



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

**Twenty-fourth Session**

**Brisbane, Australia, 22 - 26 October 2018**

**PROPOSED DRAFT GUIDANCE ON USE OF SYSTEMS EQUIVALENCE**

**Comments at Step 3 (Replies to CL 2018/51/OCS-CCFICS)**

Comments of Colombia, Cuba, Ecuador, Egypt, Guatemala, Honduras, Indonesia, Jamaica, Japan, Kenya, Nicaragua, Norway, Paraguay, Philippines, Sri Lanka, Zambia and FAO.

**Background**

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2017/51/OCS-CCFICS issued in August 2018 with a deadline for submission of comments of 28 September 2018.

**Explanatory notes on the appendix**

2. The comments submitted through the OCS are hereby attached as **Annex I** and are presented in table format. **Annex II** presents comments submitted directly by email.

## ANNEX 1

## COMMENTS ON THE PROPOSED DRAFT GUIDANCE ON THE USE OF SYSTEMS EQUIVALENCE

## Comments at Step 3 (Replies to CL 2018/51/OCS-CCFICS)

GENERAL COMMENTS	
Comment	Member/Observer and Rationale where applicable
Ecuador is grateful for this work, led by New Zealand with the United States and Chile. Having reviewed document CX/FICS 18/24/4, "Proposed Draft Guidance on Use of Systems Equivalence" and based on the question asked in the recommendations issued by the Committee, as to whether this work should consist of making amendments to the existing guidelines, in order to avoid duplication, or developing new work to combine the reformulation of the new guidelines, Ecuador believes that establishing systems equivalence is a complex issue and that, as a consequence, all the aspects that influence the possibility of equivalence recognition need to be thoroughly analysed. In view of the foregoing, Ecuador considers that, to provide practical guidance to Codex members and to support the adequate use of equivalence, these guidelines should be adopted as new work, and not as mere amendments that could be made to the existing guidelines. In this regard, Ecuador supports advancing this proposed draft to the next step, so that member countries may continue analysing the guidelines in the document. In addition, Ecuador would like to submit the following specific comments.	<b>Ecuador</b>
Egypt approves the draft of guidelines on recognition and maintenance of equivalence of national food control systems (nfcs) to be submitted (at step 3) with no comments	<b>Egypt</b>
Indonesia would like to express our appreciation and thanks for great efforts done by New Zealand, Chili and US for preparing Draft Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems (NFCS). In this matter, we would like to propose delete "relevant" in the phrase "the relevant part(s)" for consistency, since it is already mentioned as "in whole or in part" of NFCS in introduction.	<b>Indonesia</b>
Jamaica continue to support the work and development of this document for advancement. However, the country also support discussion to carefully assess the need to merge this draft with existing Codex Text that speak to System Equivalence. Having one standardize text speaking about system equivalence for NFCS may be an advantage over, having several fragmented text with similar deliverable. However, if this document is to remain a stand alone version with its independents in providing guidance on recognition of system equivalence then care must be taken to ensure there are no redundancies with other existing text.	<b>Jamaica</b>
We submit our general comments as follows; 1.To make consistent use of languages throughout the document. 2.Languages in the body of text and the Figure should be consistent. 3.To make the subject of each sentence clear. 4.Step1(The initial discussions) should allow an importing country to prioritize the system equivalence taking into account other food safety situation (emergency response, discussion of other system equivalence, resources etc.) in the importing country.	<b>Japan</b>

Paraguay suggests that this document should be reviewed by the Committee to see if it could be unified with any existing Codex text, in order to avoid duplicating documents. In addition, we request clarification about the meaning of “relevant parts of an NFCS”.	<b>Paraguay</b>
The Philippines would like to congratulate the Working Group led by New Zealand and co-chaired by United States of America and Chile in coming up with the proposed draft guidance on use of systems equivalence. The Philippines believes that this ‘mother document’ will provide guidance for determination of equivalence of NFCS systems and will facilitate more efficient trade between countries.  We welcome the draft presented in Appendix 1 (Draft Guidelines on recognition and maintenance of equivalence of National Food Control Systems (NFCS), at Step 3, and would like to submit our specific comments, as follows:	<b>Philippines</b>
Zambia is in the process of finalizing the Food safety bill and still needs a lot of technical support in the area of recognition and maintenance of equivalence of NFCS. It is suggested that Codex secretariat organizes a Technical support program such as a meeting to deal with the subject for countries to understand this more. However, guidelines are ok but need to be well understood by implementing countries and agencies for both import and export	<b>Zambia</b>
<b>SPECIFIC COMMENTS</b>	
<ul style="list-style-type: none"> <li>• SECTION 3 DEFINITIONS</li> </ul> <p>National Food Control System: Considering the above statements, we believe that the definition to be included should be as follows: “as defined / described by CAC/GL 82/2013”</p> <ul style="list-style-type: none"> <li>• SECTION 5 – PROCESS STEPS</li> </ul> <p>Step 2: The decision criteria for comparison</p> <p>The importing country <del>provides in consultation with the exporting country</del> <u>establishes</u> the decision criteria for determining whether the exporting country’s NFCS or the relevant part is capable of reliably meeting the objectives of the importing country’s NFCS for the products under consideration.</p>	<p><b>Ecuador</b></p> <p>RATIONALE: For consistency with paragraph 21.</p>
<p>Paragraph with the heading “Assessment”</p> <p>The assessment process should be transparent, evidence-based, it should have assessment methods, and focus on assessing whether the exporting country’s NFCS in whole or the relevant part as described meets the decision criteria.</p>	<b>Honduras</b>
<p>Paragraph “Alignment with International Standards”. We suggest considering what is described in CAC/GL – 82-2013:</p> <p>Principle 12 Harmonisation<sup>23</sup>. When designing and applying a food control system, the competent authority should consider Codex standards, recommendations and guidelines whenever appropriate as elements of their national food control system to protect the health of consumers and ensure fair practices in the food trade. Standards, recommendations or guidelines from other international intergovernmental organisations whose membership is open to all countries may also be useful.</p>	<b>Honduras</b>
Paragraph: Experience, Knowledge and Confidence	<b>Honduras</b>

