

PROPOSED DRAFT CONSOLIDATED TEXT ON THE:
PRINCIPLES AND GUIDELINES FOR THE RECOGNITION OF EQUIVALENCE OF [SANITARY MEASURES, TECHNICAL REGULATIONS, STANDARDS AND CONFORMITY ASSESSMENT PROCEDURES,] NATIONAL FOOD CONTROL SYSTEMS (NFCS) OR A PART OF A NFCS
(AT STEP 3)

SECTION 1: PREAMBLE

- 1 The recognition of equivalence is not generally required for most trade in food. However, where used it can minimise unnecessary duplication of controls and facilitate trade, while protecting the health of consumers and ensuring fair practices in the food trade. The recognition of equivalence, when it occurs, should result in positive changes to the requirements for trade.
2. Requests for the recognition of equivalence can cover [a sanitary measure, technical regulation, standard and conformity assessment procedure] those requirements for trade that relate to both the protection of the health of consumers or ensuring fair practices in the food trade and can cover the whole of an exporting country's National Food Control System¹ (NFCS) or part of its NFCS² as appropriate.
- 2.bis** [Requirements or parts of a NFCS that have the objective of protecting the health of consumers include food safety related sanitary measures, as defined by the WTO/SPS Agreement, whereas those requirements or parts of a NFCS that have the objective of ensuring fair practices in the food trade include the non-food safety technical regulations, standards, and conformity assessment procedures as covered by the WTO/TBT Agreement.]
3. The recognition of equivalence may facilitate trade by reducing the need for an exporting country to implement additional controls [over and above those already effectively being delivered by its NFCS] in order to meet [the NFCS objectives of the] importing country's requirements. It may also result in more efficient and effective use of resources in the importing and exporting countries. The recognition of equivalence may lead to efficiencies in approval, audit, inspection, and certification processes.
- 4 The consideration, assessment, recognition, and maintenance of the equivalence of one country's [sanitary measure, technical regulation, standard and conformity assessment procedure], NFCS or part of a NFCS is independent of any reciprocal process occurring. Reciprocal considerations, where requested, may have different scopes and durations, and may also arrive at different conclusions.
5. These guidelines consolidate and replace the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CXG 34-1999), *Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CXG 53-2003) and *Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems* (CXG 101-2023). {**Drafting note:** this paragraph may be retained as a footnote – decision to be made once draft has progressed in step process.}
6. These guidelines are intended to be read in conjunction with other existing Codex text including *Principles and Guidelines for National Food Control Systems* (CXG 82-2013) the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CXG 26-1997), the *Guidelines for Food Import Control Systems* (CXG 47-2003), and the *Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food* (CXG 89-2016).

SECTION 2: PURPOSE / SCOPE

7. This document provides 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 a [sanitary measure(s) or technical regulation(s), standard(s) and conformity assessment procedure(s)]NFCS or a part of a NFCS.

[**ALTERNATIVE** Para 7 edited from 34-1999] This document provides practical guidance for governments desiring to enter into [consultations with the aim of achieving] bilateral or multilateral equivalence arrangements / agreements concerning a NFCS or a part of a NFCS [a sanitary measure(s) or technical regulation(s), standard(s) and conformity assessment procedure(s), or a NFCS or a part of a NFCS]. It

¹ *Principles and Guidelines for National Food Control Systems* (CXG 82-2013).

² 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.

includes the process for assessing, recognising and maintaining the equivalence of a NFCS or a part of a NFCS.

- 8 A request to enter into consultations with the aim of achieving bilateral or multilateral equivalence agreements [/ arrangements] on the recognition of equivalence may relate to requirements that have the objective of 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 requirements for trade covered by the request.

SECTION 3: DEFINITIONS

Equivalence: The capability of a different [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS's or parts of a NFCS to achieve the same objectives. *[New Definition adapted from CXG 101-2023]*

Decision Criteria: Those factors used to objectively determine whether the exporting country's NFCS or the relevant part its NFCS achieve the objectives, of the importing country's NFCS or the relevant part for the products under consideration. *[From CXG 101-2023].*

Outcomes: Intended effects or results that contribute to achieving the relevant NFCS objectives. *[From CXG 101-2023 and CXG 91-2017]*

Requirements: are the criteria set down by the competent authorities relating to trade in food covering the protection of the health of consumers and ensuring fair practices in the food trade. *[From CXG 20-1995, 26-1997 and 34-1999].*

SECTION 4: PRINCIPLES

9. The consideration, assessment, recognition, and maintenance of equivalence should be based on the following principles.

