



**Food and Agriculture
Organization of the
United Nations**



**World Health
Organization**

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 6

**CX/FICS 21/25/6 Add.1
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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION
AND CERTIFICATION SYSTEMS**

Twenty-fifth Session

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

Comments in reply to CL 2021/17/OCS-FICS

Comments of Australia, Canada, Chile, Cook Islands, Ecuador, European Union, Honduras, Iran, Iraq, Japan, Mexico, New Zealand, Peru, Republic of Korea, Thailand, United States of America, and FAO

GENERAL COMMENTS	
Comment	Author
<p>Canada would like to thank the Chair and co-chairs and members of the electronic working group for their work on the further elaboration of the draft guidelines. Canada supports this work and would like to see the guidance advance in a timely manner to allow further work on consolidation of relevant text on the subject of equivalence. As such, Canada is pleased to provide the following comments and suggestions:</p> <ul style="list-style-type: none"> • Canada notes that the draft guidelines are to “be read in conjunction with the Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997) and the Guidelines for Food Import Control Systems (CAC/GL 47-2003)”. These guidelines present a common theme that encourages importing countries to apply a practical approach to provide consumers with access to safe, wholesome food that is traded in a fair manner. They also recognize that import controls will vary depending on the nature of the food and its source. As such, countries are encouraged to apply sound principles of risk analysis when determining the best approach to control food imports. • In determining the best approach to the oversight of food imports, importing countries are encouraged to consider the controls that are applied in the exporting countries and collaborate with each other to determine if the outcome achieved by the controls of the exporting country are equivalent to the outcomes achieved by the controls followed by domestic producers in the importing country. • System equivalency determinations can provide a mechanism for both importing and exporting countries to make the best use of their inspection resources. Recognition of equivalency provides options for both sides to simplify and streamline administratively burdensome processes such as lot by lot certification, physical checks at the border, and establishment approvals based on inspection. The committee recognized that guidance in this area is lacking, resulting in the draft guidelines under discussion. • Canada’s comments reflect the intention to produce guidance that assists countries in tackling the complexities regarding systems equivalency in a manner that saves competent authorities in both importing and exporting countries resources by removing redundancies in inspection procedures, including those that could contribute to unnecessary trade barriers. • Canada notes that the document could be read as primarily providing guidance to allow exporting countries to resolve trade issues. Canada agrees that systems equivalence provides a means for importing and exporting countries to collaborate in a manner that allows better use of resources by both sides, which has an added benefit of resolving issues that lead to trade issues. However, Canada is concerned that text that places emphasis on the use of this guidance to primarily resolve trade issues could be misinterpreted as indicating that 	<p>Canada</p>

<p>equivalence is the only manner for countries to address unnecessary impediments to trade. There are a number of bilateral, plurilateral, and multilateral mechanisms available to address trade barriers. Hence, Canada has proposed revisions in the text to address these concerns.</p> <ul style="list-style-type: none"> In its previous comments, submitted in response to CL 2020/02/OCS-FICS and to the electronic working group, Canada has emphasized the importance of providing examples, both SPS and TBT, to illustrate the practical implementation of the draft guidelines, in particular the relationship between “objectives” and “outcomes”, and how that relationship would be used to formulate the “decision criteria” that would be used by the importing country to determine if the exporting country’s approach would be equivalent in meeting those objectives. We appreciate the efforts of the New Zealand lead of the informal virtual working group meeting, held March 23, 2021, in presenting a practical example. We reviewed the report of the virtual working group meeting (CRD2) and note that the example provided in Appendix II of the report only speaks to “objectives” and “decision criteria”, and does not include reference to outcomes. Canada would suggest that there would be benefit to further elaborate on the example during the plenary session of CCFICS25 or an in-session working group to ensure a common understanding of the draft guidelines and the concepts of objectives, outcomes and decision criteria therein. 	
Australia has no comments on this circular letter.	Australia
No comments	Cook Islands
<p>The European Union and its Member States (EUMS) would like to thank New Zealand, the United States and Chile 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 21/25/6. They will provide useful guidance for exporting and importing countries in determining the equivalence of NFCS.</p>	European Union Mixed Competence European Union Vote
<p>First and foremost, we wish to express our appreciation to Chair and Co-Chair for their hardworking and effort in preparing the revised draft Guideline. We view that this revised text could be moved forward to the Step procedure and we have no objection for the accelerated advancement upon the finalization of this draft Guideline, taking into consideration of Member’s comments</p> <p>Further, our specific comments will be provided under the relevant sections of the document.</p>	Thailand
Peru has no comments concerning the document presented for comments.	Peru
Ecuador agrees with the comments presented by the Delegation of the United States concerning the treatment of SFMs and TBTs when they are separated in the WTO and different parameters are used to assess the importing country’s compliance with the requirements.	Ecuador
Agree with proposed.	Iraq
<p>Chile would like to thank the Chair and co-chairs of the electronic working group for their work.</p> <p>It would also like to recognise the ongoing work on this subject and confirms its support for the application of a practical approach to the processes and procedures that might assist countries in considering system equivalence.</p> <p>Chile has noted that the document collates many of the concerns that have been raised throughout this process, nonetheless, there are issues that need to be resolved or clarified.</p> <p>Consequently, we do not consider that any hasty progress with this document is appropriate, given that it still requires many adjustments as indicated in the comments below.</p>	Chile
<p>General comment: FAO wishes to acknowledge the progress made in drafting this document. There is better recognition that this complement and expands the suite of tools on equivalence. The structure is logical and the basic process is helpful. As the linkages with pre-existing documents are many, we would recommend using consistent terminology with concepts used elsewhere in CCFICS guidance and avoid, to the extent possible, introducing too many notions that may not be concretely useful to the process.</p>	FAO

<p>1) Issue of legal interpretation</p> <ul style="list-style-type: none"> - R.O.K. noted that CRD #2 on Agenda #6 (CX/FICS 21/25/6), which was prepared by New Zealand, Chile, and the United States, mentions that “The draft guidance is cognisant of, but not intended to be a legal interpretation of, specific WTO articles as contained in the WTO TBT and SPS Agreements” with WG Chairperson’s comments. (Source from: Part 2, 2nd paragraph, p.2 of CRD #2, April 2021) - According to the texts of the WTO SPS Agreement, especially Art 3(Harmonization) mentions WTO member’s obligations on international standard, guidelines, or recommendations. In Art 3.1, “... Members shall base their SPS measures on international standard, guidelines, or recommendations, ...”. Also, In Art 3.2, “SPS measures which conform to international standard, guidelines, or recommendations” - We also searched WTO dispute cases and found that WTO Dispute Settlement Body has reviewed WTO member’s compliance with the WTO SPS Agreement, with reference to the Codex/IPPC/OIE texts. Also, the WTO DSB concluded whether or not the WTO member complied the obligations under Article 3, based on the Codex/IPPC/OIE texts - So, R.O.K. considers that it is an important issue to determine whether or not the phrase “TBT Agreements and technical regulations” is included in CX/FICS 21/25/6. Though WG Chairperson explained such that “The draft guidance is cognisant of, but not intended to be a legal interpretation of, specific WTO articles...”, it is evident that Codex texts could be the reference to WTO DSB’s legal interpretation. - Also, in respect of WTO TBT Agreement, Art 1.5 mentions that the Articles of TBT Agreement do not apply to SPS measure as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures. - In conclusion, it is understood that SPS and TBT Agreement could not be intermingled and coexisted within the same document, and if not, this could lead to the confusion of legal interpretation by the WTO DSB. - For those reasons, R.O.K. proposes not to mention “TBT Agreements and technical regulations” within the Codex texts, especially CX/FICS 21/25/6. <p>2) The Report of 24th session of CCFICS (REP19/FICS, 18.10.22.-10.26.)</p> <ul style="list-style-type: none"> - R.O.K. looked into the result of the 24th session of CCFICS, and found that Codex Members had decided in para #17 as below: “(Section 1 — Preamble/Introduction) It was clarified that the term “level of protection” applied to the SPS Agreement and not the TBT Agreement, thus “TBT” should be deleted from footnote 3.” - It could be known that CCFICS tried not to intermingle the TBT and SPS concepts within CCFICS texts, even after the discussions of the 24th session of CCFICS. Thus, it could be led to redundancy of the past activities that were not accepted in the past. From this reason, R.O.K. proposes not to mention “TBT Agreements and technical regulations” within the Codex texts, especially CX/FICS 21/25/6. 	<p>Republic of Korea</p>
<ul style="list-style-type: none"> • The United States continues to have concerns that the equivalence concepts for sanitary and phytosanitary (SPS) and technical barriers to trade (TBT) are intermingled. While we recognize the intent for CCFICS to include both TBT and SPS concepts in these guidelines, through the drafting process, it appears as though that approach is not feasible, as the document is currently drafted. We believe the inclusion of TBT, conflated with SPS equivalence, continues to create confusion. • We agree that the intent of these guidelines is not to interpret WTO Agreements, however, these critical issues must be addressed before moving forward with the drafting process in order to ensure that the guidelines do not create more problems than those they were intended to help resolve. • The document does not clearly differentiate the basis for determining equivalence for food safety (SPS measures) or for technical regulations, conformity assessment, or standards (TBT measures) - such as product description and composition, weights and measurements, packaging, product durability, labeling or grading. Instead, a concept of objectives and performance based on TBT equivalence concepts is broadly applied to the definition of an NFCS to include all measures 	<p>USA</p>

