

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda item 5.1

CX/FICS 23/26/5 Add.1

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

Twenty-Sixth Session

Hobart, Tasmania, Australia

1 – 5 May 2023

PROPOSED DRAFT CONSOLIDATED CODEX GUIDELINES RELATED TO EQUIVALENCE

Comments in reply to CL 2023/10/OCS-FICS

Comments of Australia, Brazil, Canada, Colombia, European Union, Honduras, India, Iraq, Japan, Kenya, Mauritius, Paraguay, Peru, Republic of Korea, Uruguay, USA and ICUMSA

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2023/10/OCS-FICS issued in March 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.

ANNEX I

GENERAL COMMENTS	MEMBER / OBSERVER
Australia thanks the Co-Chairs New Zealand, USA and Kenya for the significant work done to progress this document prior to CCFICS26. Comments are provided throughout the text.	Australia
<p>Canada thanks the Chairs for their work and looks forward to participating in discussions during the Physical Working Group. Canada supports efforts to consolidate Codex guidance on equivalence in order to improve consistency in the text and remove areas of duplication.</p> <p>The consolidated text on equivalence should continue to reflect the wide range of applications for using equivalence to manage risks. The guidance should recognize that equivalence may be used establish market access for high risk products. In other cases, equivalence allows exporting and importing countries to make better use of their resources by setting conditions of trade that recognize the exporting country's domestic and import controls.</p> <p>Canada recognizes that there may be opportunities to update text on equivalence , but views that most of the existing Codex texts remains relevant and provides valuable information that should be maintained in the consolidated new guidance. This includes text which has been developed in the proposed guidance on equivalence of a national food control system that will be discussed at CCFICS as Agenda item 4.</p>	Canada
<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 the consolidation of Codex guidelines on equivalence. The EUMS support further work on this topic.</p> <p>The EUMS would like to make the following comments on the proposed draft guidelines and the specific questions as presented in Appendix 1 of document CX/FICS 23/26/5.</p>	European Union
India appreciate the work done by the eWG chaired by New Zealand and Co-chaired by USA and Kenya	India
Once the consolidated document is finalized, what the fate of existing three equivalence documents? We recommend it is better to agree on the document structure which committees aims to achieve before discussion goes further.	Japan
Kenya supports the advancement of the draft guidelines to the next step.	Kenya
Mauritius thanks New Zealand (Chair) and the United States of America and Kenya (Co-chairs) for the progress made in advancing the draft consolidated Codex guidelines on equivalence. Cognizant of the improvements made on the draft guideline, Mauritius supports progression of the development of the draft text. To further improve the document, some suggestions are made.	Mauritius
ROK prefers to prioritize discussing specific measures on the equivalence. ROK considers it is more appropriate to address sanitary measures in the current consolidated guidelines and then review technical barriers thereafter.	Republic of Korea
<p>The United States appreciates the work to consolidate Codex guidance on equivalence to facilitate its understanding and use. Following are general and overarching comments on the current draft. The United States also has several suggested edits to the consolidated document for clarity, precision, and consistency with the NFCS equivalence document that we can share during working group discussions. We look forward to further discussion and refinement of the consolidated guidance</p> <ul style="list-style-type: none"> As would be expected in a consolidated equivalence document, there is a lot of overlap between this document and the NFCS equivalence document. However, the language in those overlapping portions in this consolidated document differs substantively 	USA