<p>We suggest to specify: Which international organizations does the text refer to? What are the competences and powers of these organizations? Which are the IO that could have that degree of confidence of countries to facilitate trade?</p> <p>The document establishes the assessment criteria between the importing and exporting country, but it does not establish the international organizations' assessment criteria.</p>	
<p>Section 2 - National Food Control System. The FAO document "Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems" defines "food control" as:</p> <p>...a mandatory regulatory activity of enforcement by national or local authorities to provide consumer protection and ensure that all foods during production, handling, storage, processing, and distribution are safe, wholesome and fit for human consumption; conform to safety and quality requirements; and are honestly and accurately labelled as prescribed by law.</p> <p>In addition, it describes the term "National Food Control Systems" as follows:</p> <p>Food Control System is used in these Guidelines to describe the integration of a mandatory regulatory approach with preventive and educational strategies that protect the whole food chain. Thus an ideal food control system should include effective enforcement of mandatory requirements, along with training and education, community outreach programmes and promotion of voluntary compliance.</p> <p>We suggest considering these definitions / descriptions in developing the definition of NFCS in this document.</p>	<b>Honduras</b>
<p>Section 3 - Definitions</p> <p>The definition is vague and there is no clear description or definition in CAC/GL 82/2013.</p> <p>New definition.</p> <p>It is not relevant to continue with this proposal.</p>	
<p>Paragraph 5: The wording needs to be improved; the repetition of "guidance" is redundant in both English and Spanish.</p> <p>These guidelines further elaborate the guidance contained within the foundation guidance on FICS and NFCS and complements the existing Codex guidelines on the exchange of information to support trade in food as well as those that focus primarily on the development of equivalence agreements<sup>4</sup> and the judgement of the equivalence of specified sanitary measures<sup>5</sup>.</p>	<b>Honduras</b>
<p>A large majority of trade in food occurs without exporting countries being required to undergo a detailed assessment of their National Food Control System (NFCS) or having to replicate all or parts of an importing country's NFCS. However, where additional assurance is required, several mechanisms as outlined in various existing Codex guidelines may be available to facilitate this. For example CAC/GL 89-2016<sup>1</sup> provides guidance on the exchange of NFCS information between importing and exporting countries to support trade in food and CAC/GL 26-1997<sup>2</sup> provides guidance on the assessment of a Food Inspection and Certification System.</p>	<b>Norway</b> We would suggest a footnote to NFCS with reference to CAC/GL 82 – 2013 to explain the concept of NFCS. We also consider that there is no need to define NFCS as 82-2013 explains NFCS as a whole.

<p>1 A large majority of trade in food occurs without exporting countries being required to undergo a detailed assessment of <del>by</del> their National Food Control System (NFCS) or having to replicate all or parts of an importing country's NFCS. However, where additional assurance is required, several mechanisms as outlined in various existing Codex guidelines may be available to facilitate this. For example CAC/GL 89-2016<sup>1</sup> provides guidance on the exchange of NFCS information between importing and exporting countries to support trade in food and CAC/GL 26-1997<sup>2</sup> provides guidance on the assessment of a Food Inspection and Certification System.</p>	<p><b>Sri Lanka</b></p>
<p>1 A large majority of trade in food occurs without exporting countries being required to undergo a detailed assessment of their National Food Control System (NFCS) or having to replicate all or parts of an importing country's NFCS. However, where additional assurance is required, several mechanisms as outlined in various existing Codex guidelines may be available to facilitate this. <del>For example CAC/GL 89-2016<sup>1</sup> provides guidance on the exchange of NFCS information between importing and exporting countries to support trade in food and CAC/GL 26-1997<sup>2</sup> provides guidance on the assessment of a Food Inspection and Certification System.</del></p>	<p><b>Kenya</b> Kenya proposes the example to be placed as a footnote as a partial deletion of the example since it has a purpose as part of the development of the draft.</p>
<p>3 Existing guidelines address equivalence in terms of food import and export inspection and certification systems as opposed to how the operation of a NFCS in whole or in part can provide assurances. Current guidance primarily focuses on the development of equivalence agreements and the judgement of the equivalence of specified sanitary measures within a Food Inspection and Certification System <del>System (FICS).</del></p>	<p><b>Indonesia</b> 1. abbreviation of Food Inspection and Certification System as [FICS] should be mentioned first. 2. Indonesia would like to clarify what the current guidance means in this para. Is it "existing guidance" or "this guidance"?</p>
<p>5 These guidelines further elaborate the guidance <del>contained within the foundation guidance</del> on FICS and NFCS and <u>to</u> complements the existing Codex guidelines on the exchange of information to support trade in food as well as those that focus primarily on the development of equivalence agreements<sup>4</sup> and the judgement of the equivalence of specified sanitary measures<sup>5</sup>.</p>	<p><b>Indonesia</b> to make it concise</p>
<p><b>SECTION 2 –SCOPE / PURPOSE</b></p>	
<p><b>SECTION 2 –SCOPE / PURPOSE</b></p>	<p><b>Guatemala</b> It is important to develop the guidelines of this proposed draft. However, the other guidelines on systems equivalence and information exchange should be considered, to determine whether there is a need to create new guidelines or to amend the existing ones.</p>
<p>6 This document provides practical guidance for competent authorities prior to formal requests for consultations on the recognition of equivalence; and then on the process for undertaking considerations, assessments, recognitions and maintenance of the equivalence of the whole or a relevant part of the NFCS.</p>	<p><b>Philippines</b> We suggest that the phrase 'recognition of equivalence of food control systems or their components' on Para 6 and 7 be reflected throughout the text to ensure clear understanding on the intent of the document and to be consistent with existing Codex texts (CAC/GL 82-2013).</p>
<p>7 A request for a recognition of equivalence may relate to either the protection of the health of consumers or ensuring fair practices in the food trade and be associated with an entire NFCS or only to that part of a NFCS relevant</p>	<p><b>Philippines</b> To ensure consistency in the language with existing</p>