A: Equivalence

Countries should recognize that different [sanitary measure(s), technical regulation(s), standard(s) and conformity assessment procedure(s),] NFCS[s] or a part of a NFCS[s] although designed and structured differently, may achieve the same objectives, [and related outcomes or level of protection] and can therefore be recognized as equivalent.

ALTERNATIVE (FROM 101-2023): 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.

B: Experience, Knowledge and Confidence

Importing countries should consider relevant experience, knowledge and confidence in the exporting country's [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS, or relevant part, and may consider appropriate assessments by other countries or relevant international organizations.

C: Scope of the request and assessment

The scope of any request or any subsequent assessment should focus on those products and requirements affecting trade where the exporting country considers its [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS, or relevant part of its NFCS already achieves the same objectives, and related outcomes or level of protection, as achieved by the importing country [and the scope of the assessment should be [discussed in good faith with the aim of reaching] agreed[ment] between the importing and exporting countries].

[ALTERNATIVE: The scope of an equivalence request and any subsequent assessment should be [discussed in good faith with the aim of reaching] agreed[ment] between the importing country and the exporting country.]

D: Alignment with International Standards

The use of or reference to Codex standards, guidelines and/or codes of practice, or other relevant international standards by the importing and exporting countries can facilitate the consideration, assessment and recognition of the equivalence of a [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS, or the relevant part of a NFCS.

E: Transparency and co-operation

The importing country and the exporting country should work through the process in good faith, in a reasonable timeframe and in a transparent, evidence-based[, and] outcome-focused [and proportionate] manner.

F: Demonstration and Recognition of Equivalence

Where the exporting country objectively demonstrates that its [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or relevant part of its NFCS, achieves the importing country's objectives the importing country should recognise their equivalence.

[ALTERNATIVE: The exporting country should objectively demonstrate that its measures, technical regulations, NFCS or relevant part, achieve the importing country's objectives and the related outcomes or level of protection and the importing country should recognise their equivalence].

G: Documentation and maintenance

The importing country and the exporting country should document any agreement / arrangement reached, and how the recognition of equivalence will be implemented and maintained for the trade in foods between the countries.

H: Technical assistance / Regulatory co-operation

Importing countries should consider upon request providing technical assistance to exporting developing countries, particularly least developed countries, to facilitate the assessment and recognition of equivalence.

SECTION 5: INITIAL DISCUSSIONS

- 10 It is recommended that the competent authorities of importing and exporting countries have initial discussions prior to the exporting country formalizing a request for a recognition of equivalence, noting that such a request may be made at any point during these discussions
- 11 These discussions can help identify if commencing an assessment of equivalence of the exporting country's [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or the relevant part of its NFCS is the most appropriate approach or if another mechanism would be better to address the matters under discussion.

Appropriateness of an equivalence process

- 12 Relevant considerations for the initial discussions may include:
 - the nature and impact of the requirements which the exporting country [ORIGINAL: considers are restrictive] [ALTERNATIVE: wishes to discuss]
 - the importing and exporting countries' relevant NFCS objectives, and the related outcomes or level of protection
 - whether a recognition of [the] equivalence [of the sanitary measure, technical regulation, standard and conformity assessment procedure, NFCS or the relevant part] will likely facilitate trade, for example by resulting in cost and resource savings, reduced duplication of control activities and/or removal of unnecessary impediments [while protecting the health of consumers and ensuring fair practices in the food trade]
 - [the experience, knowledge and confidence the importing country has with the exporting country (refer para 16 – 18)]
 - what evidence the exporting country may have that its [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or relevant part of its NFCS, achieve the importing country's NFCS objectives, and the related outcomes or level of protection
 - whether the importing country has legislated procedures that need to be met when evaluating the recognition of equivalence of a [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or a relevant part of a NFCS
 - [the different level of development between the countries' NFCS]
 - [any differences in the presence or prevalence of particular food safety hazards, national choice about management of food safety risks and differences in the level of development of each country's NFCS.]