<ul style="list-style-type: none"> When determining food safety equivalence, an exporting country is required to objectively demonstrate that their controls meet the importing country's appropriate level of protection. The importing country considers the level of protection that the exporting country's controls actually achieve, not what the exporting country intends their controls to achieve. While an importing country is free to consider an exporting country's objectives, those objectives cannot be used to assess the safety that an exporting country's system delivers. 	
<p>New Zealand thanks the members of the working group and the co-Chairs for their on-going engagement with this work. As Chair of the working Group New Zealand has very much appreciated the active, open and constructive approach taken by the working group and the CCFICS plenary in the development of this guidance.</p> <p>We recall that the mandate from CCFICS was "to provide guidance to competent authorities of importing and exporting countries on the use of systems equivalence recognition as a means to further facilitate protection of the health of consumers and ensuring fair practices in the food trade" and "the guidance is intended to apply to the process for importing and exporting countries to follow when a request has been made by an exporting country for the recognition of the equivalence of the whole or part of its NFCS. In this regard it is noted that a NFCS includes import and export inspection and certification systems and has the objective of both protecting public health and ensuring fair practices in trade" (CAC/GL 82/2013 para 2 and para 6).</p> <p>New Zealand believes that this tasking from CCFICS and endorse by the CAC has been fulfilled and it is now appropriate for CCFICS to recommend accelerated progress within the step process</p> <p>Given the extensive and transparent process followed during the many rounds of comment and review that have occurred in the development of this draft guidance and noting the timeframes set out in the original Project Document New Zealand supports, following this final CCFICS consideration, the advancement of the draft to steps 5/8.</p>	<p>New Zealand</p>

SECTION 1 – PREAMBLE / INTRODUCTION

<p>New Zealand notes that while some countries wanted to expand the preamble and make specific points within the preamble, New Zealand's view is that the preamble should be kept short and its role is solely to set the context of the guidance relative to:</p> <ol style="list-style-type: none"> The issue the guidance is trying to address (e.g. the problem definition), Which existing Codex guidance, in particular, it needs to be read in conjunction with, Then describe what the new guidance attempts to do relative to both the problem described above and the existing guidance (e.g. how it fills a needed gap) <p>The role of the preamble is not to offer specific guidance nor replicate other parts of the guidance.</p> <p>Further, while Codex standards need to be cognisant of the overriding principles and commitments contained within the various international trade agreements, they are not in themselves legal interpretations of specific articles in isolation. Rather Codex standards are intended to provide practical guidance for countries to resolve actual issues impacting trade between them. In the case of this guidance, it was explicitly linked to wider NFCS import / export issues across the full scope of Codex's mandate.</p>	<p>New Zealand</p>
<p>Section 1 – PREAMBLE Delete the word 'Introduction'</p>	<p>Chile</p>
<p><u>Paragraph 1</u></p> <p>Most trade in food occurs without exporting countries being required to undergo a detailed assessment of their National Food Control System (NFCS)² or assessments of product specific Inspection and Certification systems. <u>The objective of the country's NFCS is to provide safe food for its consumers and ensure fair practices in the food trade.</u> However, some importing countries do require exchange of information, assessment and or assurances from the exporting country's competent authority to support the trade in certain foods. Such processes may relate to both the protection of the health of consumers and ensuring fair practices in the food trade.</p> <p>Consider including a sentence in the opening paragraph that includes the objective of a NFCS, as defined by Codex in CXG 82-2013 (Principles and Guidelines for National Food Control Systems), which is footnoted in paragraph 1. If this is included in the Introduction</p>	<p>USA</p>

<p>Section, then the definition for NFCS Objectives included in Section 3 would be deleted. Rationale: Redefining NFCS Objectives in this guidance results in two definitions in Codex standards. Further, the current definition in the draft Guidelines on Systems Equivalence (CX/FICS 21/25/6) provides a footnote for the SPS Agreement (ALOP) but does not account for the TBT Agreement (technical regulations/standards). NOTE: If the definition for NFCS Objectives is retained in the Systems Equivalence guidance, the United States suggests the TBT Agreement be added to the footnotes.</p>	
<p>Paragraph 1</p> <p>Canada recommends deletion of paragraph 1 for the following reasons: exchange of information to support the trade in food is more clearly elaborated in the Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food; there is no flow/linkage between the first two paragraphs and paragraph 3, which actually describes the focus of the document; and lastly, using paragraph 1 as the preamble of draft guidelines on systems equivalence could lead the reader to understand that systems equivalency and/or the exchange of information is required as a condition of trade for those products that are currently traded without such a requirement.</p>	Canada
<p>Footnote 2: Principles and guidelines for National Food Control Systems (CXG 82-2013)</p> <p>Canada suggests paragraph to be removed</p>	Canada
<p>Paragraph 2</p> <p>2 Several mechanisms already outlined in existing Codex guidelines may facilitate the exchange and assessment of additional information between competent authorities where required. For example, CXG 89-2016³ provides guidance on the exchange of information on the whole or parts of NFCS between importing and exporting countries to support trade in food, CXG 26-1997⁴ provides guidance on, the assessment of a Food Inspection and Certification System, and CXG34-1999 on the development of equivalence agreements⁵. Countries may also use CXG 53-2003⁶ where a more specific evaluation of a single sanitary or group of sanitary measures associated with Food Inspection and Certification Systems is justified.</p> <p>Pursuant to Canada's proposal to delete paragraph 1, paragraph 2 becomes out of place and should be deleted. Instead, a list of relevant Codex texts can be included following paragraph 3 or in the footnotes.</p>	Canada
<p>Paragraph 2</p> <p>2 Several mechanisms already outlined in existing Codex guidelines may facilitate the exchange and assessment of additional information between competent authorities where required. For example, CXG 89-2016³ provides guidance on the exchange of information on the whole or parts of NFCS between importing and exporting countries to support trade in food, CXG 26-1997⁴ provides guidance on, the assessment of a Food Inspection and Certification System, and CXG 34-1999 on the development of equivalence agreements⁵. Countries may also use CXG 53-2003⁶ where a more specific evaluation of a single sanitary or group of sanitary measures associated with Food Inspection and Certification Systems is justified.</p> <p>Chile recommends deleting "where required", as it adds nothing.</p> <p>Chile recommends replacing "For example" with "Such as".</p> <p>Chile suggests adding a sentence at the end of this paragraph to explain that these texts are additional to the current directive. The proposed text would be:</p> <p>"This Directive may be read in conjunction with the existing documents as indicated."</p>	Chile
<p>Paragraph 2</p> <p>2 Several mechanisms already outlined in existing Codex guidelines may facilitate the exchange and assessment of additional information between competent authorities where required. For example, CXG 89-2016³ provides guidance on the exchange of information on the whole or parts of NFCS between importing and exporting countries to support trade in food, CXG 26-1997⁴ provides guidance on, the assessment of a Food Inspection and Certification System, and CXG34-1999 on the development of equivalence agreements⁵. Countries may also use CXG 53-2003⁶ where a more specific evaluation of a single sanitary</p>	Ecuador