<p>from the agreed-upon language in the current NFCS equivalence document. The United States recommends that the language from the NFCS equivalence document be used in this consolidated document for consistency.</p> <ul style="list-style-type: none"> It is not clear whether language gathered from other texts has been modified, and if so, what the changes are. A crosswalk that indicates what text came from what documents and what text is new, as well as any edits to the text that has been sourced from other texts would facilitate a more informed review by member countries. (This would not be included in the final consolidated text.) The document is too prescriptive in several places. The terms “should” and “must” indicate requirements rather than guidance and the United States recommends replacing them with “may”, “might”, or “can” as appropriate. Mandatory language should be avoided in guideline documents. The term “conditions of trade” is used throughout the document. This is not a widely used term in Codex and the United States recommends that an alternative term be identified. If it is used, it should be defined. With respect to definitions in general, the United States appreciates the addition of references to indicate the sources of definitions in this draft. In many definitions, however, the language used differs from the source material. Using the definitions from the source material rather than modifying the language would be preferable. Some definitions may not be needed, especially if the terms are not used elsewhere in the text. Codex should also avoid attempts to paraphrase World Trade Organization agreements in Codex texts. 	
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SPECIFIC COMMENTS	MEMBER / OBSERVER
SECTION 1: PREAMBLE	
<p>Para 2. Suggest to delete the last sentence, "Requests for the recognition of equivalence normally relate to just those conditions of trade an exporting country considers are unnecessarily restricting their existing or proposed trade".</p> <p>In the PREAMBLE, it is more reasonable and recommendable to describe the necessity and effectiveness of recognizing equivalence. However, the last text of paragraph 2 emphasizes the negative aspect of recognition of equivalence and thus it is suggested to be deleted because it is also contrary to the meaning of core content of the following paragraph 3.</p>	<p>Republic of Korea</p>
<p>Para 2. Debería decir: “ (...) Las solicitudes de reconocimiento de la equivalencia pueden referirse a aquellas condiciones comerciales relacionadas tanto con la protección de la salud de los consumidores como con las prácticas de comercio de alimentos...”</p> <p>Comentario: Se sugiere colocar “prácticas comerciales de alimentos” y eliminar la palabra “justo”. En concordancia con el acuerdo de MSF de la OMC la cual no menciona en las disposiciones de equivalencia el termino justo o reciproco.</p>	<p>Peru</p>
<p>Para 4. Honduras sugiere que se describa si estas directrices continuarán siendo vigentes o serán reemplazadas por las directrices unificadas.</p>	<p>Honduras</p>
<p>Para 5. Deberia decir: Incluir en el párrafo a la R el documento CXG 82-2013 sobre Principios y directrices para los sistemas nacionales de control de los alimentos.</p> <p>Comentario: Se sugiere incluir dicho documento dado que el anteproyecto de directrices que se viene revisando es de aplicación sobre los sistemas nacionales de control de los alimentos.</p>	<p>Peru</p>

SECTION 2: PURPOSE/SCOPE (of guideline)	
Separating the headings of purpose and scope will add clarity to these points	Australia
Brazil is of the opinion that it is not necessary to split into a section on purpose and a separate section on scope. Brazil prefers a section 2 titled as “purpose” consistent with other Codex standards.	Brazil
El objetivo debería ir en una sección independiente del ámbito de aplicación. Se considera que este documento debe llevar el mismo desarrollo de los demás documentos del Comité.	Colombia
Purpose and scope should appear as a single section.	European Union
Honduras sugiere que estas dos secciones estén claramente definidas y separadas en el documento.	Honduras
Yes, it would be useful to split into two sections.	ICUMSA
The existing documents developed by CCFICS so far include Sections like Preamble, Introduction, Objectives, Scope however Section on Purpose is not common (except in CXG91-2017). Purpose of the document is generally reflected under Introduction/Preamble/Objective in different CCFICS document. The scope specifies the boundaries of the document i.e. what is included and what is not included and therefore should be separate Section as done in other documents of CCFICS. Further, Paragraphs 6 and 7 of the existing document broadly specifies the scope of the document and therefore word “Purpose” could be removed.	India
No, we think scope enough	Iraq
Mauritius supports splitting the Purpose and Scope into two separate sections with paragraph 6 as the Purpose and paragraph 7 as the Scope. The Scope and Purpose serve different functions in a standard/guideline and given that the consolidated guidelines bring together texts from several Codex texts on equivalence that use scope or purpose interchangeably, separation of the two will serve to provide clarity.	Mauritius
Paraguay cree conveniente dividir las secciones de Objetivos y Ámbito de Aplicación ya que son dos cosas distintas.	Paraguay
El comité considera que no es necesario dividir esta sección en 2 secciones.	Peru
Uruguay entiende que para ser consistentes con el resto de los documentos del CCFICS, no es necesario separar en dos secciones objetivo y ámbito de aplicación. Siempre y cuando se incluya información que indique el objetivo y ámbito de aplicación del documento.	Uruguay
SECTION 3: DEFINITIONS	
Question to CCFICS26: <i>The Committee is asked to indicate if there are additional definitions that should be included OR if any of the below are not required.</i> yes, we think Definitions for terms are necessary.	Iraq
Question to CCFICS26: <i>The Committee is asked to indicate if there are additional definitions that should be included OR if any of the below are not required.</i> It is observed that some of the new proposed definitions like Technical Measure, Equivalence specified technical measures, are beyond the agreed the process of consolidation because these definitions were not the part of the CCFICS texts which need to be consolidated. Further, in the context of equivalence of sanitary measure, it would be	India