Initial scope discussions

- 13 The initial discussions should be used to potentially refine both the scope of any request by the exporting country as well as to identify and clarify what additional information and / or evidence may be required for the importing country' assessment process.
14. The scope may relate to the protection of the health of consumers or fair practices in the food trade or both and can cover an entire NFCS or only a part of a NFCS as relevant to the foods and requirements to be covered by the request.

15. Relevant considerations for the initial scope discussions may include:
- the range of foods currently being traded or proposed for future trade and the importing country requirements for which the exporting country is seeking a recognition of equivalence
 - whether the objective of relevant requirements is to protect the health of consumers or to ensure fair practices in the food trade or a combination of both
 - the resources likely to be necessary to undertake the assessment process relative to the possible benefits, and
 - any ways to simplify the assessment process to make it more efficient and less burdensome on both countries.

Experience, Knowledge and Confidence

- 16 The use of or reference to existing experience, knowledge and confidence can reduce the amount of information and evidence the exporting country needs to provide. It can also reduce the resources and timelines for the importing country's assessment and decision-making processes.
- 16biz When an importing country has prior experience, knowledge, and confidence and the countries agree that [the objectives of the] import requirements are being fully met, the recognition of equivalence may be made without further information exchange and assessment being required.
- 17 Existing experience, knowledge and confidence may take the form of, for example:
- existing agreements or arrangements
 - previous assessments, audits, study and technical visits or other related information exchanges that may have already occurred (e.g. in accordance with CXG 89-2016)
 - the history in food trade between the importing country and the exporting country
 - the level of compliance of the exporting country's food products with the importing country's requirements
 - the level of familiarization and/or cooperation that exists between the NFCS competent authorities of the importing country and the exporting country
 - the similarity in design, laws, regulations and operational principles and practices between the importing country and the exporting country's NFCS
 - the similarity in design and operational principles and practices of the exporting country's NFCS or relevant part of the NFCS with the relevant Codex texts, or the texts of other relevant international standard setting bodies, and
 - other relevant assessments of the exporting country's [sanitary measures, technical regulations, standards and conformity assessment procedures,] NFCS or parts of its NFCS, performed by the importing country, by recognized conformity assessment bodies, by other countries, or by international organizations.
- 18 Importing and exporting countries should develop a clear understanding of the role and the extent to which existing experience, knowledge and confidence will be used by the importing country in any consideration or assessment of equivalence and how it will affect:
- the assessment and decision-making processes applied within the scope of the request, and
 - the amount, nature and scope of evidence and information the exporting country should provide.

Outcome of initial discussions

- 19 Where the conclusion of the initial discussions between the exporting and importing countries is that an equivalence process is the appropriate mechanism for facilitating trade, the exporting country should proceed to document the request for consultations in accordance with process step one (section 6).
- 20 Where the initial discussions indicate the potential need for more data than currently available the competent authorities in the importing and exporting countries may agree to the conduct of a trial or pilot study to help provide the necessary objective evidence. [The pilot study protocol may include, but are not limited to, provisions in relation to:
- description and time frame of the trial program;

- roles and capabilities of involved government and officially recognized private organizations;
- procedures for inspection and certification;
- audit procedures and frequency;
- description of training or information needs.]

- 21 Where the initial discussions identify that an equivalence process may not be the most appropriate mechanism, the countries may wish to consider working jointly towards other mechanisms to help facilitate trade. For example:
- the importing country may identify flexibility or options within its requirements for trade on how its objectives, and related outcomes or level of protection, may be met by the exporting country
 - the exporting country may decide to make changes to a [sanitary measure, technical regulation, standard and conformity assessment procedure, or] relevant part of its NFCS to more closely align with or better achieve the importing country's objectives, and related outcomes or level of protection,
 - the two countries may decide to engage in further cooperation and/or capacity building so as to better understand and address the relevant challenges impacting trade between them. Further cooperation may include, for example, information exchange, joint training, technical cooperation, or other support to help develop or strengthen the NFCS or the relevant part of the NFCS.
- 22 Importing countries considering providing the exporting country technical assistance, may wish to consider the following:
- assistance in evaluating which requirements could be the subject of an equivalence assessment
 - assistance with the preparation of documentation, including the submittal package
 - assistance in undertaking any necessary risk assessments
 - assistance with data analysis
 - [assistance in suggesting changes to the exporting country's NFCS or part of its NFCS that would allow it to better meet the objectives of the importing country's requirements]