to the <del>particular products</del> certain type of food or group of foods that are traded or are intended to be traded and that are covered by the request <sup>6</sup> .	Codex texts (i.e.CAC/GL 53-2003), we recommend that reference to products be revised to refer to 'certain type of food or group of foods' and for this to be reflected throughout the text.
8 [The consideration, assessment and recognition of the equivalence of one country's NFCS in whole or the relevant part is independent of any reciprocal process occurring.Where appropriate, countries may choose to undertake reciprocal consideration of the other country's NFCS in parallel with the original request.Reciprocal considerations may have different scopes and may arrive at different conclusions.]	<b>Norway</b> We support the inclusion of this paragraph, this provides clarity about an important concept, and provides sufficient flexibility to choose.Remove square brackets.
8 <del>[The</del> The consideration, <del>assessment and</del> assessment, recognition and maintenance of the equivalence of one country's NFCS in whole or the <del>relevant</del> part is independent of any reciprocal process occurring.Where appropriate, countries may choose to undertake reciprocal consideration of the other country's NFCS in parallel with the original request.Reciprocal considerations may have different scopes and may arrive at different conclusions.]	<b>Indonesia</b> to be consistent with the title of the draft guidelines
8 [The consideration, assessment and recognition of the equivalence of one country's NFCS in whole or the relevant part is independent of any reciprocal process occurring.Where appropriate, countries may choose to undertake reciprocal consideration of the other country's NFCS in parallel with the original request.Reciprocal considerations may have different scopes and may arrive at different conclusions.]	<b>Philippines</b> We proposed to include the word 'and maintenance' after equivalence, consistent with para 6.  On the bracketed text, we express reservations on the conduct of parallel or simultaneous consideration, assessment and recognition of several parts of the NFCS.We are of the view that the intent of the proposed draft document is to consider one country's NFCS as a whole – as it applies to certain type of food of group of foods, thereby making the process more efficient and cost-effective.
8 <del>[The</del> The consideration, assessment and recognition of the equivalence of one country's NFCS in whole or the relevant part is independent of any reciprocal process occurring.Where appropriate, countries may choose to undertake reciprocal consideration of the other country's NFCS in parallel with the original request.Reciprocal considerations <del>may have different scopes should be within the set standards and may arrive at different conclusions.]</del> guidelines	<b>Kenya</b>
8 [The consideration, assessment and recognition of the equivalence of one country's NFCS in whole or the relevant part is independent of any reciprocal process occurring. Where appropriate, countries may choose to undertake reciprocal consideration of the other country's NFCS in parallel with the original request. Reciprocal considerations may have different scopes and may arrive at different conclusions.]	<b>Colombia</b> Colombia considers that, in addition, this aspect must be reviewed considering other existing texts of CCFICS on systems equivalence. Thus, paragraph 8 is supported, with the abovementioned comment.
<b>SECTION 3 – DEFINITIONS</b>	

<b>Alternative:</b>	<b>Philippines</b> We are amenable with the alternative text and would like to suggest the following revision.
[National Food Control System: a system wherein its framework consists of the policy settings, system design, implementation and monitoring and review of the production, packing, storage, transport, handling and sale of foods within national borders, including import and export control systems, as established and maintained by national governments and their competent authority for the protection of the health consumers and ensuring fair practices in the food trade.]	<b>Philippines</b>
<del>[National Food Control System: consists of the policy settings, system design, implementation and monitoring and review of the production and processing, packing, storage, transport, handling and sale of foods within national borders, including import and export control systems, as established and maintained by national governments and their competent authority for the protection of the health of consumers and ensuring fair practices in the food trade.]</del>	<b>Kenya</b> Kenya adopts the alternative definition as amended and noted the description in CAC/GL 83:2013 as inadequate.
[National Food Control System: consists of the policy settings, system design, implementation and monitoring and review of the production, packing, storage, transport, handling and sale of foods within national borders, including import and export control systems, as established and maintained by national governments and their competent authority for the protection of the health consumers and ensuring fair practices in the food trade.]	<b>Colombia</b> Colombia agrees with the first alternative about the National Food Control System, which refers to and is broadly supported in document CAC/GL 82/2013.  Finally, Colombia considers that it would be advisable to develop a new document to consolidate and modernize the Guidelines about the use of equivalence.
<del>Equivalence: the capability of different inspection and certification systems to meet the same objectives.</del>	<b>Japan</b> Japan proposes to delete the definition "Equivalence" because this guidance intends to provide clear recommendation for developing and implementing systems equivalence and therefore this could contradict such concept.
Equivalence: the capability of different inspection and certification systems NFCS or parts of a NFCS to meet the same objectives.	<b>Indonesia</b> referring to the equivalence in the title, the definition of equivalence should be broader and describing the NFCS as in draft guidelines
Equivalence: the capability of different inspection and certification systems to meet the same objectives.	<b>Nicaragua</b> For consistency between the definitions of equivalence and system equivalence, we propose deleting the terms "inspection and certification", since these are components of the NFCS. In addition, since the definition is general in scope, it is not appropriate to include elements which are specific to the NFCS.