appropriate to include the definition of Appropriate Level of Protection (ALOP) which is there in the text to be consolidated.	
<p>Question to CCFICS26: <i>The Committee is asked to indicate if there are additional definitions that should be included OR if any of the below are not required.</i></p> <p>ROK prefers to prioritize discussing specific measures on the equivalence. ROK considers it is more appropriate to address sanitary measures in the current consolidated guidelines and then review technical barriers thereafter.</p>	Republic of Korea
<p>Question to CCFICS26: <i>The Committee is asked to indicate if there are additional definitions that should be included OR if any of the below are not required.</i></p> <p>At this stage, the definitions can stay as they are. They will need to be revisited when the rest of the text is further developed.</p>	European Union
<p>Question to CCFICS26: <i>The Committee is asked to indicate if there are additional definitions that should be included OR if any of the below are not required.</i></p> <p>Measures are controls within a NFCS, and it is not necessary to state both 'in whole or in part' as well as 'different specified measures' in this definition. In line with the terminology used in the current Draft Guidelines on Recognition and Maintenance of Equivalence of NFCS definition Australia suggests 'NFCS or relevant parts'</p>	Australia
<p>Pregunta para el CCFICS, en su 26.ª reunión: <i>Se pide al Comité que indique si existen definiciones adicionales que deban incluirse O si alguna de las que figuran a continuación no es necesaria.</i></p> <p>Honduras sugiere que se incluya la definición de "requisitos" establecida en CAC/GL 34-1999 y el concepto de nivel adecuado de protección sanitaria (NADP) establecido en CAC/GL 53-2003</p>	Honduras
<p>Pregunta para el CCFICS, en su 26.ª reunión: <i>Se pide al Comité que indique si existen definiciones adicionales que deban incluirse O si alguna de las que figuran a continuación no es necesaria.</i></p> <p>A la pregunta de indicar si existen definiciones adicionales, consideramos que las contempladas son suficientes. Sin embargo, líneas abajo se sugiere incluir como definición lo contemplado en el párrafo 62. El documento contempla las definiciones necesarias y no requiere adicionar otras.</p>	Colombia
<p>Pregunta para el CCFICS, en su 26.ª reunión: <i>Se pide al Comité que indique si existen definiciones adicionales que deban incluirse O si alguna de las que figuran a continuación no es necesaria.</i></p> <p>Paraguay cree conveniente que las definiciones estén ordenadas en orden alfabético para un mejor ordenamiento</p>	Paraguay
<p>Equivalencia de las medidas sanitarias estipuladas: Capacidad de una medida o medidas sanitarias alternativas aplicadas por el país exportador para alcanzar el mismo nivel de protección que el logrado por la medida o medidas sanitarias especificadas del país importador. [Nueva definición extraída de los textos existentes del Codex y de la OMC para recoger la diferencia entre la equivalencia de la totalidad o de la parte pertinente del SNCA y la equivalencia de una medida o medidas específicas.]</p> <p>Incluir el termino "sanitarias"</p>	Uruguay
<p>Decision Criteria: Brazil understands that the definition for decision criteria should also consider the outcomes and level of protection concepts. And we would suggest that CCFICS reevaluate this definition to consider these concepts.</p>	Brazil
<p>Measure: Australia considers that a measure is something that may be in place within a NFCS to achieve certain objectives regardless of trade. Removing the reference to importing country requirements would be consistent with the above definition for equivalence, and the below definitions for sanitary and technical measures. Suggested</p>	Australia

definition below is drawn from the previous draft of these guidelines: Measure: a type of control designed to achieve NFCS objectives, and related outcomes or level of protection as they relate to the protection of the health of consumers or ensuring fair practices in the food trade.	
Objetivo del SNCA: Uruguay entiende que en la versión en español es necesario definir objetivo político para valorar si estamos de acuerdo con la definición	Uruguay
Technical measure: Any measure other than a sanitary or phytosanitary measure as required by the importing country for the trade in food to ensure the protection of the health of consumers or fair practices in the food trade ¹ . [<i>Derived from the WTO TBT Agreement</i>] <u>Level of protection: appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health.</u> Brazil wants to add the definition of "level of protection" on this document. The term appears many times throughout the text. Therefore, it is important to clarify its meaning. We do not agree that "level of protection" is a way to express the desired or intended outcome and that is the reason we understand it is highly recommended to add this definition. It is worth mentioning that this definition was obtained from the SPS/WTO Agreement.	Brazil
Medida técnica: A Uruguay no le queda claro que las medidas técnicas sean implementadas con el fin de garantizar la protección de la salud de los consumidores. Entendemos que la redacción debe modificarse y redactarse de manera de que pueda entenderse la diferencia entre una medida técnica y una medida sanitaria.	Uruguay
SECTION 4: PRINCIPLES	
Debería decir: i) El comité considera que debería incluirse en el texto principal del documento, como parte del proceso de evaluación. ii) El comité está de acuerdo con la incorporación de un principio referido a la obligación de la parte importadora. <u>Comentario:</u> i) A fin poder contar con una mayor comprensión del documento. ii) A fin de propiciar que la parte importadora no exceda sus medidas más allá de lo necesario.	Peru
a. Countries should recognize that different measures, NFCS, or parts of NFCS although designed and structured differently, may achieve the same objectives, and can therefore be recognized as equivalent. The referral to 'measures, NFCS, or parts of NFCS' should be made consistent throughout the document. As raised above, 'NFCS or relevant parts' would be consistent with other guidance	Australia
Ámbito de aplicación No es claro el título de ámbito de aplicación para el principio, debido a que éste ya se encuentra en la sección 2 del documento. Al referirse a asuntos comerciales, se sugiere ubicar un título relacionado para este principio.	Colombia
d. Requests for recognition of equivalence should be made in writing by the exporting country and should be addressed in a timely manner. The principle on timeliness could be combined with the principle on transparency and cooperation.	European Union
f. Los países importadores y los países exportadores deben cooperar para llevar a cabo el proceso de forma transparente, basado en pruebas y centrado en los resultados	Paraguay

