



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

Twenty-Fifth Session

Virtual, 31 May – 8 June 2021

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

REPORT ON THE INFORMAL VIRTUAL WORKING GROUP MEETING

Prepared by New Zealand, Chile and United States of America

The working group met virtually on 23 March 2021 from 20:00 to 23:00 CET working in English and Spanish. The meeting was attended by delegations from 65 Codex Members and observers, the Chairperson of CCFICS, and the Codex CCFICS Secretariate.

The objectives of the meeting were to:

- provide an opportunity for ongoing discussions and any necessary clarifications on the *Proposed draft guidelines on recognition and maintenance of equivalence of national food control systems (CX/FICS 21/24/6)* prior to the closing date for submission of comments (as requested via Circular Letter CL 2021/17/OCS-FICS); and
- facilitate an appropriate level of comfort to help the plenary progress the draft guidance at CCFICS25.

The programme for the meeting was presented in four parts:

Part 1 Welcome and Introductions.

Part 2 Background.

Part 3 Discussion on the current draft of the guidelines and presentation and discussion on examples of some possible decision criteria.

Part 4 Closing remarks and a brief update on the linkage between this work and the subsequent new work on the consolidation of Codex Guidelines related to Equivalence and the proposed next steps.

A summary report of the meeting is provided as **Appendix I** and an overview of the presentation and discussion on examples of decision criteria is attached at **Appendix II**.

APPENDIX I

SUMMARY REPORT OF VIRTUAL WORKING GROUP MEETING ON GUIDELINES RELATING TO EQUIVALENCE

Part 1: CCFICS Chairperson Ms Fran Freeman, opened the meeting and provided a short of history of work and why it came about and outlined the expectations for the meeting. She noted:

- The need for work in this area was initially identified at CCFICS21 in 2014 after consideration of a discussion paper (prepared by the USA) on emerging issues and future directions for the work of CCFICS. In 2016, CCFICS22 then considered a discussion paper and draft project document and decided to set up an Working Group (Chaired by New Zealand with USA and Chile as co-chairs) and asked this WG to specifically consider broadening the scope to include the full mandate of Codex. In 2017, CCFICS23 endorsed the project document's proposal for new work to be started, to develop practical guidance on processes and procedures that could assist countries in approaching systems equivalence considerations covering the full scope of Codex's mandate. This was subsequently approved by CAC40 in July 2017.
- Since that time, New Zealand, with the support of Chile and the US, has progressed this work via several rounds of electronic working group comments, two physical working group meetings and plenary discussion and formal country comments at CCFICS24 (2018). The CCFICS Chairperson stated that her expectation of the pre-meeting was to ensure the membership was set up to achieve a positive outcome at CCFICS25 (2021). She noted that she did not want to open up discussion on topics that have been settled, and that the meeting sought to provide any necessary clarification and identify if there are any remaining areas of possible concern with a view to coming up with a way forward to help this work progress to completion.

Part 2: The CCFICS Chairperson handed over to the WG Chairperson, Dr Bill Jolly, who provided further background as follows:

- The key focus in proposing and developing guidance on the equivalence of National Food Control Systems (NFCS) is a desire to facilitate trade, by providing a process that could help importing and exporting countries make progress on removing unnecessary duplicative restrictions affecting trade between them. Importantly, saving competent authority resources on both sides, while continuing to ensure protection of the health of consumers and fair practices in the food trade. This focus was clearly articulated in the discussion paper and the project document.
- The terms of reference as previously endorsed by CCFICS and then approved by CAC were clear. The proposed guidance was intended to help members work through actual trade issues, such as issues around establishment listings and port of entry inspection rates, noting the working group was specifically asked to ensure it covered the full spectrum of the Codex mandate. The intent was for guidance that build upon the broader understandings resulting from the Principles and Guidelines on National Food Control Systems and the Principles and Guidelines on the Exchange of Information to Support the Trade in Food, both of which explicitly covered the full mandate of Codex. 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.
- An overview was given of what has happened since CCFICS24 (the last time the full committee discussed the draft) and the process and changes to the draft guidelines following the submission of formal comments on the 2020 CCFICS agenda paper and the postponement of the CCFICS 2020 meeting. In doing so the WG Chairperson highlighted the information set out in the updated CCFICS25 agenda paper (CX/FICS 21/24/6) particularly paragraphs 9 to 20. The participants were reminded that the focus of the pre-meeting was not to undertake any formal redrafting, as the draft document had already been circulated to members via circular letter for them to submit their formal country

comments. Notwithstanding this limitation discussion on any remaining areas that participants believe could be improved is welcome.