<p>or group of sanitary measures associated with Food Inspection and Certification Systems is justified.</p> <p>To accommodate the fundamental differences between the SFM and TBT equivalence concepts, the difference between these two concepts should be placed in the Introduction and addressed clearly and separately throughout the document. Therefore, the following reference should be included in paragraph 2 of the first section:</p> <p>“2b. An NFCS includes components that are subject to the provisions of the WTO SFM Agreement and the WTO TBT Agreement. The standard of equivalence under these two agreements is different. These guidelines explain how to implement or address a revision of these different standards in the context of a system equivalence assessment.”</p>	
<p>Footnote 3: Principles and guidelines on the Exchange of Information between Importing and exporting Countries to Support Trade in Food (CXG 89-2016)</p> <p>Canada suggests paragraph to be removed</p>	Canada
<p>Footnote 4: Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems (CXG 26-1997)</p> <p>Canada suggests paragraph to be removed</p>	Canada
<p>Footnote 5 : Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CXG 34-1999)</p> <p>Canada suggests paragraph to be removed</p>	Canada
<p>Footnote 6 : Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (CXG 53-2003)</p> <p>Canada suggests paragraph to be removed</p>	Canada
<p><u>Paragraph 3</u></p> <p>3 Recognition of the equivalence of the whole or a part of an exporting country’s NFCS as relevant to the trade in foods under consideration can also provide an effective means for protecting the health of consumers and ensuring fair practices in the food trade while minimizing unnecessary duplication of controls. The recognition of equivalence, where it occurs, should<u>may</u> result in both positive changes to the conditions of trade and should<u>may</u> facilitate the more efficient and effective use of resources in the importing and exporting countries (for example recognition countries.3bis. A NFCS comprises components that are <u>disciplined by the WTO-SPS Agreement and the WTO-TBT Agreement. The concepts of lists of eligible export establishments, alternative processing equivalence and inspection procedures</u>how it is determined are different under these two agreements. This guideline provides an approach on how to review different sanitary measures, technical regulations, conformity assessment, or reduced rates standards in the realm of port-of-entry inspection)a systems equivalence evaluation.</p> <p>Rationale: The United States suggests replacing "should" with "may", given there is no guarantee that recognition of equivalence will result in positive changes to the conditions of trade or more efficient and effective use of resources. We also do not support the inclusion of examples in the introduction. These examples are narrowly focused on port-of-entry (border) measures and may or may not be an outcome of an equivalence determination.</p> <p>3bis Rationale: In order to accommodate the fundamental differences between the concepts of SPS and TBT equivalence, the difference between these two concepts should be placed in the Introduction and addressed clearly and separately throughout the document.</p>	USA
<p><u>Paragraph 3</u></p> <p>3 (bis) These guidelines should be read in conjunction with other relevant guidance related to the design of import/export inspection and certification systems and equivalence. Relevant texts include, but are not limited to:</p> <ul style="list-style-type: none"> • Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999); • Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013); 	Canada

<ul style="list-style-type: none"> • Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003); • Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997) • Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995); • Guidelines for Food Import Control Systems (CAC/GL 47-2003); and • Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food (CAC/GL 89-2016). <p>Canada suggests including the list of relevant texts in new paragraph 3(bis) or alternatively, in a footnote. The list of relevant texts is from the list included in paragraph 6 of the project document that was endorsed at CCFICS23 (REP17/FICS Appendix III). Further, GL 20-1995 includes principles that are relevant to the draft guidance on systems equivalence and should be included in this list.</p>	
<p>Paragraph 3</p> <p>3 Recognition of the equivalence of the whole or a part of an exporting country’s NFCS as relevant to the trade in foods under consideration can also provide an effective means for protecting the health of consumers and ensuring fair practices in the food trade while minimizing unnecessary duplication of controls. The importing and exporting countries may choose to work towards the recognition of equivalence, where equivalence when it occurs, should would result in both positive changes to the conditions of trade and should trade, facilitate the more efficient and effective use of resources in the importing and exporting countries and/or reduce impediments to trade (for example recognition of lists of eligible export establishments, alternative processing and inspection procedures, or reduced rates of port of entry inspection).</p> <p>Editorial comments to improve the flow and clarity of the preamble/introduction</p>	<p>Canada</p>
<p>Paragraph 3</p> <p>3 Recognition of the equivalence of the whole or a part of an exporting country’s NFCS as relevant to the trade in foods under consideration can also provide an effective means for protecting the health of consumers and ensuring fair practices in the food trade while minimizing unnecessary duplication of controls. The recognition of equivalence, where it occurs, should result in both positive changes to the conditions of trade and should 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 reduced rates of port of entry inspection) <u>exporting countries.</u></p> <p>Chile suggests removing the text struck through as the paragraph is understandable without it.</p>	<p>Chile</p>
<p>Paragraph 3</p> <p>3 Recognition of the equivalence of the whole or a part of an exporting country’s NFCS as relevant to the trade in foods under consideration can also provide an effective means for protecting the health of consumers and ensuring fair [In Spanish text: for ‘fair’ replace leales with <u>equitativas</u>; has no impact on the English version] practices in the food trade while minimizing unnecessary duplication of controls. The recognition of equivalence, where it occurs, should result in both positive changes to the conditions of trade and should 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 reduced rates of port of entry inspection).</p> <p>To maintain linguistic consistency, Chile suggests deleting “leales” and replacing it with “equitativas” as that is the term used in the Codex Commission Manual, Ensure fair practices in the food trade.</p>	<p>Chile</p>
<p>Paragraph 3</p> <p>3 Recognition of the equivalence of the whole or a part of an exporting country’s NFCS as relevant to the trade in foods under consideration can also provide an effective means for protecting the health of consumers and ensuring fair practices in the food trade while minimizing unnecessary duplication of controls. The recognition of equivalence, where it</p>	<p>Chile</p>

<p>occurs, should result in both positive changes to the conditions of trade and should 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 reduced rates of port of entry inspection).</p> <p>Chile suggests deleting the text struck through ("as relevant to the trade in foods under consideration"), because it is redundant. It is understood since paragraph 1 that the context is food trade.</p>	
<p>Paragraph 3</p> <p>3 Recognition of the equivalence of the whole or a part of an exporting country's NFCS as relevant to the trade in foods under consideration can also provide an effective means for protecting the health of consumers and ensuring fair practices in the food trade while minimizing unnecessary duplication of controls. The recognition of equivalence, where it occurs, should result in both positive changes to the conditions of trade and should 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, <u>or lesser intensity or reduced rates frequency of inspections</u> in the port of entry inspection).</p> <p>Highlight the fact that the lesser frequency of intensity of inspections is a benefit as it may have an effect on tariff reductions.</p>	Mexico
<p>Paragraph 4</p> <p>4 The consideration, assessment, recognition, and, maintenance of the equivalence of one country's NFCS in whole or the relevant part is independent of any reciprocal process occurring. Reciprocal considerations, where requested, may have different scopes and durations and may also arrive at different conclusions.</p> <p>Delete the "and" before "recognition",</p> <p>Improved wording [For the Spanish only and has no impact on the English version]</p>	Mexico
SECTION 2 – PURPOSE / SCOPE	
<p>Chile suggests leaving only "SCOPE".</p> <p>We consider that the scope is very unclear, given that the document's scope should be entirely clear here.</p>	Chile
<p>5 These guidelines provide practical guidance, information and recommendations for importing and exporting countries to use when considering the appropriateness and/or scope of, as well as the process for assessing, recognising and maintaining the equivalence of the whole or a part of the NFCS at the system level.</p> <p>Propose to delete "at system level" at the end of the paragraph</p> <p>Rationale: redundant with the concept of equivalence of whole or part of a NFCS</p>	FAO
<p>5 These guidelines provide practical guidance, information and recommendations for importing and exporting countries to use when considering the appropriateness and/or scope of, as well as the process for assessing, recognising and maintaining the equivalence of the whole or a part of the NFCS at the system level.</p> <p>Chile suggests replacing paragraph 5) with the following:</p> <p>"These guidelines provide practical guidance, information and recommendations for importing and exporting countries about how to achieve recognition and maintaining equivalence of whole or a part of the NFCS".</p> <p>We consider that this working provides greater clarity of the scope.</p>	Chile
<p>6 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 or both and include the entire NFCS or a part of a NFCS as relevant to the trade in foods and the conditions of trade covered by the request.⁷</p> <p>Suggest to delete text as of "as relevant to the trade in foods" until end of sentence.</p> <p>Rationale: doesn't add specific information and makes sentence heavy to read.</p>	FAO

