



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (CCFICS)

Twenty-Sixth Session

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

Comments at Step 3 in reply to CL 2023/09/OCS-FICS

*Comments of Argentina, Brazil, Canada, Chile, Colombia, Ecuador, Egypt,
European Union, Indonesia, Iraq, Japan, Mauritius, New Zealand, Norway, and Peru*

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2023/09/OCS-FICS issued in February 2022. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the Annex

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

GENERAL COMMENTS

COMMENT	MEMBER / OBSERVER
In general, Argentina agrees with the document and has only minor comments to make.	Argentina
Upon review of the document "Proposed Draft Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems (NFCS)" at Step 3, I would like to point out that we have no comments. However, I wish to highlight that we support further work on the document because we consider that the equivalence of the whole or a part of an exporting country's National Food Control System (NFCS) is relevant to the trade in foods and can provide an effective means for minimizing unnecessary duplication of controls, while protecting the health of consumers and ensuring fair practices in the food trade; in addition, it facilitates the more efficient and effective use of resources in the importing and exporting countries.	Ecuador
<p>The European Union and its Member States (EUMS) would like to thank New Zealand, the United States and Kenya for leading the work on systems equivalence.</p> <p>The EUMS support the proposed draft Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems (NFCSs) as contained in Appendix 1 of CX/FICS 23/26/4. They will provide useful guidance for exporting and importing countries in determining the equivalence of NFCS.</p>	European Union
Indonesia would like to express her appreciation to New Zealand as a Chairperson and United States and Kenya as Co-Chairs of EWG for their efforts to prepare the proposed draft Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems (NFCS). Please find below Indonesia specific comments on the draft guidelines.	Indonesia
Agree with no comments.	Iraq
<p>New Zealand thanks the co-chairs and members of the working group for their active participation in and contributions to the development of this guidance document. This work had its genesis almost 10 years ago when CCFICS 21 discussed emerging issues and the direction of future work. It became an active work item following CCFICS23 and over this time period has involved extensive discussion in electronic and physical working groups held in various locations around the world. This has provided the opportunity for Codex members to ask questions and seek clarification across a wide range of issues related to the recognition of equivalence. As noted by CCFICS 22 equivalence is a complex topic but it is important to expand the suite of tools available to competent authorities.</p> <p>New Zealand considers the current draft fulfils the task set out in the project document for this work and believes that this text provides guidance that will assist Codex members in their efforts to utilise equivalence as a tool to facilitate trade while protecting the health of consumers and ensuring fair practices in the food trade.</p> <p>New Zealand supports the recommendation to CCFICS 26 that the proposed draft Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems should be progressed to steps 5 and 8 and this work be considered completed</p>	New Zealand

SPECIFIC COMMENTS**SECTION 1 – PREAMBLE**

<p>Paragraph 1. Recognition of the equivalence of the whole or a part of an exporting country's National Food Control System (NFCS)^[1], as relevant to the trade in foods under consideration, can provide an effective means for minimizing unnecessary duplication of controls, while protecting the health of consumers and ensuring fair practices in the food trade. The recognition of equivalence, where it occurs, should result in positive changes to the conditions of trade, and facilitate the more efficient and effective use of resources in the importing and exporting countries (for example: recognition of lists of eligible export establishments; alternative processing and inspection procedures; or a reduced intensity and frequency of routine port of entry inspection).</p>	
<p>Japan considers that the examples should not be retained in the guidelines. However, the examples may be useful for facilitating understanding during the discussion.</p>	Japan
<p>For better readability throughout the document: we would like to suggest a footnote or another practical way of explaining that this document relates to "the whole or a part of the NFCS", it seems unnecessary to repeat this everytime NFCS is mentioned.</p>	Norway
<p>Recognition of the equivalence of the whole or a part of an exporting country's National Food Control System (NFCS)¹, as relevant to the trade in foods under consideration, can provide an effective means for minimizing unnecessary duplication of controls, while protecting the health of consumers and ensuring fair practices in the food trade. The recognition of equivalence, where it occurs, should result in positive changes to the conditions of trade, and facilitate the more efficient and effective use of resources in the importing and exporting countries (for example: recognition of lists of eligible export establishments; alternative processing and inspection procedures; or a reduced intensity and frequency of routine port of entry inspection).</p> <p>We suggest deleting the last part of the text, i.e., the examples. We consider that the main text is clear enough, so this example is not required.</p>	Chile
<p>Paragraph 2.</p>	
<p>These guidelines are intended to be read in conjunction with other existing Codex text including the <i>Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems</i> (CAC/GL (CXG 26-1997), and the <i>Guidelines for Food Import Control Systems</i> (CAC/GL (CXG 47-2003).</p> <p>Indonesia proposed changes of the document code in this para, to comply with the new writing rules in Codex (using CXG).</p>	Indonesia
<p>This paragraph would need to be updated as the document contains reference to several CCFICS texts as CAC/GL 34, 53, 82, 89 and 91. It could even be shortened saying that this document includes references to other relevant CCFICS texts and annex the list.</p>	Norway