SECTION 6: PROCESS STEPS

The process steps are:

Step 1: Exporting country formalizes its request for consultations on equivalence

Step 2: Importing country describes its [NFCS, part of its NFCS and/or] relevant requirements and objectives

Step 3: Importing country documents the decision criteria

Step 4: Exporting country documents its case for equivalence

Step 5: Assessment process

Step 6: Decision process and final decision

Step 7: Documenting the agreement / arrangement

- 23 Once a formal request for consultations on a recognition of equivalence has been made (see **step one** for further guidance), the two countries should agree on a plan:

- for the exporting country to provide the appropriate submission; and then
- for the importing country to work through its assessment and decision-making process.

This plan may also include anticipated timeframes and if necessary, priorities. Further guidance on the recommended process steps is provided below and a simplified flow diagram of the process steps is included at **Annex 1**.

Step 1: Exporting country formalizes its request for consultations on equivalence

- 24 The exporting country requesting consultations with the aim of achieving agreement on the recognition of equivalence should discuss and document the scope of the request, drawing on the initial scope discussions, where these have been held. The description of the scope of the request should include for example:

- the specific foods or group of foods, including where relevant any types of secondary processing
- the importing country's requirements³ for which the exporting country is seeking a recognition of equivalence
- a brief description of the exporting country's [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or relevant part of its NFCS for which the exporting country is seeking an equivalence determination.

Step 2: Importing country describes its [NFCS, part of its NFCS and/or] relevant requirements and objectives

- 25 The importing country should discuss and document the basis for its relevant requirements, for the scope of products covered by the request. This should include as appropriate:
- the scientific or policy basis justifying the necessity for the requirements under consideration, including risk assessment where appropriate
 - how the requirements contribute to achieving the NFCS objectives, related outcomes or level of protection⁴
 - where appropriate, an expression of the level of control of the hazard in a specific food or group of foods that is achieved by the requirement
 - the identification of the specific objectives and or risks and level of control required as it relates to the protection of the health of consumers or ensuring fair practices in the food trade that the requirements are intended to address
 - the justification for the requirements, as relevant to the bilateral circumstances existing between the two countries and
 - any additional information that may assist the exporting country in presenting an objective demonstration of equivalence.
- 26 The importing country should also describe⁵, with appropriate references, how its own NFCS or relevant part of its NFCS, achieves its NFCS objectives, and related outcomes or levels or protection. As relevant to the scope of the request, the importing country may provide a description of the relevant underpinning components of its NFCS or the relevant part of its NFCS such as:
- regulatory and legislative framework
 - control and approval requirements (for example establishment, process and product programs)
 - verification or conformity assessment, and audit programs
 - monitoring, surveillance, investigation and food safety incident response programs
 - enforcement and compliance programs
 - stakeholder engagement, communication and rapid alert systems
 - system overview monitoring and evaluation programs, or existing conformity assessment procedures, or
 - any other elements directly relevant to the specific requirements, products or programs under consideration.
- 27 In describing its own [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or the relevant part of its NFCS, the importing country may include reference to relevant standards, guidelines, and/or codes of practice from Codex or other relevant international standard setting bodies.

Step 3: Importing country documents the decision criteria

28. The decision criteria provide the objective basis for comparison for use in the importing country's assessment.

³ the range of requirements to be included in the request may for example relate to general or specific food safety outcomes, production claims such as organics, other qualitative claims or conformity assessment, certification requirements, or any other matters relating to the protection of the health of consumers or ensuring fair practices in the food trade

⁴ Including the quantitative or proportionate effect of their contribution.