<del>System Equivalence: the capability of different NFCS or parts of a NFCS to meet the same objectives.</del>	<b>Indonesia</b> As the proposed definition of equivalence, we propose to delete the definition of systems equivalence
<del>NFCS Objectives: the intent or purpose of the core elements of the NFCS or the relevant part including how these contribute to the overarching goals of the NFCS to protect the health of consumers and ensure fair practice in the food trade.</del>	<b>Nicaragua</b> According to paragraph 6 of CAC/GL 82-2013
<del>Outcome: Intended effects or results that contribute to achieving the NFCS Objectives. Outcomes may be categorized at different levels, such as ultimate, high-level, intermediate, preliminary, or initial.<sup>7</sup></del>	<b>Nicaragua</b> We propose reviewing the definition, considering that "outcome" refers to the consequence or effect of an action; thus, the outcome may or may not meet the intended objectives. In addition, outcomes cannot be considered as being intended, since this would create a bias at the moment of evaluation.
<del>Decision Criteria: those factors used to determine whether the exporting country's NFCS or relevant part is capable of reliably adequately meeting the objectives of the importing country's NFCS or the relevant part for the products under consideration.</del>	<b>Japan</b> Japan proposes to replace "reliably" with "adequately" for clarification.
<b>SECTION 4 – PRINCIPLES</b>	
<b>SECTION 4 – PRINCIPLES</b>	<b>Philippines</b> We are of the position that open communication or timely exchange of information should be included as one of the principles when considering the equivalence of systems. There should be one principle referring to CAC/GL 89-2016 Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food.
9 Consideration of the equivalence of <u>national food control</u> systems should be based on the application of the following principles:	<b>Indonesia</b> consistency
<b>Equivalence of Systems</b>	
<del><b>Equivalence of Systems</b></del>	<b>Nicaragua</b>
	<b>Indonesia</b> to make it clear.
<del>a. Countries should recognize that NFCS's, or the relevant parts thereof, of importing and exporting countries, although designed and structured differently, are capable of meeting the same objectives with respect to protecting the health of consumers and ensuring fair practices in the food trade and can therefore be found to be equivalent.</del>	<b>Nicaragua</b> According to this definition, the equivalence of systems consists of the judgement of a Competent Authority about the capability of different systems or

	<p>parts thereof to meet the same objectives with regard to food safety and fair practices in the food trade.</p> <p>Therefore, we consider that the term should not be included in this section, since the “equivalence of systems” is the expected result if the evaluation performed by an Authority is positive.</p>
<p>b. Countries should consider existing experience, knowledge and confidence and may consider where appropriate relevant assessments by other countries or international organizations.</p>	<p><b>Norway</b> We support the text, as this is a very important concept. However, we would like to suggest including a sentence: Existing trade, not perceived to be subjected to trade barriers, should be noted and excluded from the ongoing assessment of equivalence. Reason: To avoid trade barriers to existing ongoing trade, while undergoing an equivalence assessment.</p>
<p>c. The use of Codex or other relevant international standards, guidelines or recommendations can facilitate the consideration, assessment and recognition of the equivalence of <del>systems</del> <u>NFCS</u>.</p>	<p><b>Indonesia</b> to be consistent with the title of draft guidelines</p>
<p>e. The decision criteria used for assessing system equivalence should reflect the objectives of the importing country’s own NFCS, or the relevant part, and focus on whether the exporting country’s NFCS, or relevant part, is [likely to / will] reliably achieve the same objectives.</p>	<p><b>Norway</b> We would welcome more explanation on how the parties interpret “reliably”, and would suggest likely to achieve as sufficient text.</p>
<p>e. The decision criteria used for assessing <del>system</del> <u>equivalence of system</u> should reflect the objectives of the importing country’s own NFCS, or the <del>relevant</del> part, and focus on whether the exporting country’s NFCS, or <del>relevant</del> part, is [<del>likely to / will</del>] <u>will</u> reliably achieve the same objectives.</p>	<p><b>Indonesia</b> to be consistent with the title of draft guidelines and editorial</p>
<p>e. The decision criteria used for assessing system equivalence should reflect the objectives of the importing country’s own NFCS, or the relevant part, and focus on whether the exporting country’s NFCS, or relevant part, is [likely to / will] reliably achieve the same objectives.</p>	<p><b>Philippines</b> On the bracketed text, we recommend the following text: “The decision criteria used...and focus on whether the exporting country’s NFCS or relevant part ‘is likely’ to reliably achieve the same objectives.</p>
<p>e. The decision criteria used for assessing system equivalence should reflect the objectives of the importing country’s own NFCS, or the relevant part, and focus on whether the exporting country’s NFCS, or relevant part, is [likely to / will] reliably achieve the same objectives.</p>	<p><b>Kenya</b> Its a decision criteria</p>
<p>e. The decision criteria used for assessing system equivalence should reflect the objectives of the importing country’s own NFCS, or the relevant part, and focus on whether the exporting country’s NFCS, or relevant part, is [<del>likely to / will</del>] <u>will</u> reliably achieve the same objectives.</p>	<p><b>Kenya</b></p>
<p>(f) The processes and decisions relating to the assessment of systems equivalence should focus on objectives; be documented and transparent; evidence-based; efficient; and conducted in a cooperative [and timely] manner; and</p>	<p><b>Norway</b> We would support keeping “and timely”.</p>