SECTION 2 – PURPOSE

<p>Paragraph 4.</p>	
<p>These guidelines provide 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 the whole or a part² of the NFCS at the system level.</p>	Mauritius

SECTION 3 – DEFINITIONS

<p><u>Outcome</u>: Intended effects or results that contribute to achieving the NFCS objectives.</p> <p>The Spanish word “<i>resultado</i>” is defined in the English document as "OUTCOME: Intended effects or results [...]". Since "outcome" is translated as "<i>resultado</i>", we suggest deleting the word "<i>resultado</i>" from the definition in Spanish, so that the definition will not contain the same word that must be defined. It could be replaced by "<i>consecuencias</i>" ("consequences"). [<i>Translator's note: This only applies to the Spanish version.</i>]</p>	Argentina
<p><u>Resultado</u>: Efectos o resultados previstos que contribuyen a lograr los objetivos del SNCA. (“Outcome: Intended effects or results that contribute to achieving the relevant NFCS objectives.”)</p> <p>We suggest that “o resultados” should be deleted, because a word cannot be defined by using the same word. Another option is to replace “<i>resultados</i>” with “<i>consecuencias</i>” ("consequences"). [<i>Translator's note: This only applies to the Spanish version.</i>]</p>	Chile
<p>Egypt Agrees on proposed definitions and recommends to add the definitions for the following terms:</p> <p>1- National food control food system 2- Equivalence</p>	Egypt
<p><u>Decision Criteria</u>: Those factors used to objectively determine whether the exporting country’s NFCS or the relevant part achieve the objectives of the importing country’s NFCS or the relevant part for the products under consideration. <u>Level of protection</u>: appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health.</p> <p>We suggest the inclusion on the definition of "level of protection". The proposed definition was obtained from the SPS Agreement/WTO, since this term is cited many times in the text and its meaning differs from "outcome", opposing to the provisions of bullet 4, item 25 of the document CX/FICS 23/26/4 (fc26_04e), transcribed below:</p> <p>Consistent with the above and as discussed at the workshop, while the definitions and some of the higher-level statements continue to refer to achieving the objectives, where the intent of the subsequent paragraphs is to explain how this may be more fully described or achieved the expanded format of objectives, and related outcome or level of protection, is then used. Noting also that level of protection is a way to express the desired or intended outcome thus the use of the word “OR”.</p>	Brazil
<p><u>Decision Criteria</u>: Those factors used to objectively determine whether the exporting country’s NFCS or the relevant part achieve achieves the objectives of the importing country’s NFCS or the a relevant part <u>thereof</u>, for the products under consideration.</p>	Mauritius
<p><u>Decision Criteria</u>:</p> <p>Indonesia seeks for clarification for the definition of Decision Criteria, whether the addition of the word "objectively" which quantifies appropriate level of protection could be interpreted that this guideline will lean towards the SPS aspect only.</p>	Indonesia