<p><u>y evidencias objetivas.. La obligación de demostrar objetivamente la equivalencia recae en el país exportador.</u></p> <p>Paraguay cree que debe establecerse la obligación del país exportador como un requisito unido a la transparencia y cooperación.</p>	
<p><i>Demostración de la equivalencia</i></p>	<p>Paraguay</p>
<p>f (bis) <u>The obligation to objectively demonstrate equivalence rests with the exporting country. Considering the criteria defined on initial discussions, the importing party shall ensure their measure is only applied to the extent necessary to achieve their level of protection relative to the bilateral risks.</u></p> <p>In reply to question "i" related to f(bis) Brazil understands that there is no need for a separate principle. And regarding question "ii", Brazil is of the opinion there must be a balance between the responsibilities of both exporting and importing parties. In that sense we propose an amendment for f(bis). It can also be split in two paragraphs, adding a paragraph f (bis) (bis) with the amendment proposed.</p>	<p>Brazil</p>
<p>f (bis) The obligation to objectively demonstrate equivalence rests with the exporting country.</p> <p>f (bis) is not listed in the definitions or described before appearing here. If "Demonstration of Equivalence" is a description, anything under this title should be formatted the same as for previous demonstrations. Therefore, if "f (bis) is an explanation, it should be indicated with a letter (as is shown for "Transparency and co-operation" where it is "f. Importing...".</p>	<p>ICUMSA</p>
<p>f (bis) La obligación de demostrar objetivamente la equivalencia recae en el país exportador. Ya no existe la necesidad debido a que se encuentra en el párrafo anterior. <u>Principios</u></p>	<p>Paraguay</p>
<p><i>i) the appropriateness of f(bis) as a separate principle or whether it is better stated in the main text as a component of the assessment process; and</i></p> <p>It would not be appropriate to include f(bis) as a separate principle because Principles generally covers the broad rules which need to be adhered by all the parties who are part of the process. As the obligation to demonstrate equivalence of their measure or system unilaterally lies with exporting country, it would be more appropriate to include it in main text.</p>	<p>India</p>
<p><i>i) the appropriateness of f(bis) as a separate principle or whether it is better stated in the main text as a component of the assessment process; and</i></p> <p>bis as a separate principle</p>	<p>Iraq</p>
<p><i>i) the appropriateness of f(bis) as a separate principle or whether it is better stated in the main text as a component of the assessment process; and</i></p> <p>ROK considers it is appropriate to keep both f. and f(bis) as a separate principles because each provision(i.e. transparency vs. demonstration of equivalence) are two different contents.</p>	<p>Republic of Korea</p>
<p><i>i) the appropriateness of f(bis) as a separate principle or whether it is better stated in the main text as a component of the assessment process; and</i></p> <p>This point may be appropriate as a principle, as multiple parts of this document include reference to this responsibility.</p>	<p>Australia</p>
<p><i>i) la idoneidad de mantener el apartado f(bis) como un principio independiente o si sería preferible incluirlo en el texto principal como parte del proceso de evaluación, y</i></p> <p>Honduras considera que este texto no debería considerarse un principio y se sugiere que se incluya en el texto principal como parte del proceso de evaluación.</p>	<p>Honduras</p>