<p>should not introduce an objective, outcome, standard or process in excess of what is being applied within the importing country without justification.</p>	<p>Reason:Time is very important, there is also a reference to time in step 5 and 6 to underline the importance.We would also like to refer to CAC/GL 89 – 2016 where time is included in the principles.</p>
<p>f. The processes and decisions relating to the assessment of systems equivalence should focus on objectives; be documented and transparent; evidence-based; efficient; and conducted in a cooperative [and timely] manner; and should not introduce an objective, outcome, standard or process in excess of what is being applied within the importing country without justification.</p>	<p><b>Philippines</b> We accept the text in square brackets and recommends removing the square brackets surrounding the text.</p>
<p>(f) The processes and decisions relating to the assessment of systems equivalence should focus on objectives; be documented and transparent; evidence-based; efficient; and conducted in a cooperative <del>[and timely]</del> and timely manner; and should not introduce an objective, outcome, standard or process in excess of what is being applied within the importing country without justification.</p>	<p><b>Kenya</b></p>
<p>g. Recognitions <u>equivalence</u> of system <del>equivalence</del> should be documented including how the recognition of equivalence impacts the conditions of <u>consumer health and trade</u> between the two countries.</p>	<p><b>Indonesia</b> consistency and the objectives of NFCS are health and trade</p>
<p>h. Recognitions <del>of systems</del> equivalence <u>of system</u> should include provisions for the maintenance and review of the recognition arrangement.</p> <p><b><u>Formalization</u></b></p> <p>i.<u>Recognitions equivalence of system should be formalized by the two countries</u></p>	<p><b>Indonesia</b> 1.Consistency 2.Indonesia propose to add new bullet in principles about formalization because the principle of formalization is necessary to explain about step 7 – formalization and maintenance of the recognition</p>
<p>h. Recognitions of systems equivalence should include provisions for the maintenance and review of the recognition arrangement.</p> <p><b><u>Trade Facilitation</u></b></p> <p><u>Countries should establish the conditions that may make it possible to simplify their inspection, certification and/or authorization procedures; the equivalence of systems can contribute to this result. This should not reduce their rights and obligations to protect human and animal health, or to preserve plants, and ensure fair practices in the food trade.</u></p>	<p><b>Nicaragua</b> One of the countries’ guiding principles for establishing systems equivalence are the benefits derived from the simplification of procedures and the increased confidence between the authorities. Therefore, we propose including trade facilitation as a principle, with a footnote containing a link to a WTO information note regarding the relationship between the Trade Facilitation Agreement and the SPS Agreement.  The relationship between the Trade Facilitation Agreement and the Agreement on the Application of Sanitary and Phytosanitary Measures is discussed in the following information note:<a href="https://www.wto.org/english/tratop_e/sps_e/tps_e.pdf">https://www.wto.org/english/tratop_e/sps_e/tps_e.pdf</a></p>

<b>SECTION 5 – PROCESS STEPS</b>	<b>Philippines</b> We are of the view that element of time should be included in the process steps.
10 The process steps related to consideration, assessment, <del>recognition-determination</del> and maintenance of the equivalence of NFCs include the following <sup>8</sup> and are expanded in the following subsections and illustrated as a simplified flow chart at Figure 1:	Japan proposes to change "recognition" into "determination" for consistency with GL53.
10 The process steps related to consideration, assessment, recognition and maintenance of the equivalence of NFCs <u>should</u> include <sup>8</sup> the following and are expanded in the following subsections and illustrated as a simplified flow chart at Figure 1:	<b>Nicaragua</b>
<b>STEP 1:Initial discussions and decision to commence:</b>	
<b>Step 1:Initial discussions and decision to commence:</b>	<b>Nicaragua</b> The term “Consultas” is proposed for the translation into Spanish, since it is more widely used and consistent with the practice of the national competent authorities. [ <i>Translator’s Note: The amendment proposed does not change the meaning of the English version.</i> ]
Prior to countries formally requesting consultations, initial discussions should occur to determine whether to commence a system equivalence assessment and whether any preliminary considerations <del>are met</del> <u>should have been sufficiently performed</u> .The countries should then agree the potential scope of the assessment and identify the gaps in existing experience, knowledge and confidence relating to that scope.Once the decision to commence and the associated scope has been discussed the exporting country should formalise its request.	<b>Japan</b> Japan proposes to modify the wording for clarification.
Prior to countries formally requesting consultations, initial discussions should occur to determine whether to commence a system equivalence assessment and whether any preliminary considerations are met. The countries should then agree the potential scope of the assessment and identify the gaps in existing experience, knowledge and confidence relating to that scope. Once the decision to commence and the associated scope has been discussed the exporting country should formalise its request.	<b>Nicaragua</b> We propose including the following footnote so as to link steps 3 and 4 to CAC 82-2013. Proposal:For steps 3 and 4, refer to CAC/GL 82-2013.
Prior to countries formally requesting consultations, initial discussions should occur to determine whether to commence a system equivalence assessment and whether any preliminary considerations are met. The countries should then agree the potential scope of the assessment and identify the gaps in existing experience, knowledge and confidence relating to that scope. Once the decision to commence and the associated scope has been discussed the exporting country should formalise its request. [ <i>Translator’s Note: The amendments proposed do not change the meaning of the English version.</i> ]	<b>Nicaragua</b>
<b>Step 5:Assessment</b>	
<b>Step 5:Assessment <u>process</u></b>	<b>Japan</b> Japan proposes to insert "process" for consistency with Step 6.