SECTION 4 – PRINCIPLES

Equivalence of National Food Control Systems (NFCS)	
Equivalence of National Food Control Systems (NFCS) (NFCS's) to be in line with the paragraph 6a	Mauritius
a. Countries should recognize that NFCS's, or the relevant parts thereof, of importing and exporting countries, although designed and structured differently, may be capable of achieving the same objectives, and related outcomes or level of protection <u>outcomes</u> , with respect to protecting the health of consumers and ensuring fair practices in the food trade and can therefore be found to be In Section 3, the definition Equivalence of NFCS is only to achieve the same objectives. Moreover, Indonesia thinks related outcomes already includes the level of protection so no need to add "or level of protection" equivalent.	Indonesia
Experience, Knowledge and Confidence	
b. Countries should consider relevant experience, knowledge and confidence and may consider appropriate assessments by other countries or international organizations. Do these terms relate to existing trade. It might be useful to specify too.	Mauritius
Alignment with International Standards	
c. The use of or reference to Codex standards, guidelines, and/or codes of practice, or other relevant international standards by importing and exporting countries can facilitate the consideration , alignment , assessment and recognition of the equivalence of a NFCS, or the relevant part. In this text, replace "consideration" with "alignment".	Colombia
Assessment	
. The assessment process should evaluate whether the relevant objectives, and related outcomes or level of protection, of the importing country's NFCS are achieved and the process should be documented; transparent; evidence-based; outcome-focused; efficient; and be conducted in a cooperative and timely manner. <u>Comments</u> – We suggest adjusting the second part of the text as follows: The assessment process should be documented; transparent; evidence-based; outcome-focused; efficient; and be conducted in... – In this text, replace " <i>basado en pruebas</i> " with " <i>evidencias</i> ". [<i>Translator's note: This only applies to the Spanish version.</i>]	Colombia
We suggest deleting the colon, since it is not present in the English version.	
d. The assessment process should evaluate whether the relevant objectives, and related outcomes or level of protection, of the importing country's NFCS are achieved and the process should be documented; transparent; evidence-based; outcome-focused; efficient; and be conducted in a cooperative and timely manner. We suggest replacing the Spanish word " <i>evaluar</i> " with " <i>definir</i> " (define), " <i>considerar</i> " (consider) or " <i>determinar</i> " (determine). [<i>Translator's note: This only applies to the Spanish version.</i>]	Argentina

<p>d. The assessment process should evaluate whether the relevant objectives, and related outcomes or level of protectionoutcomes, of the importing country's NFCS are achieved and the process should be documented; transparent; evidence-based; outcome-focused; efficient; and be conducted in a cooperative and timely manner.</p> <p>Same as above</p>	Indonesia
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SECTION 5 – PROCESS STEPS

Step 7: Final documentation	
<p>Step 7: Final documentation Formalization and maintenance of the recognition</p> <p>Revision made to be conformed with wording in section 5.7 step 7: Formalization and maintenance of the recognition</p>	Indonesia
Paragraph 9	
<p>The following comment would apply throughout the document:</p> <p>For readability and updating purposes, we would suggest to include the concepts of the paragraphs referred to in this document if considered necessary. We have supported the current approach of referring to paragraphs in other documents up until the final document. However, for the reader of the final document though, having to look at so many different other documents while reading this guidance, it seems overly complicating. If kept in this text, we would suggest active links to relevant paragraphs.</p>	Norway
<ul style="list-style-type: none"> <u>Bullet 3</u> - experience, knowledge and confidence derived from, for example: the history and level of trade between the countries; the history of compliance with the importing country's requirements; the level of familiarization and/or cooperation between the competent authorities; and the exporting country's trade in the same or similar products with other countries⁷; <u>for this purpose, the interested countries will provide any information that is necessary for making the related decisions.</u> <p>Add text at the end of paragraph 9 for clarity, as follows: 9 - experience, knowledge and confidence derived from, for example: the history and level of trade between the countries; the history of compliance with the importing country's requirements; the level of familiarization and/or cooperation between the competent authorities; and the exporting country's trade in the same or similar products with other countries; for this purpose, the interested countries will provide any information that is necessary for making the related decisions.</p>	Colombia
<ul style="list-style-type: none"> <u>Bullet 4</u> the different difference in the level of development between the countries countries' NFCS⁸; <u>Bullet 5</u> - the similarity of design of each country's NFCS in whole or the relevant part including the legislative framework and the relevant objectives, and related outcomes or level of protection; <p>This statement is repeated throughout the text. If applicable/relevant, we could indicate in the introduction that the assessment may pertain to whole NFCS or part (scope of assessment)?</p> <ul style="list-style-type: none"> <u>Bullet 6</u> - the information exchanges and assessments that may have already occurred (e.g. in accordance with CXG 89-2016) or the existence of other relevant recognitions of equivalence between the two countries or with third countries. <p>Perhaps we could also refer to the use of the FAO tool for assessment of food control systems?</p>	Mauritius
<ul style="list-style-type: none"> <u>Bullet 6</u> - the similarity to or harmonisation of the whole or the relevant part of the NFCS with standards, guidelines, and/or codes of practice from Codex or other recognized relevant international standard setting bodies; and 	Canada

