

CODEX ALIMENTARIUS

INTERNATIONAL FOOD STANDARDS



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

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1. PREAMBLE

Recognition of the equivalence of the whole or a part of an exporting country's national food control system (NFCS),ⁱ as relevant to the trade in foods under consideration, can provide an effective means for minimizing unnecessary duplication of controls, while protecting the health of consumers and ensuring fair practices in the food trade. The recognition of equivalence, where it occurs, should result in positive changes to the conditions of trade, and facilitate the more efficient and effective use of resources in the importing and exporting countries (which could include, but is not limited to, recognition of lists of eligible export establishments; alternative processing and inspection procedures; or a reduced intensity and frequency of routine port of entry inspection).

These guidelines are intended to be read in conjunction with other existing Codex texts including but not limited to the [Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems \(CXG 26-1997\)](#),¹ and the [Guidelines for Food Import Control Systems \(CXG 47-2003\)](#).²

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.

2. PURPOSE

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 partⁱⁱ of the NFCS at the system level.

A request for a recognition of equivalence may relate to either the protection consumer health 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.

3. DEFINITIONS

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

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

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

4. PRINCIPLES

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

4.1 Equivalence of national food control systems

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

4.2 Experience, knowledge and confidence

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

4.3 Alignment with international standards

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.

ⁱ *Principles and Guidelines for National Food Control Systems (CXG 82-2013)*.

ⁱⁱ 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.

4.4 Assessment

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

4.5 Final documentation

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

5. PROCESS STEPS

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

Step 1: Initial discussions, scope and decision to commence

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

Step 3: The decision criteria for comparison

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

Step 5: Assessment process

Step 6: Decision process

Step 7: Final documentation

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

5.1.1 Initial discussions

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

Relevant matters for the initial discussions may include:^{vi}

- regulatory and/or legislative frameworks, should they exist, establishing the procedures and/or steps to be followed when evaluating the recognition of equivalence of a NFCS;
- whether recognition of the equivalence of the NFCS or the relevant part will likely result in cost and resource savings, reduced duplication of control activities and/or removal of unnecessary impediments to trade, while protecting the health of consumers and ensuring fair practices in the food trade;
- the potential scope of an equivalence request;
- experience, knowledge and confidence derived from, for example: the history and level of trade between the countries; the history of compliance with the importing country's requirements; the level of familiarization and/or cooperation between the competent authorities; and the exporting country's trade in the same or similar products with other countries;^{vii}

ⁱⁱⁱ The principles and processes described in the *Principles And Guidelines for the Exchange of Information Between Importing and Exporting Countries to Support the Trade in Food* (CXG 89-2016) are also useful in informing the exchange of information.

^{iv} Noting that countries may make a request for consultations on equivalence at any point during the initial discussions.

^v Other mechanisms may include but not be limited to: The exchange of information to support trade (CXG 89-2016); equivalence of a specific sanitary measure or group of measures; compliance with importing county requirements; harmonisation of requirements; mutual recognition; memoranda of understanding; or assurances based on some other means acceptable to both countries.

^{vi} Paragraphs 9 and 11 of the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CXG 34-1999) and paragraph 3 of the Appendix of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CXG 53-2003) provide additional guidance.

^{vii} Paragraph 10 of the Appendix to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CXG 53-2003) provides some further possible examples which may or may not be relevant depending on the circumstance.

- the different level of development between the countries' NFCSs;^{viii}
- the similarity of design of each country's NFCS in whole or the relevant part including the legislative framework and the relevant objectives, and related outcomes or level of protection;
- the similarity to, or harmonisation of, the whole or the relevant part of the NFCS with standards, guidelines, and/or codes of practice from Codex or other relevant international standard-setting bodies; and
- the information exchanges and assessments that may have already occurred (e.g. in accordance with the *Principles and Guidelines for the Exchange of Information Between Importing and Exporting Countries to Support the Trade in Food* [CXG 89-2016])³ or the existence of other relevant recognitions of equivalence between the two countries or with third countries.

5.1.2 Scope considerations

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

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;^{ix}
- identification of those requirements where recognition of the equivalence of the NFCS or the relevant part will allow better use of resources, including resolution of issues affecting trade;
- the range of NFCS assurances to be addressed (e.g. food safety, qualitative claims, labelling, or other matters relating to technical regulations, conformity assessment procedures or standards);
- the level of trust and confidence in the performance of the exporting country's NFCS in whole or the relevant part relating to those products already being traded or those proposed for future trade; and
- the availability of resources likely to be necessary to undertake the process as it relates to the whole or the relevant part of the NFCS proposed to be considered and the possible benefits.

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.^x

5.1.3 Decision whether to commence

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

The two countries may then agree on a plan for undertaking the assessment which may include for example, timeframes and if necessary, priorities.^{xi}

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. The *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CXG 34-1999)⁴ (paragraph 11) also identifies that amongst other things, information exchange, joint training, technical cooperation and support, and the development of infrastructure and strengthening of the food control systems can serve as building blocks for a future request for recognition of the equivalence of systems.