<p><i>i) la idoneidad de mantener el apartado f(bis) como un principio independiente o si sería preferible incluirlo en el texto principal como parte del proceso de evaluación, y</i></p> <p>A la pregunta i) respondemos que la información del apartado f (bis) es completa y suficiente y queda bien tanto como un principio independiente si se incluye en el texto principal como parte del proceso de evaluación.</p>	Colombia
<p><i>i) la idoneidad de mantener el apartado f(bis) como un principio independiente o si sería preferible incluirlo en el texto principal como parte del proceso de evaluación, y</i></p> <p>Uruguay está de acuerdo en que se mantenga el apartado f(bis) como un principio independiente.</p>	Uruguay
<p><i>ii) is there also a need for a balancing statement / principle re the importing party's obligation to ensure their measure is only applied to the extent necessary to achieve their level of protection relative to the bilateral risks?</i></p> <p>Such statement toward obligation on part of importing country could be useful to avoid unnecessary measure beyond ALOP and risk involved, therefore, can be included in the main text.</p>	India
<p><i>ii) is there also a need for a balancing statement / principle re the importing party's obligation to ensure their measure is only applied to the extent necessary to achieve their level of protection relative to the bilateral risks?</i></p> <p>No</p>	Iraq
<p><i>ii) is there also a need for a balancing statement / principle re the importing party's obligation to ensure their measure is only applied to the extent necessary to achieve their level of protection relative to the bilateral risks?</i></p> <p>It is useful to have the principle on the obligation of the exporting country to objectively demonstrate equivalence. The obligation of the importing country to ensure their measure is only applied to the extent necessary to achieve their level of protection is a key obligation in the SPS Agreement and should not be repeated in this text.</p>	European Union
<p><i>ii) is there also a need for a balancing statement / principle re the importing party's obligation to ensure their measure is only applied to the extent necessary to achieve their level of protection relative to the bilateral risks?</i></p> <p>Australia considers this point is covered clearly in the SPS agreement and does not require elaboration in this document.</p>	Australia
<p><i>ii) ¿es también necesaria una declaración/principio compensatorio sobre la obligación de la parte importadora de garantizar que su medida se aplica únicamente dentro de los límites necesarios para alcanzar el nivel de protección necesario con respecto a los riesgos bilaterales?</i></p> <p>Honduras considera que esto podría incluirse en el paso 2 de la evaluación.</p>	Honduras
<p><i>ii) ¿es también necesaria una declaración/principio compensatorio sobre la obligación de la parte importadora de garantizar que su medida se aplica únicamente dentro de los límites necesarios para alcanzar el nivel de protección necesario con respecto a los riesgos bilaterales?</i></p> <p>Consideramos que sí es necesaria una declaración/principio compensatorio sobre la obligación del importador de garantizar que su medida se aplica dentro de límites establecidos para garantizar el nivel de protección necesario</p>	Colombia
<p><i>ii) ¿es también necesaria una declaración/principio compensatorio sobre la obligación de la parte importadora de garantizar que su medida se aplica únicamente dentro de los límites necesarios para alcanzar el nivel de protección necesario con respecto a los riesgos bilaterales?</i></p>	Uruguay

Uruguay entiende que es necesario que también se incluya un principio compensatorio sobre la obligación de la parte importadora	
g. Los países importadores y los países exportadores deben documentar en un acuerdo cualquier reconocimiento alcanzado, donde se especifiquen los productos alimenticios y las medidas incluidos o excluidos, además de las disposiciones y requisitos para la aplicación y el mantenimiento del reconocimiento de la equivalencia en el comercio de productos entre ambos países. Para una mejor comprensión	Paraguay
SECTION 5: INITIAL DISCUSSIONS	
Para. 9 Se recomienda que las autoridades competentes de los países importadores y exportadores mantengan conversaciones iniciales antes de formalizar una solicitud de reconocimiento de la equivalencia, habida cuenta de que dicha solicitud puede presentarse en cualquier momento durante las conversaciones deliberaciones.	Paraguay
Para 10. En las conversaciones deliberaciones iniciales debe examinarse la naturaleza y la pertinencia de las condiciones comerciales que el país exportador considera innecesariamente restrictivas. Estas deben servir para determinar si se trata de medidas sanitarias o técnicas, o de una posible combinación de ambas. Ambos países deben plantearse si existen otras soluciones o procesos alternativos, al margen de la evaluación de la equivalencia, para responder a esas inquietudes.	
Para 11. Las conversaciones deliberaciones deben contribuir tanto a precisar el alcance de cualquier consideración como a determinar qué información adicional o pruebas objetivas pueden ser necesarias para el proceso de evaluación. Deben, asimismo, arrojar luz dar claridad sobre el posible uso de los conocimientos, la experiencia y la confianza existentes, o de la información o la evaluación intercambiadas previamente, incluido también para simplificar los procesos.	
Para 12. Entre las cuestiones pertinentes que deben contemplarse para determinar si un proceso de equivalencia es el más adecuado para las condiciones comerciales objeto de examen puede figurar el estudio de los siguientes aspectos:	
Para 12 last bullet - whether a recognition of equivalence will likely further facilitate trade result in cost and resource savings, reduced duplication of control activities and/or removal of unnecessary impediments to trade, while still ensuring the importing country's relevant NFCS objectives, and the related outcomes or level of protection are met.	European Union
Para 12 last bullet - la posibilidad de que un reconocimiento de equivalencia facilite aún más el comercio sin dejar de garantizar el cumplimiento de los objetivos pertinentes del SNCA del país importador y los resultados o el nivel de protección correspondientes.	Paraguay
Initial scope discussions Addressing scope prior to the 'appropriateness of an equivalence process' section may provide more logical flow.	Australia
Para 13. Initial discussions on scope should focus on both the nature of the conditions of trade and why the exporting country considers these are unnecessarily restrictive. This is repeated from point 10 and 12. Suggest deletion.	Australia
Para 14. El ejemplo incluido en el párrafo 14 es muy claro y completo y por tanto se sugiere incluirse en el ámbito de aplicación del documento.	Colombia
Para 14. Las condiciones comerciales pueden referirse a uno o varios controles adicionales que el país exportador puede verse obligado a aplicar, pero también pueden incluir cualquier proceso adicional aplicado por el país importador. Por ejemplo, pueden referirse a procesos e inspecciones suplementarios específicos que el país exportador debe realizar antes de la exportación o a procesos adicionales de aprobación de	Paraguay