Canada recommends deletion of the word “recognized” for consistency with the principle on the alignment with international standards which refers to “relevant international standards”.	
<ul style="list-style-type: none"> • <u>Bullet 7</u>-The information exchanges and assessments that may have already occurred (e.g. in accordance with CXG 89-2016) or the existence of other relevant recognitions of equivalence between the two countries or with third countries. • <u>if it exists, in the importing country, a regulatory and/or legislative framework establishing the procedures and/or steps to be followed when evaluating the recognition of equivalence of the NFCS of the exporting country.</u> <p>We suggest the addition of this bullet since it is common for importing countries/markets to issue rules/legislation regulating the procedures and steps of the equivalence recognition process for exporting countries. Therefore, we understand that, when existing, such regulations must be cited by importers and understood by exporters in the initial discussions.</p>	Brazil
Paragraph 11.	
<ul style="list-style-type: none"> • <u>Bullet 3</u> - the range of NFCS assurances to be addressed (e.g. food safety, qualitative claims, labelling, or other matters relating to technical regulations, conformity assessment procedures or standards); <p>Substitute a comma for the semi colon: “the range of NFCS assurances to be addressed (e.g. food safety.” [<i>Translator’s note: This only applies to the Spanish version.</i>]</p>	Colombia
<ul style="list-style-type: none"> • <u>Bullet 4</u> - the level of trust and confidence in the performance of the exporting country’s <u>NFCS system</u> in whole or the relevant part relating to those products already being traded or those proposed for future trade; and <p>Replace “<i>rendimiento del SNCA</i>” with “<i>desempeño del sistema</i>”. [<i>Translator’s note: The replacement of “rendimiento” with “desempeño” only applies to the Spanish version.</i>]</p>	
Paragraph 13	
Para 13. Change some expressions in the paragraph for clarity: 13. Where the conclusion of the initial discussions between the exporting and importing countries is that a recognition of equivalence is the appropriate mechanism, a request should be made and submitted in writing to consult on, among other aspects, a description of the scope of products and conditions of trade to be covered.	Colombia
Decision whether to commence	
Paragraph 15	
For clarity, and in line with the text in English, we propose to rephrase the paragraph as follows: “CXG 34/1999 (paragraph 11) also identifies that amongst other things, information exchange, joint training, technical cooperation and support, and the development of infrastructure and strengthening of the food control systems can serve as building blocks for a future request for recognition of the equivalence of systems.” [<i>Translator’s note: The suggestion made for the text in Spanish involves no change to the English version.</i>]	Argentina
Where the initial discussions between the two countries conclude that an assessment of the equivalence of the exporting country’s NFCS is not the most appropriate mechanism, the countries may wish to consider working jointly towards some other mechanisms to help facilitate the trade. Alternative mechanisms to address the matters discussed could be considered. —CXG 34/1999 (paragraph 11) also identifies that amongst other things, information exchange, joint training, technical cooperation and support, and the development of infrastructure and strengthening of the food control systems can serve as building blocks for a future request for recognition of the equivalence of systems. This sentence seems to repeat the idea provided in the previous sentence that countries could work towards alternate mechanisms when equivalence is not an appropriate mechanism.	Canada

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

Paragraph 16.	
<p>For clarity, we propose to rephrase the paragraph as follows:</p> <p>"As relevant to the scope of the request and to facilitate the exporting country in describing its own systems, the importing country should provide information to describe, with appropriate references, the related elements with the objectives, and relevant outcomes or level of protection, of its NFCS that are to be part of the assessment". [<i>Translator's note: The suggestion made for the text in Spanish involves no change to the English version.</i>]</p>	Argentina
<p>As relevant to the scope of the request and to facilitate the exporting country in describing its own systems, the importing country should provide information to describe, with appropriate references, the related elements with the objectives, and relevant outcomes or level of protection, of its NFCS that are to be part of the assessment. for example:¹²</p> <ul style="list-style-type: none"> • 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 products or programs under consideration. <p>The examples do not help understand the substantive idea of the text. For the purpose of equivalence, the relevant aspects of the importing country's NFCS or its parts are its objectives and outcomes, not how it is structured. The examples give the idea that the NFCS should be described in full and do not help exemplify objectives or outcomes. We suggest that they should be deleted.</p>	Chile
<p>Japan thinks that a comprehensive list is not needed.</p> <p>Rational: Heavy burden on the importing countries.</p>	Japan
<p>As relevant to the scope of the request and to facilitate the exporting country in describing its own systems, the importing country should provide information to describe, with appropriate references, the related elements with the objectives, and relevant outcomes or level of protection, of its NFCS that are to be part of the assessment <u>assessment, with the objectives and relevant outcomes or level of protection,</u> for example:¹²</p>	Mauritius
<p>In describing its own NFCS or the relevant part, the importing country may include reference to relevant standards, guidelines, and/or codes of practice from Codex or other recognised international standard setting bodies.</p> <p>Consider replacing the term "relevant" by "selected component" or "chosen element" to avoid repeating the word " relevant"</p>	