⁵ ref: CXG 82-2013, paragraph 43 and CXG 89-2016 Section 7

29. Discussions should occur between the exporting and the importing country to assist the development of the decision criteria, and better understanding of how the decision criteria to be applied.
30. Following the discussions, the importing country should document the decision criteria and how they will be applied to evaluate the exporting country's request and submission..
31. The decision criteria should facilitate the importing country's to assess whether or not the exporting country's design and implementation of its [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or relevant part of the NFCS achieves the importing country's relevant objectives, and related outcomes or level of protection, associated with the scope of the request.⁶
32. The decision criteria may contain qualitative or quantitative [elements, or both,] and should include for example:
- the relevant importing country NFCS objectives, and related outcomes or level of protection;
 - the type of evidence expected to objectively demonstrate equivalence;
 - an indication of the amount or level of qualitative or quantitative evidence that is expected;
 - any indicators⁷ of outcomes required that may be used to demonstrate equivalence; and
 - how existing experience, knowledge and confidence may be used [to both reduce the amount of information required to be submitted by the exporting country and what the importing country may need to conduct a more detailed assessment of.
- [33. The decision criteria should not apply a standard or level of performance that exceeds that achieved by the importing country's [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or relevant part of the NFCS [and avoid creating unnecessary obstacles to trade].

Step 4: Exporting country documents its case for equivalence

34. The exporting country should submit or make available appropriate information and evidence, including relevant references that demonstrate how its [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or the relevant part of its NFCS, achieves the importing country's NFCS objectives, and related outcomes or level of protection, as relevant to the scope of the equivalence request.
35. The submission should cover all relevant aspects of the decision criteria and objectively demonstrate that the exporting country's [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or the relevant part of its NFCS, meets those criteria.
36. The submission should include the additional relevant information and evidence that the importing and exporting country have agreed is not already covered by the importing country's existing knowledge, experience, and confidence in the exporting country's NFCS.
37. As far as practical, and especially where consistent with the relevant Codex guidance and other international standards, importing countries should allow the exporting country flexibility in the format of the information it submits.
38. Subject to the scope of any request for recognition of equivalence, additional information exchanges may be required to clarify or supplement information provided by the exporting country. Any requests for additional information should, where appropriate, be specific, relevant to the scope of the request, and avoid duplication of information.

Step 5: Assessment process

39. 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 [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or the relevant part of the NFCS meets the decision criteria. The development of

⁶ One example of a decision criteria could be: Regulatory decisions are based on sound scientific analysis and evidence, involving a thorough review of available relevant information (e.g. historical regulatory decisions, published risk assessments, or compliance actions).

⁷ See Appendix B of CXG 91-2017 for some illustrative examples of outcomes and examples of potential indicators for those selected outcomes.

the assessment process should also consider any ways to simplify the assessment process to make it more efficient and less burdensome on both countries. There should be an effective communication mechanism between both countries, for providing feedback.

40 The assessment process will normally comprise a number of steps but may vary (refer paragraph 42 below). 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 request 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 where the addition of one or more specific controls to their NFCS could facilitate the assessment process
- consider any additional controls proposed by the exporting country to facilitate a positive determination.

41 The importing country's assessment process should:

- focus on whether the exporting country's [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or the relevant part of the NFCS achieves the objectives, and related outcomes or level of protection, of the importing country's [sanitary measure, technical regulation, standard and conformity assessment procedure,] 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 in the exporting country)
- consider the use of indicators of outcomes that may be different from the importing country's that may be used by the exporting country to demonstrate the performance of its [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or the relevant part of its NFCS, to achieve the importing country's objectives, and related outcomes or level of protection
- assess the outcome of the various elements of the exporting country's [sanitary measure, technical regulation, standard and conformity assessment procedure,] 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 or virtual assessments / audits⁸ where justified as necessary to demonstrate the exporting country's [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or the relevant part of the NFCS, meet the decision criteria
- 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.

42 The depth and breadth of the assessment process may vary depending on:

- the scope of the request including, the range of foods and the requirements for which equivalence is sought, and whether it is limited to a specific requirement [sanitary measure, technical regulation,] or a larger part of a NFCS
- the complexity of the exporting country's controls to be assessed
- whether additional evidence, information or clarifications are needed, and / or
- whether an in-country visit will likely be necessary.

43 An in-country visit may be justified [as necessary] as part of an assessment, for example in situations where:

⁸ See the Annex to [CXG 26-1997](#) for further guidance on the conduct of assessments; and CXG 102-2023 *Principles and guidelines on the use of remote audit and inspection in regulatory frameworks*.