<p>Importing country assesses the submission to determine where the exporting country's NFCS or relevant part meets the objectives of the importing country's NFCS. The assessment process should be transparent, evidence-based and focus on assessing whether the exporting country's NFCS in whole or the relevant part as described meets the decision criteria.</p>	<p><b>Japan</b> Japan proposes to add this sentence because it could be clarified who is responsible for this action.</p>
<p>The importing country should perform an assessment process that 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. To the extent possible, there should be an adequate communication mechanism between both countries, for effective feedback.</p>	<p><b>Nicaragua</b> We propose this amendment so that all the steps start with the same wording. In addition, we include a proposed text indicating that both authorities should establish communication mechanisms to resolve doubts during the assessment process.</p>
<p>The assessment process should be transparent, evidence-based and focus on assessing whether the exporting country's NFCS in whole or the relevant part as described meets the decision criteria. [<i>Translator's Note: The amendment proposed does not change the meaning of the English version.</i>]</p>	<p><b>Paraguay</b></p>
<p><b>Step 6: Decision process</b></p>	
<p><b>Step 6: <del>Decision</del> Judgement process</b></p>	<p><b>Japan</b> Japan proposes to change "decision" into "judgement" for consistency with GL53 section 8 titled "judgement".</p>
<p>The decision process- Importing country should be ensure the judgement process is transparent and the result of the assessment documented with the results should be discussed with the exporting country prior to finalisation.</p>	<p><b>Japan</b> Japan proposes to modify this paragraph for clarification on who ensures the transparency of the process.</p>
<p><b>Step 7: Formalization and maintenance of the recognition</b></p>	
<p><b>Step 7: Formalization and maintenance of the <del>recognition</del> determination</b></p>	<p><b>Japan</b> Japan proposes to change "recognition" into "determination" for consistency with GL53.</p>
<p><del>Recognitions</del> Determinations of system equivalence should be documented and subject to regular review.</p>	<p><b>Japan</b></p>
<p>Recognitions of system equivalence should be documented and subject to regular review. <u>Step 8: Publication:</u> In order to improve the understanding of all stakeholders and to reinforce transparency in the food trade, countries should publish the establishment of equivalence recognition through accessible media.</p>	<p><b>Nicaragua</b> NI proposes to include this step considering the recommendations of the WTO SPS Committee.</p>
<p><b>INITIAL DISCUSSIONS AND DECISION TO COMMENCE</b></p>	
<p><b>5.1 STEP 1: INITIAL DISCUSSIONS AND DECISION TO COMMENCE</b> [<i>Translator's Note: The amendment proposed does not change the meaning of the English version.</i>]</p>	<p><b>Nicaragua</b></p>

<p><u>Initial discussions</u></p> <p>11 Initial discussions including identification of the relevant competent authorities should occur before an exporting country formally requests the importing country enter into consultations on recognition of equivalence of systems.</p>	<p><b>Japan</b> Japan proposes to add the subtitle for consistency with Figure 1.</p>
<p>11 Initial discussions including identification of the relevant competent authorities should occur before an exporting country formally requests the importing country enter into consultations on recognition of equivalence of systems. [<i>Translator's Note: The amendment proposed does not change the meaning of the English version.</i>]</p>	<p><b>Nicaragua</b> <i>EDITORIAL CORRECTION</i></p>
<p>12 These discussions should identify if commencing an equivalence of systems assessment is appropriate and if so identify the scope of the assessment to be undertaken. The discussions are also useful to identify where experience, knowledge and confidence relating to that scope already exists and or where there are potential gaps. [<i>Translator's Note: The amendment proposed does not change the meaning of the English version.</i>]</p>	<p><b>Nicaragua</b> <i>EDITORIAL CORRECTION</i></p>
<p><b>Preliminary considerations</b></p>	<p><b>Japan</b> Japan proposes to move this subtitle under Para 13 sets out initial discussion.</p>
<p><b>Preliminary considerations</b></p>	<p><b>Norway</b> We would suggest including some questions/examples related to the preliminary considerations: •What is the potential scope of the assessment?  • What are the gaps (if any) in existing experience? •“Describe” existing knowledge and confidence related to the scope of the assessment</p>
<p>13 The initial discussions should reflect on whether an equivalence of systems recognition is the most appropriate approach to reduced impediments to trade and duplication of control activities while protecting the health of consumers and ensuring fair practices in the food trade, or whether some other mechanism is more appropriate for the circumstances. The discussions should cover any matters that the importing country considers are a prerequisite for a successful system equivalence recognition. The initial discussion should also address the potential scope of any equivalence of systems assessment.</p>	<p><b>Japan</b> Japan proposes to add the sentence because we believe that work on system equivalence should not prevent other food safety work from being compromised.</p>
<p><u>14 In the initial discussions, consideration should be given to allow the importing country to prioritize the equivalence of system recognition with other food safety issues already in place.</u></p>	
<p>14 Relevant matters relating to preliminary considerations <u>by importing country</u> and the likelihood of success may include:</p>	<p><b>Japan</b> Japan proposes to add the words for clarification.</p>
<p><u>Preliminary considerations</u></p> <p>14 Relevant matters relating to preliminary considerations and the likelihood of success may include:</p>	<p><b>Japan</b></p>
<ul style="list-style-type: none"> <li>(See bullet 2) similarity of design and or consistency of each country's NFCS in whole or the relevant part with international standards, including the legislative foundations and objectives underpinning the NFCS;</li> </ul>	<p><b>Philippines</b> We recommend the deletion of the phrase 'similarity of design'. We are of the position that countries' NFCS</p>