^{viii} See also paragraph 15.

^{ix} Paragraph 5 of the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CXG 34-1999).

^x See the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CXG 53-2003), paragraphs 11 and 12 and paragraphs 9–13 of the Appendix for additional guidance.

^{xi} Paragraph 4(d) of Appendix to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CXG 53-2003) and paragraphs 8 and 9 of the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CXG 34-1999) refers.

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

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

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

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 relevant international standard setting bodies.

5.3 STEP 3: THE DECISION CRITERIA FOR COMPARISON

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

The decision criteria should facilitate the importing country's assessment process being able to determine whether or not the exporting country's system design and implementation achieves the importing country's relevant objectives, and related outcomes or level of protection, associated with the scope of the request.^{xiii}

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

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

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

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

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

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.

^{xii} See: *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CXG 34-1999), Section 7; *Principles and Guidelines for National Food Control Systems* (CXG 82-2013), paragraph 43, and *Principles and Guidelines for the Exchange of Information Between Importing and Exporting Countries to Support the Trade in Food* (CXG 89-2016), Section 7.

^{xiii} 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).

^{xiv} See Appendix B of the *Principles and Guidelines for Monitoring the Performance of National Food Control Systems* (CXG 91-2017) for some illustrative examples of outcomes and examples of potential indicators for those selected outcomes.

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

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

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

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

5.5 STEP 5: ASSESSMENT PROCESS

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

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

- consider whether the information submitted by the exporting country, or otherwise available, is sufficient to enable an appropriate assessment;
- proceed with an assessment applying the decision criteria and requesting additional information if deemed necessary;
- consider any additional information submitted by the exporting country at the request of the importing country that could facilitate the assessment process;
- where appropriate, convey to the exporting country any information for the addition of one or more specific controls to their NFCS that could facilitate the assessment process; and
- consider any additional controls proposed by the exporting country to facilitate a positive determination. The importing country's assessment process should:
 - focus on whether the exporting country's NFCS in whole or the relevant part achieves the objectives, and related outcomes or level of protection, of the importing country's NFCS or the relevant part in accordance with the decision criteria (as opposed to whether specific procedures or functions, undertaken by certain parties in the importing country, are replicated);
 - consider the use of indicators of outcomes – different to the importing country's – to be used by the exporting country to demonstrate the performance of its NFCS in full or the relevant part to achieve the importing country's objectives and related outcomes or level of protection;
 - weigh the outcome of the various elements of the exporting country's NFCS relative to their impact on achieving the objectives and related outcomes or level of protection 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^{xvi} where justified as necessary to demonstrate the NFCS in full or relevant part;
 - 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.

^{xv} See paragraph 6 d) of the *Principles and Guidelines for the Exchange of Information Between Importing and Exporting Countries to Support the Trade in Food* (CXG 89-2016).

^{xvi} See the Annex to the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CXG 26-1997) for further guidance on the conduct of assessments.

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;^{xvii} and
- the availability of resources and infrastructure to continue to implement the NFCS or the relevant part.

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 possible, the provision of technical assistance may also be used to support the assessment process.^{xviii}

5.6 STEP 6: DECISION PROCESS

The decision process should:

- be transparent and conducted in a timely manner; and
- focus on whether the exporting country's NFCS or the relevant part meets the decision criteria; and
- not introduce a new objective or outcome in excess of what is being applied within the importing country without justification.

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

In the case where the exporting country's NFCS or the relevant part is assessed as not equivalent the two countries may, if they wish, agree to a plan and timeframe for the exporting country to provide any additional information or controls for the identified parts of the NFCS that were determined not to be equivalent. Subsequent additional information should be reviewed by the importing country without requiring all aspects of the assessment process to be repeated so long as the additional information is provided in a timely manner. The importing country should document the final assessment conclusions and the associated rationale.

5.7 STEP 7: FINAL DOCUMENTATION

The importing and exporting countries should document any recognition reached including how the recognition of equivalence will be implemented for the trade in food between the countries (e.g. recognition of lists of establishments; or modification to point of entry, or additional in-country process prescriptive requirements). Such documentation may be done for example, through an exchange of letters or through the negotiation of a more comprehensive equivalence agreement or arrangement.^{xix}

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, programmes and oversight to evolve over time. The documentation should include what level of change to the exporting or importing country's NFCS or other changes in circumstance requires notification to the other country and when a review of the recognition of equivalence may be required.

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

^{xvii} Paragraph 36, *Principles and Guidelines for National Food Control Systems* ([CXG 82-2013](#)).

^{xviii} 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.