Part 3: Participants were invited to provide comment or ask questions for any necessary clarification as the WG Chairperson gave a section-by-section overview of the draft guidelines, presented in CX/FICS 21/24/6, (including a brief history and highlighting of any significant changes).

Section 1 – Introduction and Preamble

- One delegation indicated a concern. In their view, the draft intermingled the concept of equivalence as it related to the WTO SPS and TBT agreements which are fundamentally different and need to be addressed and discussed separately throughout the text where appropriate. Otherwise the guideline could be inconsistent with those agreements. They indicated they would propose additional text for the Introduction in their formal country comments that could address their concern.
 - In response the WG Chairperson recalled that the original joint discussion paper had specifically considered this aspect and had identified that the NFCS guidance had provided a mechanism to appropriately link the two. He noted that most NFCSs and many real-life importing country requirements, that may on occasion be considered by an exporting country to be unnecessarily constraining trade, involve NFCS objectives which include both WTO SPS and TBT aspects. He elaborated using the example of system equivalence requests associated with intensive port of entry inspection regimes. In these cases, the importing country's NFCS objectives often involve everything from ensuring appropriate labelling, through to ensuring compliance with standards relating to food safety hazards, qualitative defects, and composition. Hence, there was a need for some overarching terminology and approach that can be used when considering requirements classified within the different WTO disciplines.
 - The WG Chairperson also reiterated that, these draft guidelines were not meant to be a legal interpretation of specific Articles of the WTO. Rather the intent was to provide practical guidance on how countries could work through real life trade issues involving how one country's NFCS, or relevant part, meet the objectives of the other country's NFCS (including any specified measurable outcomes).
- Another delegation was concerned that the text of the Introduction section could have unintended consequences. They indicated they would provide some suggestions to make the vision for the guideline clearer.
- A third delegation stated they had not identified any discrepancies with the WTO Agreements and given the considerable amount of work that has been done believed the draft to be generally in good shape. They were however open to considering suggestions for changes to address others concerns.

Section 2 – Purpose / Scope

- No questions or comments.

Section 3 – Definitions

- The WG Chairperson noted that there had been considerable discussion on the definitions throughout the drafting process. In general, the definitions were drawn from or based on existing CCFICS definitions.
- Equivalence of NFCS – is the long standing CCFICS definition with 'food inspection and certification systems' replaced with 'NFCS' in recognition that FICS are a subpart of a NFCS.
- NFCS Objectives – recognises that no one has been able to describe the level of protection afforded by their entire NFCS. So for a comparison something at a higher level of understanding is needed, recognising also that drilling down to specific objectives and outcomes of objectives could then flow down into the decision criteria if necessary and relevant.

- Outcomes – drawn from an existing CCFICS text. The definitions relating to ‘objectives’ and ‘outcomes’ are written to ensure there was a clear hierarchy – recognising outcomes are often used in the context of procedures as opposed to what is to be achieved as a whole. Having these two definitions is intended to help ensure clarity of the hierarchy and the interpretation of this guideline.
- No comments or questions were raised.

Section 4 – Principles

- The WG Chairperson noted these are written as statements that allow you to examine if you are achieving the intent. As currently drafted, they have been drawn from or based on existing CCFICS principles and have not changed too much through the drafting process.
- No comments or questions were raised.

Section 5 – Process steps

- The WG Chairperson noted the steps were reordered following CCFICS24 and are presented in a logical flow starting with the initial conversation about what is the trade requirement of potential concern and what may be the most practical way of progressing a potential solution. Whilst the steps are presented in a logical flow, this does not preclude a different order or missing one of the steps to better suit the circumstance for the parties involved.
- No comments or questions were raised.

Section 5.1 – Step 1: Initial Discussion, Scope and Decision to Commence

- The WG Chairperson noted there has been a lot of discussion on this step. A key consideration being to ensure there is sufficient guidance so that parties do not automatically start an equivalence consideration of NFCS for every possible trade issue and that this process is used to resolve only those issues where there are actual trade restrictions or duplication of controls.
- The WG Chairperson identified that a new first bullet was included in paragraph 10 to recognise that while many countries promulgate generic import health standards and notify the WTO, ultimately trade is a bilateral process. Therefore, there needs to be a discussion specific to the conditions of trade between the parties and the particular circumstances that exist in each country. Further, part of this initial step is to also consider other mechanisms that could be used to resolve the issue and, if equivalence is identified as the best option, to allow clear consideration of what the scope will be.
- Two delegations identified potential edits to the 5th bullet of paragraph 10 (one was correcting an error which was acknowledged) the other was to add ‘Codex and OIE’ as examples of ‘relevant international standards’.
- The WG Chairperson recalled that the original project document had specifically stated that the needs of developing economies should be considered, and this is now reflected in paragraph 16.