productos, procesos o establecimientos, o a la frecuencia o el tipo de inspección que aplica el país importador a las importaciones.	
Para 17. Suggest point 17 begins the section for Experience Knowledge and Confidence.	Australia
Para 18 applicable <u>the alignment with relevant ISO guidelines and conformity assessment practices</u> practices from relevant international standards setting bodies; and/or Brazil is of the opinion that the term “alignment” is not the most appropriate and first we propose to delete the expression “the alignment with” Second, instead of mentioning ISO guidelines, we would prefer to have a more general statement referring to guidelines from relevant international standards setting bodies.	Brazil
Importing and exporting countries should develop a clear understanding of what role and to what extent existing experience, knowledge and confidence will be used in any consideration or assessment of equivalence. This understanding needs to cover how existing experience, knowledge and confidence will affect: Paragraph 19 seems redundant as its contents are covered by paragraphs 16-18.	European Union
the process applied to aspects within the scope of the request;	
the amount, nature and scope of any additional information needing to be supplied; and	
the assessment and decision-making processes.	
SECTION 6: PROCESS STEPS	
Para 22. In relation to the process steps, Brazil understands that this section should be aligned with document CX/FICS 23/26/4. It seems that the steps described in document 4 are more appropriate. In particular, we would like to highlight step 3, which demonstrates that decision criteria must be defined jointly between the parties.	Brazil
Step 1: Scope of request discussed and documented The document does not consider the eventual need for scope extension, which is something recurring in equivalence recognition processes. In this sense, we believe that this issue should be clearly stated in the document. Our suggestion is that Step 1 should describe the treatment of scope extension, and that Step 7 should make reference to the possibility of scope extension. If it is considered that scope extension is a new process, this should be clearly mentioned in the document, including the possibility of fast track.	Brazil
Para 26. The bullet points of paragraph 26 only cover the description of measures and not the description of NFCS or the relevant parts of it, i.e. elements of systems equivalence are missing.	European Union
Para 26 bullet 4 la determinación de los riesgos específicos relativos a la protección de la salud de los consumidores o a la garantía de las prácticas equitativas de comercio de alimentos que se pretenden paliar con las medidas especificadas; Se sugiere cambiar la expresión paliar por mitigar. Es un cambio de forma en el documento para mayor entendimiento.	Colombia
Para 29. The setting of the decision criteria is a prerogative of the importing country. While it should be discussed with the exporting country, there is no need to agree on it between the countries as suggested by paragraph 29.	European Union
Para 29. El país exportador y el país importador deben entablar conversaciones para facilitar el desarrollo y la mejor comprensión de los criterios de decisión que deben aplicarse, que, en la medida de lo posible, deben acordarse entre ambos países.	Paraguay