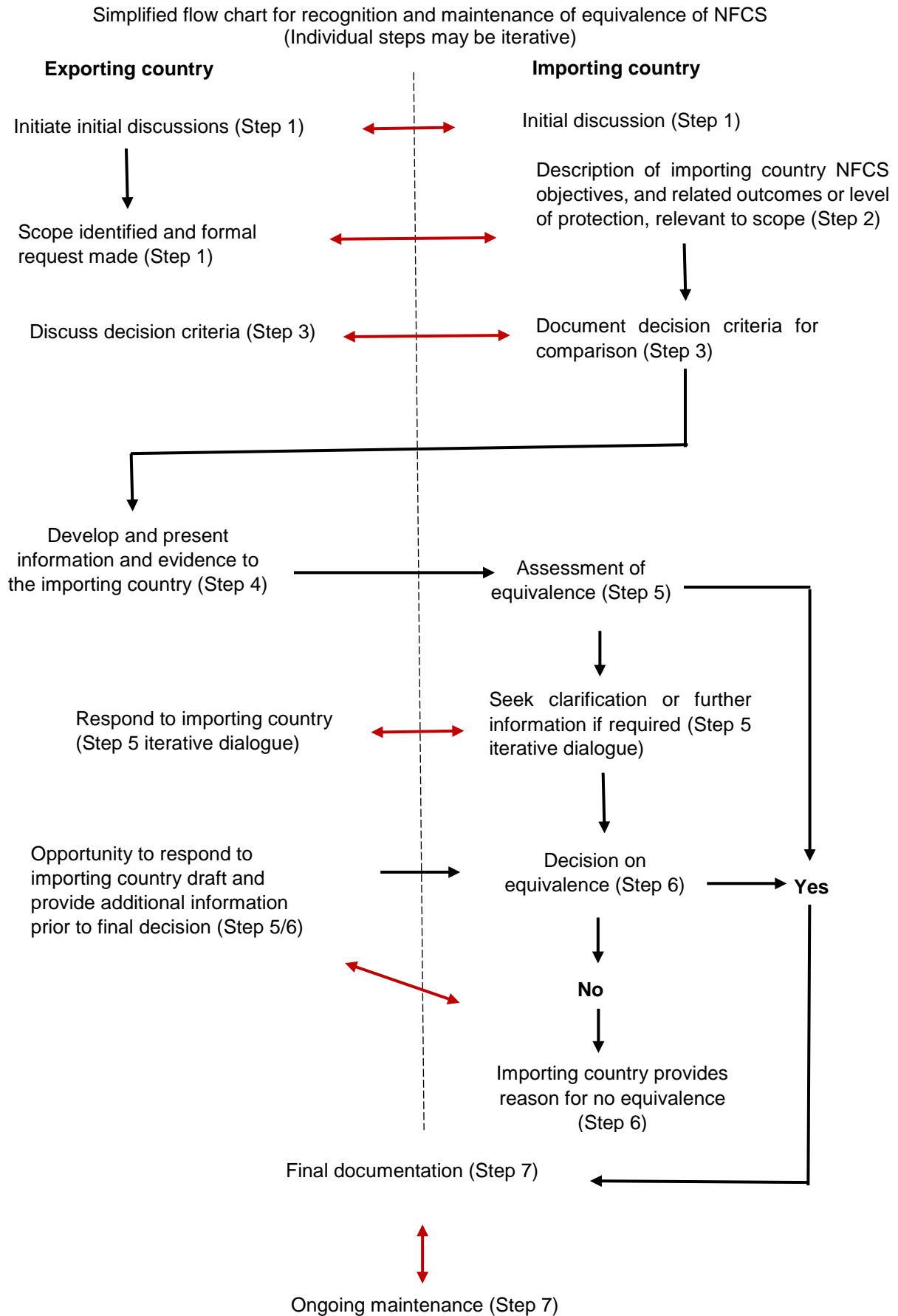
^{xix} Although this guideline refers to "countries" and "agreements," in many cases the relevant competent authorities will enter into agreements or other arrangements. *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* ([CXG 34-1999](#)). Appendix A provides a list of information that could, as appropriate, be included in an equivalence agreement.

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; and
- intermittent country visits or technical exchanges so as to maintain the currency of experience, knowledge and confidence.^{xx}

^{xx} See Section 1(2) of the Annex to the *Principles and Guidelines for the Conduct of Assessments of Foreign Official Inspection and Certification Systems* ([CXG 26-1997](#)).

Figure 1: Equivalence of national food control systems process



NOTES

¹ FAO and WHO. 1997. *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems*. Codex Alimentarius Guideline, No. CXG 26-1997. Codex Alimentarius Commission. Rome.

² FAO and WHO. 2003. *Guidelines for Food Import Control Systems*. Codex Alimentarius Guideline, No. CXG 47-2003. Codex Alimentarius Commission. Rome.

³ FAO and WHO. 2016. *Principles and Guidelines for the Exchange of Information Between Importing and Exporting Countries to Support the Trade in Food*. Codex Alimentarius Guideline, No. CXG 89-2016. Codex Alimentarius Commission. Rome.

⁴ FAO and WHO. 1999. *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems*. Codex Alimentarius Guideline, No. CXG 34-1999. Codex Alimentarius Commission. Rome.