Section 5.2 – Step 2: Description of the importing country’s NFCS and associated objectives

- The WG Chairperson noted that the description only needs to relate to the trade constraining issue the two countries were trying to resolve. This means that it is not necessary to describe the whole NFCS but only those elements that are relevant to the issue. The examples given in paragraph 17 are therefore at a high level drawn from other existing Codex guidance.
- The WG Chairperson also recalled that the need for the current paragraph 19 had been a result of developing economies clearly stating they did not want to be a ‘dumping ground’ for inferior products if their own NFCS was not highly developed. Therefore, being able to

reference an international standard as their import requirement would be a way of providing a reasonable level of protection against this.

- No comments or questions were raised.

Section 5.3 – Step 3: The decision criteria for comparison.

- The WG Chairperson highlighted that decision criteria could be either qualitative or quantitative, noting that as you move up to a NFCS level these will more often be qualitative perhaps with some quantitative sub-parts.
- One delegation suggested that amending the title of this step to '*Documentation of Decision Criteria for Comparison*' could clarify what this step means.
- The WG Chairperson noted that paragraph 24 was new and was an attempt to address the issue of the relationship to the SPS Agreement. It could potentially be further improved if there were suggestions to do this. One delegation advised their intention to provide edits via the Circular Letter comment process.

Section 5.4 – Step 4: Description of Exporting Countries NFCS or Relevant Part

- The WG Chairperson noted that this section has not had significant changes and emphasised that the description should be limited to the scope of the issues under consideration.
- One delegation suggested that examples of decision criteria (particularly related to TBT matters) could be useful for both Sections 5.3 and 5.4, noting that a presentation and discussion on examples would be held later in the session.
- The WG Chairperson observed that for many specific trade issue examples, there would likely be a mix of SPS and TBT related matters (noting that the TBT Agreement relates to protecting human health as well as conformity assessment), which is why the current text is kept broad.
- The WG Chairperson also noted that equivalence is about 'how' an objective was achieved not 'what' needed to be achieved, and there would be no global trade if every country wanted to assess every procedure, in every situation associated with every product.
- Some delegations identified potential edits for the Spanish text (but not affecting the English text) which were acknowledged.

Section 5.5 – Step 5: Assessment process

- The WG Chairperson noted that this section has not had significant change.
- Some delegations identified some potential edits (including the addition of commas and the replacement of a specific word) to improve the clarity and flow for paragraphs 29, 31, and 33 which were acknowledged.

Section 5.6 – Step 6: Decision process

- There was a discussion on replacing the words 'identified deficiency' in paragraph 34 and replacing these with 'identified non-equivalence', which several delegations supported.
- Other editorial suggestions for Section 5.5 and Section 5.6 were also made and the WG Chairperson requested that these be followed up via the Circular Letter comment process.

Section 5.7 – Step 7: Formalization and maintenance of the recognition

- No comments or questions were raised.

Figure 1:

- One delegation suggested that Figure 1 should explicitly reflect paragraph 34 – that there could be a discussion between the parties to resolve any identified non-equivalence.

Discussion and presentation on Decision Criteria

- The WG Chairperson noted that a discussion with examples of Decision Criteria had been planned for last year's postponed physical working group meeting. There being a level of agreement that this may be useful to help members gain a more common understanding of the concept.
- The WG Chairperson gave a presentation on examples of decision criteria, noting:
 - The examples used were just illustrative and were not meant to represent the only NFCS Objectives or related Decision Criteria that a country could have associated with the trade example given, or other trade issues.
 - The examples were possible high-level decision criteria that have been derived, for ease of reference, from examples of NFCS objectives contained within another Codex Standard.
 - Importing countries are responsible for identifying and justifying what NFCS objectives they may consider appropriate to use as the basis for any specific bilateral systems equivalence assessment.
 - Depending on the nature of the trade requirement being discussed, the NFCS Objectives identified may solely relate to the control of risks associated with hazards (as may be covered by the WTO SPS Agreement) or other matters required for the protection of the health of consumers and ensuring fair practices in the food trade (as may be covered by the WTO TBT Agreement), or both.
- Delegations asked that the decision criteria presentation slides be included with this Summary Report to facilitate understanding.
- An annotated copy of the decision criteria presentation is at Attachment 1.

Part 4 – Closing remarks

The WG Chairperson gave a brief update on the separate work, operating to different timelines, on the Consolidation of all Codex guidance relating to equivalence.