Para 30. The meaning of paragraph 30 is unclear.	European Union
Para 32, bullet 2 No se comprende bien a que se refiere el tipo de pruebas esperadas?	Paraguay
Step 5: Assessment process There is no need to describe separate assessment processes for system equivalence and for equivalence of measures.	European Union
Para 44. Since the content is considered to be understood by all parties in the basic definition, deletion is proposed to simplify the guidelines.	Republic of Korea
Step 5a: Assessment process – System equivalence There is no need to split Step 5 into 2 sub-steps: 5a (System equivalence) e 5b (Equivalence of measures).	Brazil
Paso 5a. Proceso de evaluación: Equivalencia del sistema El comité considera que no hay necesidad de cambio.	Peru
<i>Do we need something different here?</i> System equivalence will focus on the overall capability of the system of exporting country to provide the level of protection expected by the importing country. The assessment of the system may be time taking process as various components of the system need to be looked into.	India
<i>Do we need something different here?</i> No	Iraq
<i>Do we need something different here?</i> The process steps detailed in Step 5 are broad enough to encompass the assessment of both systems equivalence and measures.	Australia
<i>¿Hay que cambiar algo en este caso?</i> Honduras no considera que deba cambiar algo sino desarrollar los pasos de la evaluación para la equivalencia de sistemas	Honduras
<i>¿Hay que cambiar algo en este caso?</i> A la pregunta de si se requiere cambiar algo en este paso, consideramos que no es clara la consulta. Consideramos necesario aclarar a qué se refiere la pregunta en cuanto a equivalencia del sistema.	Colombia
Step 5b: Assessment process – Equivalence of measures There is no need to split Step 5 into 2 sub-steps: 5a (System equivalence) e 5b (Equivalence of measures).	Brazil
Paso 5b. Proceso de evaluación: Equivalencia de medidas Deberia decir: El comité considera que no hay necesidad de cambio.	Peru
<i>Do we need something different here?</i> System equivalence will focus on the overall capability of the system of exporting country to provide the level of protection expected by the importing country. The assessment of the system may be time taking process as various components of the system need to be looked into.	India

<p><i>Do we need something different here?</i></p> <p>No</p>	Iraq
<p><i>¿Hay que cambiar algo en este caso?</i></p> <p>Honduras no considera que deba cambiar algo sino desarrollar los pasos de la evaluación para la equivalencia de medidas y describir si aplican a medidas sanitarias y/o a medidas técnicas</p>	Honduras
<p><i>¿Hay que cambiar algo en este caso?</i></p> <p>A la pregunta de si se requiere cambiar algo en este paso, consideramos que no es clara la consulta. Consideramos necesario aclarar a qué se refiere la pregunta en cuanto a equivalencia de medidas.</p>	Colombia
<p><u>Para 57.</u> Suggest to delete the entire paragraph. Because additional data is provided during the evaluation process as for supplemental information, thus para 57 seems redundant.</p>	Republic of Korea
<p><u>Para 57.</u> The draft decision document should be consulted with <u>provided to</u> the exporting country. The importing country should allow the exporting country to correct any error in fact, and in the case of a draft negative overall decision, the importing country should allow the exporting country to propose a remedy to any identified deficiency. The importing country should take any additional information provided by the exporting country into account when finalizing the decision document.</p>	Australia
<p><u>Para 58</u> is redundant as it is covered by the provisions under section 7.</p>	European Union
SECTION 7: DOCUMENTING THE AGREEMENT AND IMPLEMENTING THE DECISION	
SECTION <u>Step 7:</u> DOCUMENTING THE AGREEMENT AND IMPLEMENTING THE DECISION	Brazil
<p><i>el contenido o las disposiciones habituales del documento de equivalencia, que se incluye como apéndice.</i></p> <p>Honduras sugiere incluir el número del apéndice #2</p>	Honduras
<p><u>Para 61 bullet 2</u> Suggest to delete the text : (rationale) It is questionable whether it is appropriate to maintain equivalence (or reevaluate) in the decline in the level of protection?</p>	Republic of Korea
<p><u>Para 61 bullet 3:</u> It seems necessary to specify the scope of substantial changes to NFCS of exporting countries.</p>	Republic of Korea
<p><u>Para 62</u> This point should be clarified and revised to address the implementation of an equivalence agreement and the resolution of issues at a higher level, separate to emergency provisions.</p> <p>In an effective equivalence arrangement, individual exporter performance failures should be managed by the exporting country. A documented equivalence agreement could allow for specific verification activities, audits, and problem resolution procedure if necessary.</p> <p>CXG 34-1999 states that ‘A problem resolution procedure should be developed including provision for the importing country to re-examine products to verify that the exporting country has corrected its deficiencies.’</p>	Australia
<p><u>Para 62</u> Debido a que el texto del párrafo 62 es muy claro y necesario para el documento, se sugiere que se incluya en la sección de definiciones. Se sugiere que se incluya la información contenida en el párrafo 62 como una definición en la sección 3.</p>	Colombia