<p>6 A request for a recognition of equivalence may relate to either the protection of the health of consumers or ensuring fair [leales – equitativas – applicable solely to the Spanish version] practices in the food trade or both and include the entire NFCS or a part of a NFCS as relevant to the trade in foods and the conditions of trade covered by the request⁷.</p> <p>Chile suggests deleting “and include the entire NFCS or a part of a NFCS”.</p> <p>This is already stated in paragraph 5, insofar as we consider deleting the sentence with the one that we propose.</p> <p>Suggest deleting “as relevant to the trade in foods and the conditions of trade covered by the request”.</p> <p>Chile considers it is unnecessary.</p> <p>To maintain terminology consistency, Chile suggests deleting “leales” and replacing it with “equitativas” [applicable to the Spanish text only].</p>	Chile
<p>Given the concerns outlined above, examples could be developed and provided as an information document to complement the guidance on the equivalence of systems. The objective of a national food control system is to protect the health of consumers and to ensure fair practices in the food trade.</p> <p>If the definition of NFCS objectives is maintained in the System Equivalence guidance, it is suggested that the TBT Agreement be added to the footnotes.</p>	Ecuador
<p>6 A request for a recognition of equivalence may relate to [relacionarse a <u>relacionarse con</u> – <u>Applicable to the Spanish only</u>] either the protection of the health of consumers or ensuring fair practices in the food trade or both and include the entire NFCS or a part of a NFCS as [como según sea – <u>Applicable to the Spanish only</u>] relevant to the trade in foods and the conditions of trade covered by the request⁷.</p> <p>Improved clarity</p>	Mexico
<p>Footnote 7: Chile suggests deleting footnote 7, as it is not relevant to the definition provided.</p>	Chile

SECTION 3 – DEFINITIONS

<p>Chile suggests including the definition of equivalence, as provided in the “guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems CAC/GL 26–1997”:</p> <p>“Equivalence is the capability of different inspection and certification systems to meet the same objectives.”</p>	Chile
<p>New Zealand supports inclusion of all the definitions as they are currently written, noting that they are integral to the construct of the rest of the guidance. The definitions are also written so as to allow a logical hierarchical cascade that both spans across the broader policy objectives behind an importing country’s requirements while also allowing more discrete “outcomes” associated with subcomponents to be described, where these are known.</p> <p>In particular, and as was discussed extensively in the original discussion document, the definition of NFCS Objective is the key concept which allows the guidance to span the breadth of NFCS related import requirements that cover the full mandate of Codex, as many countries that will favour the use of system equivalence considerations of the NFCS or the relevant part will invariably be wanting to address matters that do relate to the full mandate.</p>	New Zealand
Equivalence of NFCS	
<p><u>Equivalence of NFCS: The capability of different NFCS or parts of a NFCS to meet the same objectives. [Footnote]Footnote: For the purposes of these Guidelines, any use of the term “equivalence” refers to this definition of “Equivalence of NCFS” and is not meant to replace or redefine the term “equivalence” in other relevant Codex texts or international agreements.</u></p> <p>The United States suggests the addition of a footnote to this definition stating the following:</p> <p>“For the purposes of these Guidelines, any use of the term “equivalence” refers to this definition of “Equivalence of NCFS” and is not meant to replace or redefine the term “equivalence” in other relevant Codex texts or international agreements.”</p>	USA

<p>Rationale: It is important that this new definition does not undermine or replace foundational concepts of equivalence established in other Codex texts. The addition of this footnote provides certainty that unqualified use of the term throughout this document is not misconstrued to suggest that a systems approach is the only acceptable approach to establishing equivalence going forward. This footnote will be particularly helpful in the reconciliation process as it will clarify the distinction between how the term is defined and used in these guidelines and how it is used in other Codex texts.</p>	
<p>NFCS Objectives</p>	
<p>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 consumers⁸ and ensure fair practices in the food trade.</p> <p>The United States suggests deleting the definition for NFCS Objectives.</p> <p>Rationale: See comments under Section 1: INTRODUCTION.</p>	<p>USA</p>
<p>NFCS Objectives</p>	
<p>Suggest to delete this definition.</p> <p>Rationale: This is aspirational. What is achieved, and measurable, are the outcomes.</p>	<p>FAO</p>
<p>Footnotes 7 and 8</p>	
<p>The World Trade Organisation Organization Agreement on the Application of Sanitary and Phytosanitary Agreement Measures refers to this as the country's appropriate level of sanitary protection where the conditions of trade fall within its scope of application.</p>	<p>Canada</p>
<p>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 consumers⁷ and ensure fair [replace "leales" with "equitativas" – Applicable to the Spanish only] practices in the food trade.</p> <p>To maintain terminology consistency, Chile suggests deleting "leales" and replacing it with "equitativas" [applicable to the Spanish text only].</p> <p>The definition does not provide very much clarification around the NFCS equivalence or its parts.</p> <p>Consequently, this concept requires further development.</p> <p>The definition as it stands is confusing; it is not clear how it complements the NCFS's goals as defined in CAC/GL 82-2013.</p> <p>In "Principles and Guidelines for National Food Control Systems CXG 82" it is stated in Section 2: "The objective of a national food control system is to protect the health of consumers and ensure fair practices in the food trade".</p>	<p>Chile</p>
<p>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 or both and include the entire NFCS or a part of a NFCS as relevant to the trade in foods and the conditions of trade covered by the request.⁷</p> <p>New Zealand suggests that if Footnote 7, which is a very recent addition, is retained then it should be rewritten to more correctly state:</p> <p>the scope of the term "health of consumers" includes aspects covered by both the World Trade Organisation Sanitary and Phytosanitary Agreement and the Technical Barriers to Trade Agreement.</p>	<p>New Zealand</p>
<p>Outcome</p>	
<p>Footnote 9: Making reference to the format used in footnotes 2-6, the full name of CXG 91-2017 should be included.</p>	<p>Thailand</p>
<p>Footnote 9</p>	
<p>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 initial⁹</p>	<p>Chile</p>

<p>Chile suggests removing “or results” to make the text the same as the definition provided in “Principles and guidelines for monitoring the performance of national food control systems - CXG 91-2017”.</p>	
<p>Decision Criteria: Those factors used to determine whether the exporting country’s NFCS or relevant part meet the objectives <u>importing country’s appropriate level of protection and is equally effective in achieving the same objective as the importing country’s NFCS technical regulations or the relevant part standards</u> for the products under consideration.</p> <p>The United States suggests terminology throughout the guidance to replace “NFCS objectives” with “appropriate level of protection and is equally effective in achieving the same objective as the importing country’s technical regulations, conformity assessment or standards.”</p> <p>Rationale: These edits take into account both the SPS and TBT agreements, addressing the concern that there may be confusion when the SPS measures and TBT measures are conflated into NFCS objectives.</p>	<p>USA</p>

SECTION 4 – PRINCIPLES

<p>New Zealand supports the principles as written, noting they largely reflect existing Codex principles. Specifically, the concept of NFCS Objective as the higher level for comparison (refer to the definition of equivalence) and the use of relevant international standards as being a way of helping to facilitate the process.</p>	<p>New Zealand</p>
<p>Equivalence of National Food Control Systems (NFCS)</p>	
<p>Countries should <u>may</u> recognize that NFCS’s, or the relevant parts thereof, of importing and exporting countries, although designed and structured differently, may be capable of meeting the same NFCS objectives with respect to protecting the health of consumers and ensuring fair practices in the food trade and trade. <u>When such a determination is reached by the importing country, the exporting country’s NFCS can therefore be found to be equivalent.</u></p> <p>Rationale: Changes made both for readability and substance — the initial “should” suggests that systems equivalence will always be the route that countries should opt to take to establishing equivalence.</p>	<p>USA</p>
<p>Experience, Knowledge and Confidence</p>	
<p>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 meeting the same NFCS objectives with respect to protecting the health of consumers and ensuring fair [replace leales with <u>equitativas</u> – Refers to the Spanish text only] practices in the food trade and can therefore be found to be equivalent</p> <p>To maintain terminology consistency, Chile suggests deleting “leales” and replacing it with “equitativas” [applicable to the Spanish text only].</p>	<p>Chile</p>
<p>Alignment with International Standards</p>	
<p>c. The use of or reference to Codex standards, guidelines, and/or codes of practice by importing and exporting countries can facilitate the consideration, assessment and recognition of the equivalence of a NFCS, or the relevant part. <u>Other international standards can be considered to facilitate recognition mechanisms, such as compliance assessment standards, analytical methodology standards, developed by other recognized standards organizations.</u></p> <p>ISO 17025, 17065 and other standards should be considered since the equivalence between laboratories provided by accreditation 17025 may be an element within the equivalence.</p>	<p>Honduras</p>
<p>Assessment</p>	
<p>d. The assessment process should evaluate whether the relevant NFCS objectives of the importing country are met and the process should be documented; transparent; evidence-based; outcome-focused; efficient; and be conducted in a cooperative and timely manner-. <u>The assessment process should evaluate whether the exporting country’s system meets the importing country’s appropriate level of protection and is equally effective in achieving the same objective as the importing country’s technical regulations, conformity assessment or standards.</u></p>	<p>USA</p>