- existing knowledge, experience and confidence in the exporting country's NFCS is not sufficient for the importing country to make a decision, or
 - the complexity of the assessment justifies additional verification as part of the assessment to demonstrate the decision criteria are met, or
 - sufficient confidence [in the operation of the NFCS or its relevant part] may not be [able to be ascertained] [demonstrated] through the analytical data itself, or through conformity assessment processes undertaken in accordance with international accreditation arrangements, or through cross reference to other relevant assessments.
- 44 Where an initial assessment identifies the lack of a specific control considered necessary to achieve the relevant importing country objectives, and related outcomes or level of protection, the importing country should, where appropriate, provide the exporting country an opportunity to remedy the deficiency.
- 45 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 improvement⁹, and
 - the availability of resources and infrastructure to continue to implement the NFCS or the relevant part of the NFCS.
- 46 Meetings between the importing and exporting country's competent authorities may facilitate and help expedite the assessment process and their potential use should be included in the planning for the equivalence 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.¹⁰

Step 6: Decision process and final decision

- 47 The importing country should consider its summarised assessment findings against the documented decision criteria with a view to producing a decision document.
- 48 The importing country's decision process should:
- be transparent, documented and conducted in a timely manner;
 - focus on whether the exporting country's [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or the relevant part of its NFCS meets the decision criteria; and
 - not, without justification, introduce an objective or outcome standard or process in excess of what is being applied within the importing country.
- 49 The decision document should highlight whether and, where relevant, the degree to which, each of the decision criteria have been met along with, where relevant, the relative weighting each has had on the draft final decision. Where the importing country considers one or more of the decision criteria have not been met the importing country should clearly document why it has reached this conclusion.
- 50 [The importing country should document the draft assessment conclusion and the rationale and provide the draft decision document to the exporting country. The exporting country should be given the opportunity to correct any factual errors and to comment on the draft conclusions.] In the case where the exporting country's [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or the relevant part of its NFCS is initially 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.
- 51 The importing country should review the exporting country's additional information without requiring all aspects of the assessment process to be repeated, so long as the exporting country provides the

⁹ Explanation of the meaning of these terms is found in Paragraph 36 of [CXG 82-2013](#)

¹⁰ 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.

additional information in a timely manner.

- 52 The importing country should document the final assessment conclusions and the associated rationale.
- 53 Where the importing country recognises the equivalence of the [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or the relevant part of its NFCS, both countries should then discuss how this recognition will affect the requirements for trade in food between the countries.

Step 7: Documenting the agreement / arrangement

54. Importing and exporting countries should document any recognition of equivalence reached and how the recognition affects the requirements for trade and the agreed implementation expectations of both countries. Suggested content headings for a recognition agreement / arrangement document are provided in **Annex 2**.
- 55 The recognition of equivalence may for example affect requirements relating to the acceptance of the eligibility of exporting country establishments, changes to certification requirements, expedited port of entry clearance, and enhanced cooperation for resolution of problems.
- 56 The documentation should include [the importing and exporting countries agreed expectations with respect to ongoing implementation, maintenance, review, amendment and termination of the recognition. This may include procedures:
- for notification and review of proposed substantive changes to either country's NFCS requirements that alter the required objectives, related outcomes or level of protection that the recognition is based on;
 - for information exchange in the event of a food emergency situation; and
 - to follow in the case of food shipments that are found not to comply with the terms of the equivalence agreement / arrangement.
- 57 The documentation of the recognition of the equivalence may be completed through an exchange of letters or through the negotiation of a more formal equivalence agreement or arrangement as appropriate.
- 58 As appropriate, the documentation should provide for the scope of the equivalence recognition to be amended by mutual agreement at a later time to cover additional products or processes. In such cases the level and extent of any new submission and assessment required should be discussed and agreed between the importing and exporting countries

SECTION 7: IMPLEMENTATION AND MAINTENANCE OF EQUIVALENCE [RECOGNITIONS] [AGREEMENT / ARRANGEMENT]

