initial discussions between the exporting and importing countries, the exporting country should formalise a request for a recognition of equivalence which includes a description of the scope of products and conditions of trade to be covered. The importing country considers information provided to determine whether:

- an assessment of the equivalence of the NFCS is an appropriate mechanism rather than some other mechanism (see Footnote 11);
- 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.]

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

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 mechanisms to help facilitate the trade. Alternative mechanisms to address the matters discussed could be considered, as noted in footnote 11. 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 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:¹⁵

- regulatory and legislative framework;
- control and approval programs (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 schemes and mechanisms; or
- any other elements directly relevant to the specific products or programs under consideration.

Description on how the importing country's NFCS meets the objectives

18 On request of the exporting country 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 relevant elements and objectives of its NFCS.

19 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 standardization

¹⁴ Paragraph 4(d) of Appendix to CXG 53-2003 and Paragraph 8 and 9 of CXG 34/1999 refers.

¹⁵ ref: CXG 34-1999, Section 7; CXG 82-2013, paragraph 43 and CXG 89-2016 Section 7

bodies.

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.¹⁶

22 The decision criteria should describe:

- the level of qualitative or quantitative evidence that is expected;
- the indicators¹⁷ of outcomes if these are to be used to facilitate comparisons; and
- 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. Consequently, decision criteria relating to a NFCS or its relevant part will often be more qualitative than quantitative.

24 Where the objectives of any part of the NFCS under consideration relates to food safety¹⁸ the decision criteria should relate to whether the NFCS of the exporting country achieves the appropriate level of protection as set¹⁹ by the importing country.

24-bis Where the objectives of any part of the NFCS under consideration relates to Technical Regulations, Conformity Assessment procedures, or Standards, the decision criteria should relate to whether the NFCS of the exporting country adequately fulfils the objectives of the importing country's regulations.

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.²⁰

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

¹⁶ 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).

¹⁷ See Appendix B of CXG 91-2017 for some illustrative examples of outcomes and examples of potential indicators for those selected outcomes.

¹⁸ See the definition of Sanitary Measure (as it relates to food safety) in Annex A: Definitions, of the WTO SPS Agreement.

¹⁹ See Article 5: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection, of the WTO SPS Agreement.

²⁰ See Paragraph 6 d) of CXG 89-2016

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.

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 / audits²¹ where justified as necessary²²;
- 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 improvement²³; 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

²¹ See the Annex to CXG 26/1997 for further guidance on the conduct of assessments

²² See the Appendix to CXG53-2003 paragraph 34 (Use of on-site visits) for examples of when on-site visits may be justified.

²³ Paragraph 36, CXG 82-2013

used to support the assessment process.²⁴

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 to a plan and timeframe for the exporting country to resolve the identified ~~deficiency~~ **non-equivalence**. 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~~ **point of entry, or point of control**, requirements). Such documentation may be done for example, through an exchange of letters or through the negotiation of a more comprehensive equivalence agreement or arrangement²⁵.

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.²⁶

²⁴ 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.

²⁵ 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.

²⁶ 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)