<p>The United States agrees that the assessment process is critical; however, as drafted, this Principle appears to be SPS-centric. Removing the link to the NFCS objectives and adding the application to both the SPS and TBT measures adds clarity.</p> <p>Rationale: Changes made both for readability and to ensure clarity regarding the assessment process as it applies to SPS and TBT measures.</p>	
<p>Assessment</p>	
<p>d. The assessment process should evaluate whether the relevant NFCS objectives of the importing country are met and the process should be documented; transparent; evidence-based <u>results that take into account the risks (or are risk-focused)</u>; outcome-focused; efficient; and be conducted in a cooperative and timely manner.</p> <p>The subject of risks varies depending on the sector, food chain or product.</p>	<p>Honduras</p>

SECTION 5 – PROCESS STEPS

<p>The United States notes that the process steps apply to both SPS measures and TBT technical regulations/standards. Given some Member countries’ concerns related to providing examples in the guidance, examples could be developed and provided as an information document to supplement the Systems Equivalence guidance. We believe there continues to be a need for an example of decision criteria and their use to assess a TBT issue.</p>	<p>USA</p>
<p>This section borrows (rightfully so) a lot of text form other texts relating to equivalence (CXG 34-1999; CXG 53-20030), using a different wording (e.g. "decision criteria" versus "objective level of comparison") for similar concepts. So we would suggest:</p> <ul style="list-style-type: none"> - to add cross references when possible to make these linkages clear - ensure consistency in the wording used to avoid creating confusion, especially when this is being used by non English mother tongue countries, or has to go through translation. 	<p>FAO</p>
<p>9 Prior to a country formally requesting consultations on the recognition of the equivalence of its NFCS or the relevant part, initial discussions should take place between the relevant competent authorities of both countries. These discussions should identify if commencing an assessment of the equivalence of the exporting country’s NFCS is the most appropriate approach <u>in the view of the importing country</u> or whether some other mechanism¹¹ would be better to address the matters under discussion.</p> <p>Rationale: Edit is intended to clarify that the importing country ultimately decides whether to commence a systems equivalence assessment or pursue some other mechanism.</p>	<p>USA</p>
<p>9 Prior to a country formally requesting consultations on the recognition of the equivalence of its NFCS or the relevant part, initial discussions should take place between the relevant competent authorities of both countries. These discussions should identify if commencing an assessment of the equivalence of the exporting country’s NFCS is the most appropriate approach in the view of the importing country or whether some other mechanism¹¹ would be better to address the matters under discussion</p> <p>Chile suggests adding the following new paragraph:</p> <p>The subjects raised in the initial discussions, points 9 and 10, should not be a condition preventing a country from applying for recognition of equivalence.</p> <p>Also, suggests adding “for the importing country” after “the most appropriate”.</p>	<p>Chile</p>
<p>the bilateral justification and appropriateness of the identified conditions of trade considered by the exporting country to be unnecessarily impeding trade;</p> <p>Canada suggests deleting this bullet since it is redundant and repeats the concept of “unnecessary impediment to trade” captured in the new first bullet. Further, the bullet as drafted could be misinterpreted as equivalence being the only manner for countries to address unnecessary impediments to trade. There are a number of bilateral, plurilateral, and multilateral mechanisms available to address trade barriers.</p>	<p>Canada</p>
<p>the bilateral justification and appropriateness of the identified conditions of trade considered by the exporting country to be unnecessarily impeding trade;</p> <p>Chile suggests deleting from “...unnecessary impediment to trade”, as an equivalence is not necessarily associated with an impediment to trade.</p>	<p>Chile</p>

<p>the similarity to or harmonisation of the whole of parts of or the NFCS with the relevant international standards;</p> <p>As pointed out by a delegation in the recent virtual working group meeting, there is a typo in this bullet</p>	New Zealand
<p>the similarity to or harmonisation of the whole of or parts of the NFCS with the relevant international standards;</p> <p>We believe the intent here is to indicate “or” parts of the NCFS.</p>	Canada
<p>the similarity to or harmonisation of the whole of or parts of the NFCS with the relevant international standards;</p> <p>Because the relevant international standard may be only part of the NFCS.</p>	Japan
<p>the similarity to or harmonisation of the whole <u>or the relevant part</u> of parts of the NFCS with the relevant international standards <u>standards (e.g. Codex, OIE, IPPC)</u>;</p> <p>Rationale</p> <p>As para 7c in SECTION 4 “Principles” referring to the use or reference to the Codex Standards, Guidelines and/or Code of Practices, we therefore view that the term “Codex” should be included in para 10, instead of addressing only the word “international standards”. This is also in line with Principal 12 of CXG82-2013.</p> <p>Following this, we would like to propose aligning with the text “international standards (e.g. Codex, OIE, IPPC)” used in para 19 as follows:</p> <p>“The similarity to or harmonization of the whole or the relevant part of the NFCS with the relevant international standards (e.g. Codex, OIE, IPPC)”</p>	Thailand
<p>whether recognition of the equivalence of the NFCS or the relevant part will likely result in cost and resource savings, reduced duplication of control activities and/or removal of unnecessary impediments to trade, while protecting the health of consumers and ensuring fair practices in the food trade; and</p> <p>Canada recommends moving the sixth bullet of the proposed text to become the first bullet as it elaborates the key objectives to collaborate on equivalency of systems, or parts of systems.</p>	Canada
<p>the similarity to or harmonisation of the whole of parts of the NFCS with the relevant international standards. <u>health events related to the scope of the recognition of equivalence (if any), as were addressed by the exporting and importing countries.</u></p>	Honduras
<p>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. <u>equivalence</u> between the two countries or with third countries.</p> <p>The period should be deleted.</p>	Canada
<p>whether recognition of the equivalence of the NFCS or the relevant part will likely result in cost and resource savings, reduced duplication of control activities and/or removal of unnecessary impediments to trade, while protecting the health of consumers and ensuring fair [replace leales <u>with equitativas</u> – refers to the Spanish only] practices in the food trade; and</p> <p>To maintain terminology consistency, Chile suggests deleting “leales” and replacing it with “equitativas” [applicable to the Spanish text only].</p>	Chile
<p>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 <u>international countries or organizations.</u></p> <p>Paragraph 7, subsection b of Section 4, Principles (Experience, Knowledge and Confidence) also refers to international organizations.</p>	Mexico
<p>identification of these <u>requirements (conditions of trade) considered by the exporting country where recognition of systems equivalency will allow one or both sides to be unnecessarily impeding trade</u> <u>make better use of inspection;</u></p> <p>Canada finds the original wording to be limiting in scope. The proposed revisions take into account the original text and broaden the scope beyond trade impediments. Canada agrees that systems</p>	Canada