- 59 Maintenance of recognition arrangements / agreements should allow regulatory frameworks, programs and oversight to evolve over time.
- 60 Equivalence recognition agreements / arrangements typically include expectations with respect to ongoing exchanges of information consistent with the maintenance of an appropriate level of experience, knowledge and confidence. This should be supported by regular dialogue, information exchange and, where appropriate, periodic review mechanisms to ensure the continued relevance and sustainability of the recognition.
- 61 Maintenance and review of recognitions of the equivalence of the [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or the relevant part of a NFCS may include, as applicable to the scope of the recognition, activities such as:
- regular provision of summary information on the performance of the NFCS or the relevant part;
 - notification of and potential review of any proposed significant changes to the legislation or performance measures underpinning the components of either country's NFCS or the relevant part of the NFCS covered by the recognition of equivalence;
 - regular technical discussions between relevant experts; and
 - intermittent country visits or technical exchanges so as to maintain the currency of experience, knowledge and confidence.¹¹

¹¹ 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*)

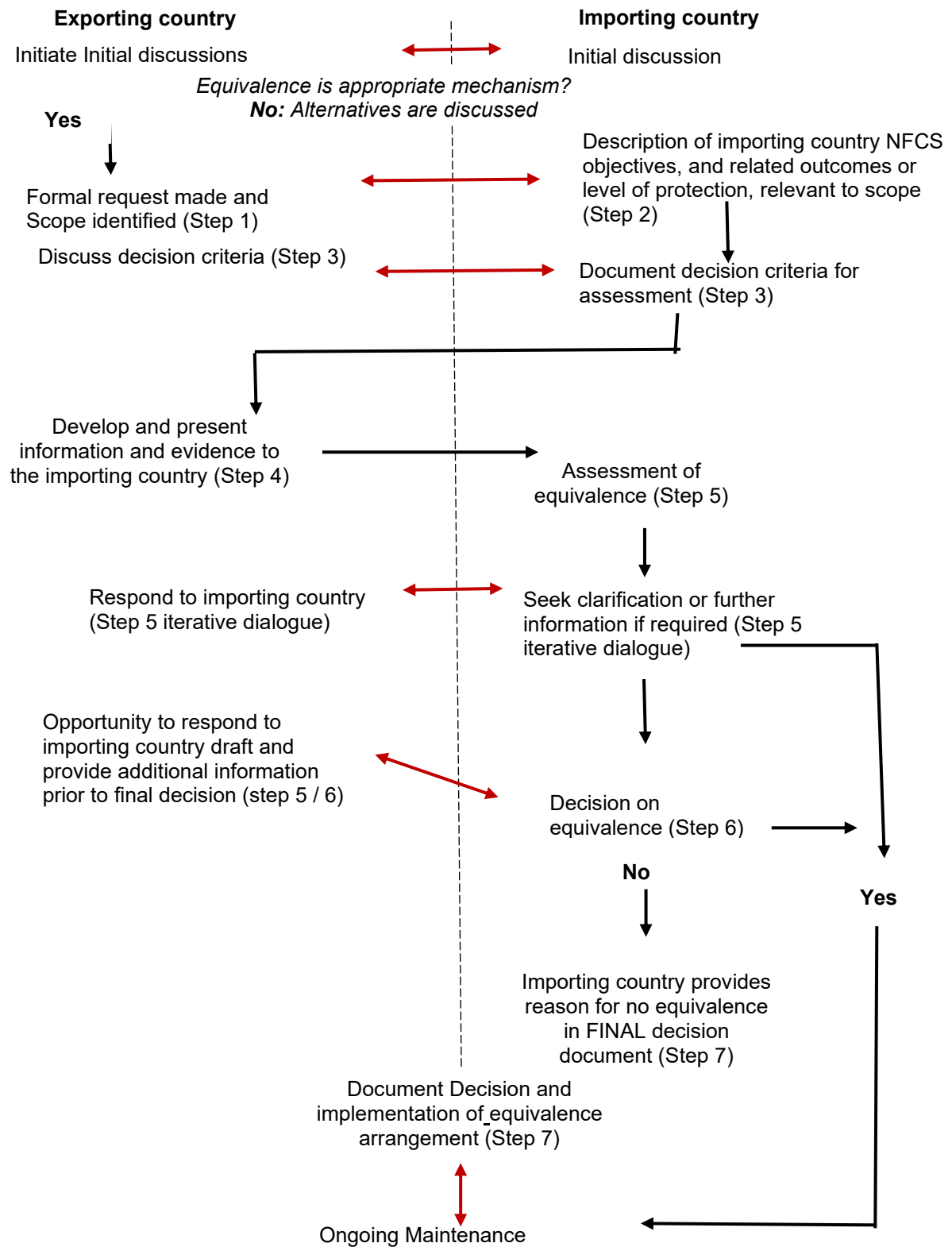
- 62 The importing and exporting countries should also discuss and agree on what level of change to the importing or exporting country's NFCS or part of a NFCS or other change in circumstances should be provided to the other country and when a review of the recognition of equivalence may be required. Generally, equivalence agreements / arrangements and the recognition of equivalence should continue to apply while any such reassessments are progressed, unless there is an increase in the risk to the health of consumers. Such changes may for example include a:
- substantive change to the level of protection of the health of consumers or fair practices in the food trade required by the importing country
 - sustained drop in the level of protection of the health of consumers or fair practices in the food trade achieved by the exporting country
 - proposed significant change to the underpinning legislative base or operational elements of the exporting country's NFCS or relevant part of its NFCS as previously evaluated
- 63 Audits, where they occur, should focus on whether the exporting country's [sanitary measure, technical regulation, standard and conformity assessment procedure,] NFCS or the relevant part of the NFCS recognized as equivalent is continuing to be effectively applied. Where deficiencies are identified in how the exporting country is applying those areas of its NFCS that have been recognized as equivalent, the countries should agree on appropriate corrective actions.
- 64 The importing and exporting countries should cooperate where instances of non-complying product or export documentation are found. Consistent with the scope of any recognition, but excepting those situations where urgent actions may be justified, the exporting country should be allowed to apply corrective actions to its own NFCS or the relevant part of its NFCS and appropriately inform the importing country rather than the importing country implementing additional requirements.
- 65 Where appropriate, the agreement / arrangement may include expectations with respect to the type and frequency of any ongoing requirements for information exchange or audits. Generally, such audits should be mutually agreed and reflect the Codex principles and guidelines¹².