5.3 STEP 3: THE DECISION CRITERIA FOR COMPARISON

<p>Paragraph 18. Once the request for consultations on a recognition of equivalence of a NFCS or the relevant part has been made, the importing country should document the decision criteria to be used to evaluate the exporting country's NFCS or relevant part associated with the scope of the request. The criteria should reference the relevant objectives, and related outcomes or level of protection, that must be shown to be achieved for recognition of equivalence. The decision criteria document should be provided to and discussed with the exporting country in a cooperative manner.</p> <p><u>Proposal:</u> or its relevant part or the relevant part thereof; Comment: this comment may be considered throughout the text</p>	Mauritius
<p>Paragraph 19. The decision criteria should facilitate the importing country's assessment process being able to determine whether or not the exporting country's system design and implementation achieves the importing country's relevant objectives, and related outcomes or level of protection, associated with the scope of the request.¹³</p> <ul style="list-style-type: none"> – Allowing assessors 	
<p>Paragraph 19. The decision criteria should facilitate the importing country's assessment process being able to determine whether or not the exporting country's system design and implementation achieves the importing country's relevant objectives, and related outcomes or level of protection, associated with the scope of the request.¹³ [<i>Translator's note: The suggestion made for the text in Spanish involves no change to the English version.</i>]</p>	Argentina
<p>Paragraph 20. the level of qualitative or quantitative evidence that is expected;</p> <p>We suggest replacing “<i>prevé</i>” with “<i>espera/pretende</i>” (is expected/intended). [<i>Translator's note: This only applies to the Spanish version.</i>]</p>	

5.5 STEP 5: ASSESSMENT PROCESS

<p>Paragraph 30. The importing country's assessment process should:</p> <p>Delete the commas: The importing country's assessment process should: [<i>Translator's note: This only applies to the Spanish version.</i>]</p>	Colombia
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DECISION PROCESS

<p>Paragraph 33 bullet 1. be transparent and conducted in a timely manner; and</p> <p>We believe that it is necessary to refer to a deadline for the decision process. “be transparent and conducted in a timely manner, and within a reasonable deadline agreed upon by both parties”</p>	Peru
<p>Paragraph 34.</p> <p>The importing country should document the draft assessment conclusion and the rationale and the exporting country should be given the opportunity to comment on the draft conclusions. In the case of an initial finding that the exporting country's NFCS or the relevant part is assessed as not equivalent, the exporting country should have the opportunity to provide additional information for consideration by the importing country prior to the finalization of the decision.</p> <p>Justification: Indeed, some flexibility is important as it could allow the country to deal with one finding of the assessment (eg if the country can close a minor non-conformity) prior to finalisation of the decision.</p>	Mauritius

5.7. STEP 7: FORMALIZATION AND MAINTENANCE OF THE RECOGNITION

<p>5.7. STEP 7: FORMALIZATION AND MAINTENANCE OF THE RECOGNITION: FINAL DOCUMENTATION</p> <p>This aligns with description of Step 7 in paragraph 7.</p>	Canada
<p>We recommend to clarify what was stated in step No. (7) in item No. (5/7) "formalization and maintenance of the recognition"</p>	Egypt
<p>Paragraph 36.</p> <p>The importing and exporting countries should document any recognition reached including how the recognition of equivalence will be implemented for the trade in food between the countries (e.g. recognition of lists of establishments; or modification to point of entry, or additional in-country process prescriptive requirements). Such documentation may be done for example, through an exchange of letters or through the negotiation of a more comprehensive equivalence agreement or arrangement¹⁹.</p> <p>Rationale: We suggest that the text between parentheses should be deleted, since it does not adequately illustrate the main idea of the paragraph.</p>	Chile
<p>Paragraph 37.</p> <p>The documentation of the recognition of the equivalence of systems should include provisions on maintenance and review of the recognition. Maintenance of recognition arrangements should allow regulatory frameworks, programs and oversight to evolve over time. The documentation should include what level of change to the exporting one country's NFCS or other changes in circumstance requires notification to the importing other country and when a review of the recognition of equivalence may be required.</p> <p>Rationale: Paragraph 37 should recognize that a change in either the exporting country's NFCS or the importing country's NFCS could impact agreement on equivalence.</p>	Canada
<p>Paragraph 39.</p> <ul style="list-style-type: none"> • Is it relevant to make use of food safety notifications systems • According to Figure 1, only the exporting country can initiate initial discussions. Does this prevent an importing country from doing so? 	Mauritius
<p>Paragraph 39.</p> <p>Maintenance and review of recognitions of the equivalence of NFCS may include activities such as:</p> <p>The scope of the stated review is not clear.</p>	Peru