<p>equivalence can allow importing and exporting countries to facilitate trade by resolving issues that may be impeding trade. However, focused reference to the objective of resolving trade barriers in this guidance could be misinterpreted as the primary purpose of systems equivalence guidance is to resolve trade issues. There are other mechanisms aside from equivalence for countries to resolve trade issues</p>	
<p>13 Discussions on scope should identify those areas where there may already be sufficient existing experience, knowledge and confidence versus those areas where additional information exchanges are likely to be required¹⁶.</p> <p>Suggest deleting "experience, knowledge and confidence" and replace with "information", as this is what will be on records for decision making.</p>	FAO
<p>The availability of resources likely to be necessary to undertake the process as it relates to the whole or a relevant part of the NFCS proposed to be considered and the possible benefits. <u>The current infrastructure, resources and abilities of testing laboratories, inspection, monitoring mechanisms and certification.</u></p>	Honduras
<p>14 At the conclusion of the initial discussions between the exporting and importing countries <u>countries, the exporting country should formalize its request for a recognition of equivalence and where it is considered that include a description of the scope of products and conditions of trade to be covered. The importing country considers information provided to determine whether:</u></p> <p>Rationale: The United States recommends the proposed edits in para 14 to clearly communicate the rights and responsibility of the importing country to ultimately decide whether to commence with a systems equivalence assessment or some other mechanism, as noted in footnote 10. We agree that the exporting country retains the right to make a formal application of equivalence, but it needs to be clearly stated that the importing country should use the criteria provided in the three bullets to determine whether to begin the formal process for assessing systems equivalence of the NFCS.</p>	USA
<p>14 an assessment of the equivalence of the NFCS is an appropriate mechanism <u>mechanism or whether some other mechanism should be used as noted in footnote 10;</u></p> <p>See rationale above for Para. 14.</p>	USA
<p>14 the request for a recognition of equivalence should be formalised and include a description of the scope of products and conditions of trade to be covered.</p> <p>See rationale above for Para. 14.</p>	USA
<p>Footnote 17</p>	
<p>Footnote 17: the word "CACGL 53-2003" should be replaced with "CXG 53-2003"</p>	Thailand
<p>16 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 arrangement to help facilitate the trade. Alternative mechanisms to address the matters discussed could be considered, as noted in footnote 10. CXG 34/1999 (paragraph 11) also identifies that 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 recognition of the equivalence of systems.</p> <p>Chile suggests adding "for the importing country" after "...appropriate mechanism".</p>	Chile
<p>5.2 STEP 2: DESCRIPTION OF THE IMPORTING COUNTRY'S NFCS AND ASSOCIATED OBJECTIVES</p>	
<p>FAO questions whether the objectives here, which are mostly aspirational. Will these help in determining equivalence? We suggest to delete this reference.</p>	FAO
<p>17 The importing country should identify those elements of its NFCS and their associated objectives relevant to the scope of the request that are to be part of the assessment for example:¹⁸</p> <p>Suggest removing reference to the objectives, as it is confusing. In this sentence, objectives relate to "elements" which are a "lower" level and adds to the confusion as to what we are measuring.</p>	FAO
<p>17 The importing country should identify those elements of its NFCS and their associated objectives relevant to the scope of the request that are to be part of the assessment for example:¹⁸</p>	Chile

<p>Suggests deleting “for example”, which might be replaced with “such as”.</p> <p>The overuse of the words “for example” tends to make the text confusing. Rather than examples, they are alternatives that provide guidance on what is stated in the text.</p>	
<p>regulatory and legislative framework; <u>the existence of regional or community regulations and experience with their application.</u></p> <p>For example, experience with Central American Technical Regulation (RTCA) is not the same if only applied at the national level</p>	Honduras
<p>control and approval programs (for example [por ej. <u>tales como</u> – Refers only to the Spanish] establishment, process and product programs);</p> <p>Chile suggests deleting “por ejemplo” and replacing it with “tales como” – Refers only to the Spanish</p> <p>The overuse of the words “for example” tends to make the text confusing. Rather than examples, they are alternatives that provide guidance on what is stated in the text.</p>	Chile
<p>enforcement and compliance programs [<u>programas de ejecución y medidas de cumplimiento</u>];</p> <p>Harmonize with the English text – Refers only to the Spanish.</p> <p>The relevant programs should be specified.</p>	Mexico
<p>system overview monitoring and evaluation programs; or <u>existing compliance assessment schemes and the mechanisms to address them, for example, accreditation or recognition requirements for compliance assessment activities, outsourcing and/or linking to voluntary schemes or private standards.</u></p> <p>This issue is very topical. The recognition of accreditation is an important tool nowadays, therefore it should also be considered within the NFCS arena, also the dissemination of private standards and their possible recognition or the extent of their use in the quality and safety culture of the private sector.</p>	Honduras
<p>system overview monitoring and evaluation programs [los programas de monitoreo <u>supervisión</u> del sistema en general y evaluación – Refers only to the Spanish]</p> <p>Alignment on the English text.</p>	Mexico
<p>Description and evidence on how the importing country’s NFCS <u>meets the objectives</u></p> <p>Suggest replacing "meets the objectives" by "reaches the specific outcomes", this should be somewhat easier to measure.</p>	FAO
<p>18 To facilitate the exporting country in describing its own systems, the importing country should describe, with appropriate references, how the elements of its NFCS relevant to the scope of the request achieve each of the identified objectives.</p> <p>Chile suggests redirecting the text, as it seems that the burden of responsibility for recognising equivalence is placed on the importer, when it is the exporter who must demonstrate that its NFCS or elements of it are equivalent.</p> <p>The paragraph should highlight an essential point: the importing country clearly describes the objectives sought by its NFCS, as this is what the exporting country must demonstrate that it achieves.</p> <p>The following text is proposed:</p> <p>“To facilitate the exporting country in describing its own systems, the importing country should describe, with appropriate references, how the elements of its NFCS relevant to the scope of the request achieve each of the identified objectives identified in the NFCS.”</p> <p>(Red is deleted, green is added.)</p> <p>[Translator’s note: It appears that Chile’s tracked changes have not been carried forward.]</p>	Chile
<p>5.3 STEP 3: THE DECISION CRITERIA FOR COMPARISON</p>	
<p>New Zealand can support the suggestion made at the recent virtual working group for the Step 3 title to be amended to 'Documentation of the Decision Criteria for Comparison'</p>	New Zealand

<p>New Zealand does not support the provision of further examples of decision criteria as part of this guidance at this time as any such examples could have the effect of narrowing the perception of both the range of situations for which this guidance could be applied as well as what individual countries may deem to be important with respect to their NFCS Objectives for any particular import requirement.</p>	
<p>19 In describing its own NFCS or the relevant part, the importing country may include reference to relevant international standards (e.g. Codex, OIE, IPPC).</p> <p>Chile suggests deleting all the text between brackets since these examples provide no additional understanding of the text.</p>	Chile
<p>21 The decision criteria should facilitate the assessment process being able to determine whether the exporting country's system design and implementation meets the importing country's NFCS objectives and any related outcomes associated with the scope of the request. ¹⁹</p> <p>Suggest deleting paragraph 21; it seems redundant with paragraph 20.</p>	FAO
<p>the level of qualitative or quantitative evidence that is expected; and</p> <p>Para 22: the word "and" in the first bullet should be removed and placed at the end of the second bullet.</p>	Thailand
<p>how experience, knowledge and confidence is <u>are</u> to be used;</p>	Canada
<p>23 The decision criteria should focus on the performance of the system as a whole as opposed to individual procedures or measures, depending on the scope of the assessment. As such decision criteria relating to a NFCS or its relevant part will often be more qualitative than quantitative.</p> <p>Rationale: The United States suggests deleting the second sentence, given para 22 bullet one addresses qualitative and quantitative decision criteria. If the second sentence is retained, then it should be replaced with: "Decision criteria may be qualitative or quantitative."</p>	USA
<p>23 The decision criteria should focus on the performance of the system as a whole as opposed to individual procedures or measures. As such Such decision criteria relating to a NFCS or its relevant part will often be more qualitative than quantitative.</p> <p>Sentence as originally drafted is incomplete.</p>	Canada
<p>24 Where the goal of any part of the NFCS under consideration relates to managing risks to human health²¹ the decision criteria should relate to whether the NFCS of the exporting country achieves the appropriate level of protection as set²² by the importing country.<u>24-bis Where the goal of any part of the NFCS under consideration relates to technical regulations, conformity assessment, or standards, the decision criteria should relate to whether the NFCS of the exporting country are equally effective in achieving the same objective as the importing country's technical measures.</u></p> <p>Rationale: For clarity, to accommodate the fundamental differences between the concepts of SPS and TBT equivalence, the United States suggests a parallel paragraph to address the assessment of the TBT measures.</p>	USA
<p>24 Where the goal of any part of the NFCS under consideration relates to managing risks <u>arising from hazards</u> to human health²¹ the decision criteria should relate to whether the NFCS of the exporting country achieves the appropriate level of protection as set²² by the importing country.</p> <p>Paragraph 24 was a relatively new paragraph that was inserted in an attempt to reflect some WG members desire for a more explicit reference to the concept of Appropriate Level of Protection (ALOP) for those trade requirements that solely came under the umbrella of the WTO SPS Agreement.</p> <p>It has subsequently been pointed out that the Codex mandate, as well as the objective of most country's NFCSs, "to protect the health of consumers" spans both the WTO TBT and the SPS Agreements and the concept of ALOP as referenced in the footnote only apply to the SPS Agreement. Accordingly, this paragraph can be corrected so that it clearly only applies to those aspects which fall under the WTO / SPS Agreement by inserting the phrase "arising from hazards" after the word risks.</p> <p>See appropriate extract (below) defining the scope of the SPS Agreement:</p>	New Zealand