END

¹² Annex to CXG 26-1997

ANNEX 1: Flow Diagram**Figure 1: Equivalence of National Food Control Systems Overall Process**

Simplified flow chart for recognition and maintenance of equivalence of the whole or a part of NFCS
(individual steps may be iterative)



ANNEX 2: CONTENT OF AN EQUIVALENCE RECOGNITION DOCUMENT

[Adapted from Appendix A of CXG 34-1999]
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Note: the specific language used will depend on whether the equivalence recognition is a cooperative arrangement between the relevant competent authorities or a treaty level agreement between the governments of the two countries.

The following information may be included, as appropriate:

- (a) **Title:** The name given to the agreement/arrangement may vary, depending on the preferences and legal requirements of the parties.
- (b) **Parties / Participants:** The name of the entities entering into the agreement/arrangement.
- (c) **Purpose:** A brief statement of the specific purpose of the agreement/arrangement.
- (d) **Scope:** Identification of the products and measures that are the subject of the agreement/arrangement.
- (e) **Definitions:** Definitions of terms used in the agreement/arrangement, as needed. Where possible, definitions in WTO and Codex documents should be used.
- (f) **Principles:** The collectively agreed principles that will apply to the administration of the agreement/arrangement.
- (g) **Equivalence finding:** A statement of the [sanitary measures, technical regulations, standards conformity assessment procedures] NFCS or relevant part that have been recognised as equivalent and the effect this has on the requirements for trade for the exporting country for products / measures within the scope of the agreement/arrangement.
- (h) **Administrative Provisions / Processes:** A description of each participant's responsibilities with respect to the implementation and ongoing maintenance of the agreement/arrangement. These may include, for example:
 - i. **Liaison channels**
 - ii. **Information exchange**
 - iii. **Meeting and consultation provisions [/problem solving mechanisms]**
 - iv. **Audit and verification**
 - v. **Notification provisions**
 - vi. **Reassessment criteria**
- (i) **Emergency measures:** The notification, cooperation and cooperation provisions that will apply should one Party / Participant need to adopt an emergency measure.
- (j) **Review, modification and termination:** The methods for the review, modification and termination of the agreement/arrangement.
- (k) **Entry into effect:** The date on which the provisions of the agreement/arrangement enter into effect.
- (l) **Signature panel:** Dates, signatures, names, titles and country / competent authority to the agreement/arrangement.