	may basically differ in design, but both can achieve the same objectives or give the same outcome
<ul style="list-style-type: none"> <li>(See bullet 4) information exchanges and assessments that may have already occurred (e.g. in accordance with CAC/GL 89-2016) occurred or the existence of other relevant equivalence determinations or recognitions between the two countries or with third countries.</li> </ul>	<b>Kenya</b> introduce the example as a footnote
<b>Scope Considerations</b>	
<b>Scope Considerations</b>	<b>Japan</b> Japan is of the view that GL53 appendix scoping the equivalence determination (paras 5-8) should be referred here.
15 It is important that exporting countries engage in preliminary initial discussions on the potential scope of any equivalence of systems assessment. The scope may relate to an entire NFCS or only to that part of a NFCS relevant to the products that are currently or intended to be traded between the two countries.	<b>Japan</b> Japan proposes to modify this sentence for clarification and consistency.
16 (Bullet 2) the range of assurances to be addressed (e.g. [food food safety, qualitative claims, labelling, or other matters relating to fair practices in the food trade]);	<b>Kenya</b>
<b>Decision whether to commence</b>	
<b>Decision whether to commence</b>	<b>Japan</b> Japan is of the view that the discussions by whom should be clarified (e.g. between exporting country and importing country).
18 The <u>importing country</u> decision to commence an equivalence of systems assessment may involve a determination that:	Japan proposes to add the words to clarify who decides.
the preliminary considerations are sufficiently <del>met</del> performed;	<b>Japan</b> Japan proposes to modify the wording for clarification.
19 Once the decision to commence and the associated scope has been discussed <u>between importing country and importing country</u> , the exporting country should formalise its request to the importing country for an equivalence of systems recognition. The two countries should then agree on a plan for progressing the assessment which may include for example milestones, timeframes and if necessary priorities.	<b>Japan</b> Japan proposes to modify the wording for clarification.
20 Where the preliminary considerations are not sufficiently <del>met</del> performed both (or <u>importing and exporting</u> ) countries may wish to consider working jointly toward identifying possible technical assistance that could support a future arrangement to reduced impediments to trade and duplication of control activities. Amongst other things, information exchange, joint training, technical cooperation, and the development of infrastructure and food control systems can serve as building blocks for a future request for equivalence of systems recognition.	<b>Japan</b> Japan proposes to modify the wording for clarification.
<b>SECTION 5.3 STEP 3: DESCRIPTION OF IMPORTING COUNTRY NFCS OBJECTIVES</b>	

<b>5.3 STEP 3:DESCRIPTION OF IMPORTING COUNTRY NFCS OBJECTIVES</b>	<b>Norway</b> This is an important step, it might be better for the flow of work to move this step before step 2.
<ul style="list-style-type: none"> <li>(see Bullet 7) - system overview monitoring and evaluation programs, [<del>periodic review and continuous improvement</del>]; and</li> </ul>	<b>Kenya</b>
<ul style="list-style-type: none"> <li>(see Bullet 7) - system overview monitoring and evaluation programs, [<del>periodic review and continuous improvement</del>]; and</li> </ul>	<b>Nicaragua</b> Nicaragua proposes including a footnote for this bullet to indicate the following: "Quality management programmes can help to build confidence between countries"
29 To facilitate the exporting country describing its own systems, the importing country should describe how the elements of its NFCS or relevant part achieves the associated objective and how they contribute to the overarching goals of the NFCS or the relevant part. Specific references should be provided to documents evidencing the implementation of the policy, system design, operation, monitoring and review elements (e.g. regulations, standards, directives and specifications). In addition, where appropriate, evidence of how the actual results of the above support the effectiveness of the elements in achieving the stated objective should be provided.	<b>Norway</b> We strongly support paragraphs 29 and 30, it is important that they are included as this will facilitate the work.
30 Information should only be required for those areas subject to a more detailed assessment (that is not for those areas covered by existing experiences, knowledge and confidence).	<b>Norway</b> see comments above
36 The assessment process may be assisted by <del>in</del> country visits, teleconferences or meetings. Where relevant, the provision of technical assistance may also support the assessment process. The use of such approaches should be included in the planning for the equivalence of systems assessment, as appropriate.	<b>Japan</b> Editorial correction
<b>5.6 STEP 6: DECISION PROCESS</b>	
STEP 6: <del>DECISION</del> JUDGEMENT PROCESS	
39 The <del>decision-judgement</del> process should be transparent, document the assessment outcome and the rationale behind the outcome. The exporting country should be given the opportunity to comment on the draft conclusions and provide additional information prior to its finalization.	<b>Japan</b> On this subsection, Japan proposes to change "decision(process)" into "judgement" for consistency with GL53 section 8 titled "judgement".
40 The <del>decision-judgement</del> process should:	
<b>SECTION 5.7. STEP 7: FORMALIZATION AND MAINTENANCE OF THE RECOGNITION</b>	
STEP 7: FORMALIZATION AND MAINTENANCE OF THE <del>RECOGNITION</del> DETERMINATION	
41 The importing and exporting countries should document any <del>recognition-determination</del> reached and its effects on future trade between the countries. This may be done for example, through an exchange of letters or through the negotiation of a more comprehensive equivalence agreement <sup>14</sup> .	<b>Japan</b> On this subsection, Japan proposes to change "recognition" into "determination" for consistency with GL53.