<p>1. Sanitary or phytosanitary measure — Any measure applied:</p> <p>(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;</p> <p>(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or</p> <p>It was also subsequently pointed out that there may be an imbalance if this paragraph is inserted without a corresponding paragraph description. New Zealand is happy to retain the current paragraph, with the suggested amendment or delete it for the above reason. If paragraph 24 is retained the footnotes also need to be kept and references to the WTO Articles should not be elevated into the body of the text.</p> <p>While this guidance is not meant to be a legal interpretation of isolated Articles of various WTO Agreements, if countries would like to insert a parallel paragraph reflecting comparator explicitly referenced by the WTO / TBT Agreement then New Zealand suggests inserting the following language which is broadly based on Article 2.7:</p> <p>24bis Where the goal of any part of the NFCS under consideration is wider than just the management of risks arising from hazards, or the importing country has not established the level of protection (cross reference footnote 21), the decision criteria should reflect criteria which objectively allows them to assess whether that part of the NFCS adequately fulfils the objectives of their own NFCS or relevant part.</p>	
<p>24 Where the goal of any part of the NFCS under consideration relates to managing risks to human health²¹ the decision criteria should relate to whether the NFCS of the exporting country achieves the appropriate level of protection as set²² by the importing country.</p> <p>As the notion of ALOP is introduced explicitly, we would suggest to explain how this relates the notion of outcomes /objectives/decision criteria.</p>	FAO
<p>24 bis. Where the goal of any part of the NFCS under consideration relates to fair trade, the decision criteria should consider if the NFCS of the exporting country adequately fulfills the objectives of the importing country's NFCS (e.g., technical regulations, conformity assessment procedures, standards).</p> <p>Canada recommends addition of a new point under this section, to balance to the SPS focus of point 24, since the document includes both food safety and fair practices in the food trade.</p>	Canada
<p>24 Where the goal of any part of the NFCS under consideration relates to managing risks to human health²¹ the decision criteria should relate to whether the NFCS of the exporting country achieves the appropriate level of protection as set<u>deemed appropriate</u>²² by the importing country.</p> <ul style="list-style-type: none"> - Firstly, R.O.K. noted that Appendix 1 of CX/FICS 21/25/6 quoting WTO SPS Agreement in footnotes #20(See Annex A, definition of sanitary measure (as it relates to food safety) of the WTO SPS Agreement) and #21(See Article 5 of the WTO SPS Agreement: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection), in relation to para #24. - So, we referred to the reference documents of footnote #20 and #21, and found that the WTO SPS Agreement comments on the ALOP as “the level of protection deemed appropriate by the Member...”, especially in the Annex A of the WTO SPS Agreement. - Thus, R.O.K. proposes to revise the original text as the Korea's proposal. 	Republic of Korea
<p>23 The decision criteria should focus on the performance of the system as a whole as opposed to individual procedures or measures. As such decision criteria relating to a NFCS or its relevant part will often be more qualitative than quantitative [más cualitativos y que cuantitativos - Refers only to the Spanish].</p> <p>The source on which this is based and clarification of this text is requested.</p> <p>It is not clear that some are more common than others. It should be left more neutral. The following modification is proposed: (red to delete and green to add).</p> <p>Proposal:</p>	Chile

<p>“The decision criteria should focus on the performance of the system as a whole as opposed to individual procedures or measures. As such decision criteria relating to a NFCS or its relevant part will often be more qualitative than quantitative [más cualitativos y que cuantitativos – Refers only to the Spanish].</p> <p>[Translator’s note: It appears that Chile’s tracked changes have not been carried forward.]</p>	
<p>Footnote 21</p>	
<p>Footnote 21: See <u>definition of sanitary measure (as it relates to food safety) in Annex A: Definitions, definition of sanitary measure (as it relates to food safety) of the WTO SPS Agreement.</u></p>	Canada
<p>Footnote 22</p>	
<p>Footnote 22: See <u>Article 5 of the WTO SPS Agreement</u>5: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection <u>of the WTO SPS Agreement.</u></p>	Canada
<p>25 The decision criteria should not apply a standard or level of performance in excess of that which the importing country’s NFCS or relevant part achieves as it relates to the protection of the health of consumers and ensuring fair practices in the food trade.</p> <p>FAO would like to seek clarification if this echoes the concept of national treatment, and if yes, would suggest to use consistent terminology.</p>	FAO
<p>5.4 STEP 4: DESCRIPTION OF EXPORTING COUNTRY’S NFCS OR RELEVANT PART</p>	
<p>27 As far as practical, and especially where consistent with the relevant Codex guidance, importing countries should allow flexibility in the format of the information submitted by the exporting countries.²³</p> <p>The reporting countries are the exporting countries.</p> <p>Align on the English text. [Refers to the Spanish text only]</p>	Mexico
<p>28 Taking into consideration the scope of the request for recognition of equivalence and existing experience, knowledge and confidence, additional information exchanges should only be required for those matters or elements of the exporting country NFCS which need to be subjected to a more detailed assessment.</p> <p>R.O.K noted that para #25 of the report of the 24th CCFICS session report (2018.10.22.-10.26.) provides “The guidelines should not put a heavy burden on the importing country, in particular to provide evidence on how its NFCS met the objectives.” R.O.K. considers that it could be burden on the importing country if “only” is included in the para #28 of Appendix #1 of CX/FICS/21/25/6. Thus, R.O.K. proposes to revise the original text as the Korea’s proposal.</p>	Republic of Korea
<p>5.5 STEP 5: ASSESSMENT PROCESS</p>	
<p>29 Once the scope of the request is clear and the relevant information and evidence are available the assessment process can proceed. The methodology used in the assessment process by the importing country should be transparent, evidence-based and focus on assessing whether the exporting country’s NFCS in whole or the relevant part as described meets the decision criteria. Where significant differences are identified the assessment should evaluate whether the objectives and any related outcomes of the importing country’s NFCS can be achieved using the exporting country’s alternative approach. There should be an effective communication mechanism between both countries, for providing feedback <u>feedback when differences are identified.</u></p> <p>Rationale: The United States recommends deleting the above sentence. The information provided will be evaluated by the importing country, according to the decision criteria outlined. Any differences that are identified during this assessment will need to be effectively communicated. This is not limited to significant differences.</p>	USA
<p>29 Once the scope of the request is clear and the relevant information and evidence are available the assessment process can proceed. The methodology used in the assessment process by the importing country should be transparent, evidence-based and focus on assessing whether the exporting country’s NFCS in whole or the relevant part as described meets the decision criteria. Where significant differences are identified the assessment should evaluate whether the objectives and any related outcomes of the importing country’s NFCS can be achieved using the exporting country’s alternative approach. There should be an effective communication mechanism between both countries, for providing feedback.</p>	Canada