<p><i>Does the information relating to maintenance of an equivalence recognition currently in Section 7 provide sufficient guidance OR should it be set out in a separate section as initially suggested?</i></p> <p>Brazil understands that Step 7 already presents information related to equivalence maintenance.</p>	Brazil
<p><i>Does the information relating to maintenance of an equivalence recognition currently in Section 7 provide sufficient guidance OR should it be set out in a separate section as initially suggested?</i></p> <p>Information in Section 7 is not sufficient as it broadly talks in terms of areas/provisions which have been agreed in the equivalence agreement. Therefore, previously proposed Section 8 on Maintenance of Equivalence Recognition could be useful in achieving wider objectives based on the equivalence arrived with lot of efforts & resources involved.</p>	India
<p><i>Does the information relating to maintenance of an equivalence recognition currently in Section 7 provide sufficient guidance OR should it be set out in a separate section as initially suggested?</i></p> <p>There is no need for a separate section for the maintenance of the equivalence recognition as it is sufficiently covered by section 7.</p>	European Union
<p><i>Does the information relating to maintenance of an equivalence recognition currently in Section 7 provide sufficient guidance OR should it be set out in a separate section as initially suggested?</i></p> <p>Australia supports the combination of these sections, the text indicates maintenance issues and conditions of the agreement to be an important aspect of the agreement document.</p>	Australia
<p>¿La información relativa al mantenimiento de los reconocimientos de equivalencia que figura actualmente en la Sección 7 proporciona orientaciones suficientes o sería preferible que figurase en una sección aparte, como se sugirió inicialmente?</p> <p>El comité considera que esta sección proporciona orientaciones suficientes.</p> <p>Comentario: No hay necesidad de adicionar otra sección</p>	Peru .
<p>¿La información relativa al mantenimiento de los reconocimientos de equivalencia que figura actualmente en la Sección 7 proporciona orientaciones suficientes o sería preferible que figurase en una sección aparte, como se sugirió inicialmente?</p> <p>Honduras considera que la sección 7 tal como se presenta en el documento no parece ser orientaciones completas para mantener acuerdos de equivalencia. La propuesta de una nueva sección 8 y el texto en la nota parece dar mejores orientaciones</p>	Honduras
<p>¿La información relativa al mantenimiento de los reconocimientos de equivalencia que figura actualmente en la Sección 7 proporciona orientaciones suficientes o sería preferible que figurase en una sección aparte, como se sugirió inicialmente?</p> <p>A la pregunta respondemos que se debería considerar una sección aparte para el mantenimiento de los reconocimientos de equivalencia de la sección 7. Consideramos necesario que se trate como una sección aparte</p>	Colombia
<p>¿La información relativa al mantenimiento de los reconocimientos de equivalencia que figura actualmente en la Sección 7 proporciona orientaciones suficientes o sería preferible que figurase en una sección aparte, como se sugirió inicialmente?</p> <p>Uruguay entiende que no es necesario que se incluya una sección específica para mantenimiento de la equivalencia. Sin embargo, está de acuerdo en que es necesario ampliar la información aportada en el párrafo 60. Se sugiere incluir lo que figura en la nota del documento sobre las posibles opciones para que los países mantengan la vigencia de los reconocimientos de equivalencia mediante:</p> <ul style="list-style-type: none"> • Intercambios periódicos de 	Uruguay

información. • Criterios acordados para determinar cuándo procede realizar algún tipo de reevaluación. • El efecto de los reconocimientos en las auditorías nacionales, etc.	
APPENDIX 1	
El comité considera conveniente la inclusión de un diagrama de flujo para los distintos tipos de evaluación de la equivalencia. Comentario: Facilidad para comprensión del documento.	Peru
A flow diagram may be useful.	Brazil
Yes, a flow diagram is useful	Iraq
Australia does not consider a flow diagram necessary for this process.	Australia
Honduras considera que los diagramas de flujo son orientaciones prácticas, se sugiere incluir diagramas específicos para los distintos tipos de evaluación de equivalencia.	Honduras
A la pregunta sobre utilidad de los diagramas de flujo, consideramos que son necesarios para dar claridad al documento sobre los pasos a seguir. Consideramos necesario incluir en el documento los diagramas de flujo explicativos para los distintos tipos de evaluación de la equivalencia.	Colombia
Flow diagram is the simplified way of indicating the various steps involved in the equivalence assessment and is always useful. It would be useful to have separate flow diagram for sanitary measure equivalence and system equivalence.	India