<p>42The documentation of the <del>recognition-determination</del> of the equivalence of systems should include provisions on maintenance of the <del>recognition</del>determination.Maintenance of <del>recognition-determination</del> arrangements should allow regulatory frameworks, programs and oversight to evolve over time.</p>	<p><b>Japan</b></p>
<p>43The 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 possible review of the recognition may be required. </p>	<p><b>Japan</b></p> <p>Regarding the figure1 - Preliminary discussion should be replaced with preliminary consideration so as to be consistent with para13.</p> <p>For consistency with Step2 of the text, the title(Document Decision criteria for comparison) should be "Decision criteria for comparison.</p> <p>For consistency with Step4 of the text, the title(Develop and present case for equivalent in line with importing country objectives and Decision Criteria) should be "Dexcription of exporting country's NFCS or relevant part."</p>
<p>43 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 possible review of the <del>recognition-determinationn</del> may be required. </p>	<p><b>Japan</b></p>

## ANNEX II

## COMMENTS FROM CUBA

The Republic of Cuba has analysed the document for Item 4 of CCFICS24 and submits its comments below.

1. Point 23, STEP 2 - THE DECISION CRITERIA FOR COMPARISON

**Comments.-** More clarity is required as to in what regard to use experience, knowledge and confidence; in other words, based on what, since this is not stated in the document.

2. Point 40, bullet 3, STEP 6 - DECISION PROCESS

Comments.- Consider or include what is said in bullet 5 of the introduction, "take into account countries' development status".

We recommend to complete and phrase bullet 3 as follows:

- not introduce an objective, outcome, standard or process in excess of what is being applied within the importing country without justification, and at the same time, take into account countries' development status.

3. Figure 1:Systems Equivalence Process

Comments.- After step 6, in which the importing country supplies the reason for denying equivalence, we recommend including a step to provide the exporting country with the possibility to request for recognition of its system again, once its weaknesses have been overcome.

## COMMENTS FROM FAO

**General comment**

FAO would like to thank New Zealand, supported by the United States and Chile for having successfully led the Physical and Electronic Working Groups towards the production of document CX/FICS 18/24/4.

Taking into account the proposal of options raised in the introduction of this document, as well as the views expressed in CX/FICS/18/24/10, FAO would support a careful consideration of merging the current new document with the "Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems" (CAC/GL 53-2003) and the "Guidelines for the Development of Equivalence Agreements regarding Food Import and Export Inspection and Certification systems" (CAC/GL 34-1999), for a number of reasons including:

- the new work covers both process and content for the development of equivalence agreements at system levels, which overlaps with the above mentioned texts;
- the concept of equivalence at system level (or parts thereof, i.e. a sector such as seafood, or a subsector, such as aquaculture, or a major processing type such as canned seafood), subject of the new text, can indeed be seen as a continuity to the concept of equivalence measure by measure (without clear cut boundaries) considered under CAC/GL 56-2003, as shown in the example provided into brackets, as extracted for the current proposed text. Therefore, having two texts with significant overlaps in terms of scope could be confusing.
- With the development of CAC/GL 82- 2013 (establishing the notion of an "overarching goal" for National Food Control Systems) and CAC/GL 91-2017 ( linking specific objectives, and outcomes to achieve this/ese goal(s), and monitored through indicators of performance), a new set of notions has been developed and with these in mind, it is not clear if the notion of "decision criteria" to which this new text refers, in relation to objectives and outcomes, bears the same meaning than the "decision criteria" referred to in CAC/GL 34-1999 (para 19-c) , which in turn derived from CAC/GL 26-1997.
- there are also quite some duplications on process issues between CAC/GL 34-1999 and the new text.

Therefore taking into account the evolution and introduction of new concepts, and need for further clarification for some of these, the overlaps, and possible confusions, FAO support a more in depth discussion of the possible merging of these texts.

**Paragraph 8- Section 3 Definitions**

National Food control system:

FAO would prefer the option to refer to CAC/GL 82-2013 ("as described in CAC/GL 82 -2013") rather than proposing a new definition (proposed under alternative).

**Paragraph 9e – Decision criteria**

FAO is not totally clear about the notion of “decision criteria” as introduced in this definition. To which extent are they the same “decision criteria” mentioned in CAC/GL 34-1999 and CAC/GL 26 -1997. Are these decision criteria at objective level or outcome level? If the purpose is to compare the deliverables of the exporting country (therefore at outcome level) to what is desired in the importing country (at objective level) then could we define these as selected key combinations of outcomes delivered by the exporting country that are meeting the objectives sought in the importing country? or are in more simple terms key objectives of importing countries that should be met by exporting countries?

**Paragraph 29**

FAO would like to seek clarification on the last sentence of this paragraph.