<p>Canada recommends deleting this sentence as it is contrary to the principle of equivalence which is to allow both parties to recognize that different approaches could lead to the same outcome. Furthermore, as written, the statement does not recognize the principle that it is up to the exporting party to demonstrate that their different approach meets the objective of the importing country. The process to assess equivalence when there are differences is described in the text that follows.</p>	
<p>29 Once the scope of the request is clear and the relevant information and evidence are available the assessment process can proceed. The methodology used in the assessment process by the importing country should be transparent, evidence-based and focus on assessing whether the exporting country's NFCS in whole or the relevant part as described meets the decision criteria objectives. Where significant differences are identified the assessment should evaluate whether the objectives and any related outcomes of the importing country's NFCS can be achieved using the exporting country's alternative approach. There should be an effective communication mechanism between both countries, for providing feedback.</p> <p>Canada recommends replacing "decision criteria" with "objectives" for consistency with the remainder of the document. The assessment focusses on evaluating whether the exporting country meets the objectives of the importing country and not the decision criteria.</p>	Canada
<p>30 The assessment process will normally comprise a number of steps. The exact process may vary depending on: the type of foods in the scope of the request and the complexity of controls; any pre-existing experience, knowledge and confidence; and what sort of modification to existing trade conditions is being sought. In general, the importing country should:</p> <p>The text in this section should balance the need for the importing country to be transparent about the assessment process with the need for the exporting country to demonstrate that its approach meets the objectives required by the importing country. As written, there is little guidance for exporting countries to assist them in understanding the nature of information that will be useful for demonstrating equivalence.</p>	Canada
<p>29 Once the scope of the request is clear and the relevant information and evidence are available the assessment process can proceed. The methodology used in the assessment process by the importing country should be transparent, evidence-based and focus on assessing whether the exporting country's NFCS in whole or the relevant part as described meets the decision criteria. Where significant differences are identified the assessment should evaluate whether the objectives and any related outcomes of the importing country's NFCS can be achieved using the exporting country's alternative approach. There should be an effective communication mechanism between both countries, for providing feedback. <u>Beforehand, the instruments or tools used to gather data, for audits or evaluations should be communicated in a transparent manner: surveys, forms, questionnaires, checklists, among others, as well as their weighting and qualification.</u></p>	Honduras
<p>be conducted in a cooperative and timely manner and may include the review of documents, and the use of in-country assessments / audits²⁴ where justified as necessary²⁵;</p> <p>Canada suggests deleting the text in strike out since it is duplicative of text in Section 4, Principle e.</p>	Canada
<p>32 Other overarching considerations relevant to the assessment process may include:</p> <p>With the deletion of the first two bullet points, para 32 could be merged with para 31.</p>	Canada
<p>freedom from conflicts of interest;</p> <p>Canada suggests deleting reference to conflict of interest since it is not specific to the process of equivalence between two competent authorities. We note that Principle 5 of the Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013) emphasizes that freedom from undue influence or conflict of interest is applicable to all aspects of a NFCS, including the competent authority and all participants acting in official functions. Hence, we do not see a particular need to highlight this principle in the draft guidelines.</p>	Canada
<p>32 (bullet 2) transparency of decisions and actions;</p> <p>Canada suggests deleting this bullet point since it is redundant. The importance of transparency in the assessment process is already emphasized in the principles (Section 4, Principle e).</p>	Canada
<p>32 (bullet 4) the ability of NFCS infrastructure and availability of resources to continue to implement the NFCS or the relevant part-parts as described and implemented by the exporting country.</p>	Canada

<p>Canada finds that the structure of this sentence is unclear. It is unusual to include reference to the “ability of infrastructure and resources to implement the NCFS....” We have proposed edits to clarify the sentence.</p>	
<p>5.6 STEP 6: DECISION PROCESS</p>	
<p>34 The decision process should be transparent. 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 not equivalent, the exporting country should have the opportunity to provide additional information for consideration by the importing country prior to the finalization of the decision. In the case where the exporting country NFCS or the relevant part is assessed as not equivalent the two countries may, if they wish, agree a plan and timeframe for the exporting country to resolve the identified deficiency<u>non-equivalence</u>. Subsequent additional information should be reviewed by the importing country without requiring all aspects of the assessment process to be repeated. The importing country should document the final assessment conclusions and the rationale for them.</p> <p>As requested at the recent virtual working group - New Zealand can support replacing 'identified deficiency' with 'non-equivalence'</p>	<p>New Zealand</p>
<p>34 The decision process should be transparent. 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 not equivalent, the exporting country should have the opportunity to provide additional information for consideration by the importing country prior to the finalization of the decision. In the case where the exporting country NFCS or the relevant part is assessed as not equivalent the two countries may, if they wish, agree <u>to</u> a plan and timeframe for the exporting country to resolve the identified deficiency. Subsequent additional information should be reviewed by the importing country without requiring all aspects of the assessment process to be repeated. The importing country should document the final assessment conclusions and the rationale for them.</p>	<p>Canada</p>
<p>34 The decision process should be transparent. 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 not equivalent, the exporting country should have the opportunity to provide additional information for consideration by the importing country prior to the finalization of the decision. In the case where the exporting country NFCS or the relevant part is assessed as not equivalent the two countries may, if they wish, agree a plan and timeframe for the exporting country to resolve the identified deficiency. Subsequent additional information should be reviewed by the importing country without requiring all aspects of the assessment process to be repeated. The importing country should document the final assessment conclusions and the rationale for them.</p> <ul style="list-style-type: none"> - Firstly, R.O.K. noted that the 4th sentence (“In the case where the exporting country NFCS or the relevant part is assessed as not equivalent the two countries may, if they wish, agree a plan and timeframe for the exporting country to resolve the identified deficiency. Subsequent additional information should be reviewed by the importing country without requiring all aspects of the assessment process to be repeated. The importing country should document the final assessment conclusions and the rationale for them”) of para #34 was not included, even, in the CX/FICS 18/24/4 and CX/FICS 20/25/6, but it was newly phrased within this year’s CCFICS document of CX/FICS 21/25/6. - R.O.K. considers the newly phrased/inserted 4th sentence of para #34 of CX/FICS 21/25/6 could be incorporated by para #29 of “Step 5: ASSESSMENT PROCESS” in its meaning, as the 4th sentence of para #34 may be addressed by the phrase “an effective communication mechanism between both countries, for providing feedback” within the framework of “Step 5: ASSESSMENT PROCESS”. R.O.K. regards that those elements mentioned in the 4th sentence of para #34, such as timeframe, plan, etc., of CX/FICS 21/25/6 could be coordinated by both countries’ communication and cooperation. - In this regard, R.O.K. proposes to delete the 4th sentence of para #34 of CX/FICS 21/25/6 in the Appendix #1 of CX/FICS/21/25/6, and revise as our proposal. 	<p>Republic of Korea</p>

<p>34 The decision process should be transparent. 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 not equivalent, the exporting country should have the opportunity to provide additional information for consideration by the importing country prior to the finalization of the decision. In the case where the exporting country NFCS or the relevant part is assessed as not equivalent the two countries may, if they wish, agree a plan and timeframe for the exporting country to resolve the identified deficiency. Subsequent additional information should be reviewed by the importing country without requiring all aspects of the assessment process to be repeated. The importing country should document the final assessment conclusions and the rationale for them.</p> <p>In the case of an initial finding that the exporting country's NFCS or the relevant part is not equivalent, the importing country shall provide detailed information and justification to the exporting country and 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>	Iran
<p>35 The decision process should:</p> <p>Canada recommends deleting paragraph 35. All three bullet points repeat information found in Section 4, Principle d; and in Section 5.3, points 21 and 25.</p>	Canada
<p>34 The decision process should be transparent. 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 not equivalent, the exporting country should have the opportunity to provide additional information for consideration by the importing country prior to the finalization of the decision. In the case where the exporting country NFCS or the relevant part is assessed as not equivalent the two countries may, if they wish, agree a plan and timeframe for the exporting country to resolve the identified deficiency <u>difference</u>. Subsequent additional information should be reviewed by the importing country without requiring all aspects of the assessment process to be repeated. The importing country should document the final assessment conclusions and the rationale for them</p> <p>If the exporting country's NFCS is found not be equivalent to that of the importing country, regardless of whether or not there may be deficiencies in the NFCS to meet the exporting country's own objectives.</p>	Mexico
<p>35 be conducted in a timely manner; and</p> <p>Canada recommends deleting paragraph 35. All three bullet points repeat information found in Section 4, Principle d; and in Section 5.3, points 21 and 25.</p>	Canada
<p>35 focus on whether the exporting country's NFCS meets the decision criteria; and</p> <p>Canada recommends deleting paragraph 35. All three bullet points repeat information found in Section 4, Principle d; and in Section 5.3, points 21 and 25.</p>	Canada
<p>35 not introduce an objective, outcome, standard or process in excess of what is being applied within the importing country without justification.</p> <p>Canada recommends deleting paragraph 35. All three bullet points repeat information found in Section 4, Principle d; and in Section 5.3, points 21 and 25.</p>	Canada
5.7. STEP 7: FORMALIZATION AND MAINTENANCE OF THE RECOGNITION	
<p>36 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 port point <u>point of entry or point of control</u> requirements). Such documentation may be done for example, through an exchange of letters or through the negotiation of a more comprehensive equivalence agreement or arrangement²⁸.</p>	European Union
<p>36 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 port of entry requirements). Such documentation may be done for example, through an exchange of letters or through the negotiation of a more comprehensive equivalence agreement or arrangement²⁸.</p>	European Union

<p>The EUMS propose the following amendment to the first sentence of paragraph 36 of Appendix 1 of document CX/FICS 21/25/6:</p> <p>“... (e.g. recognition of lists of establishments; or modification to point of entry or point of control requirements).”</p>	
<p>39 Figure 1:</p> <p>Making reference to the revised text in Para 34 allowing two countries to agree a plan and timeframe to resolve the identified deficiency, in case where the exporting country NFCS is assessed as not equivalent. Therefore, we propose that this concept should be also reflected in Figure 1.</p>	Thailand