- Following CCFICS 24, and the confirmation of the project document by CAC42 the WG commenced work electronically. This analysis and proposals were presented in an Agenda Paper for the original CCFICS25 meeting and comments were requested via circular letter.
- The comments received on the 2020 agenda paper have been incorporated into the revised 2021 Agenda paper and the next steps for the work identified.
- The 2021 Agenda paper invites the Committee to endorse the proposals set out in the paper and Appendices and to confirm the continuation of the eWG to progress the work in line with the sequence of steps set out.
- This work will be discussed by CCFICS25 as Agenda item 7 and comments on the agenda paper have been requested via a separate circular letter.

The Chairperson of CCFICS and the WG Chairperson thanked everyone for their participation and confirmed that a summary report would be made available.

APPENDIX II**Presentation on examples of decision criteria****SLIDE 1**

Examples of some decision criteria and their use in to help assess one a common trade issue example where the use of a system equivalence assessment may be appropriate:

Notes:

- This document is not intended to identify all decision criteria that may be related to the particular trade issue used as an example.
- Rather it provides some illustrative examples of some possible high-level decision criteria that have been derived from examples of NFCS objectives contained within another Codex Standard.
- Importing countries are of course responsible for identifying and justifying what NFCS objectives that they may consider appropriate to use as the basis for any specific bilateral systems equivalence assessment.
- Depending on the nature of the trade requirement being discussed, the NFCS Objectives identified may solely relate to the control of risks associated with hazards (as may be covered by the WTO SPS Agreement) or other matters required for the protection of the health of consumers and ensuring fair practices in the food trade (as may be covered by the WTO TBT Agreement), or both.

SLIDE 2

Example of an importing country requirement that an exporting country may consider is unnecessarily constraining trade where a system equivalence consideration may be helpful:

- The importing country requires that all foreign dairy processing establishments must be individually assessed and approved by them prior to being listed as eligible to export to their country.
- The exporting country is of the opinion that the relevant parts of its own NFCS should already ensure that the food safety and suitability objectives as required and achieved by the importing country's establishment assessment and approval process are already met by their own NFCS.

SLIDE 3

As part of the process outlined in the guidance:

- The exporting country asks the importing country to describe the NFCS objectives and any related outcomes that it is trying to achieve through the import requirement:
- The importing country describes the relevant NFCS Objectives (illustrative example only):
 - Example predominantly based from GENERAL PRINCIPLES OF FOOD HYGIENE: CXC 1-1969 (as last amended 2020):

List of Relevant Core Elements of NFCS potentially relevant to the request (based on CXC 1-1969):

1. ESTABLISHMENT - DESIGN OF FACILITIES AND EQUIPMENT
2. TRAINING AND COMPETENCE
3. ESTABLISHMENT MAINTENANCE, CLEANING AND DISINFECTION, AND PEST CONTROL
4. PERSONAL HYGIENE
5. CONTROL OF OPERATIONS
6. PRODUCT INFORMATION AND CONSUMER AWARENESS

SLIDE 4**REMINDER:**

Decision Criteria: those factors used to determine whether the exporting country's NFCS or relevant part meet the objectives of the importing country's NFCS or the relevant part for the products under consideration.

Potential importing country overarching Question:

Does the exporting country's NFCS have appropriate documented standards, approval and verification processes that ensure traded dairy products are processed in establishments that are constructed, maintained and operated in a manner that ensures the dairy products will consistently meet the end-product safety, suitability and eligibility standards of the importing country?

SLIDE 5

The below examples of NFCS objectives have been extracted from GENERAL PRINCIPLES OF FOOD HYGIENE: CXC 1-1969 with some suggested decision criteria developed.

This is just some selected examples to give a flavour of what decision criteria for some specified NFCS Objectives could look like.

It is noted that:

- The process of assessing and approving establishments often covers NFCS objectives which span both the protection of the health of consumers and ensuring fair practices in the food trade.
- NFCS objectives relating to the protection of the health of consumers can be within the scope of the WTO SPS or TBT Agreements or both.
- NFCS objectives relating to suitability issues or ensuring fair practices in the food trade tend to be more within the scope of the WTO TBT Agreement.

SLIDE 6

[NFCS] OBJECTIVE 1: ESTABLISHMENT - DESIGN OF FACILITIES AND EQUIPMENT

"Depending on the nature of the operations and the associated risks, [all domestic and foreign] premises, equipment and facilities should be located, designed and constructed to ensure that:

- contamination is minimized; and design and layout permit appropriate maintenance, cleaning and disinfection and minimize airborne contamination;
- surfaces and materials, in particular those in contact with food, are non-toxic for their intended use;
- where appropriate, suitable facilities are available for temperature, humidity and other controls;
- there is effective protection against pest access and harbourage; and
- there are sufficient and appropriate washroom facilities for personnel."

How this contributes to the overarching goals of the NFCS (safety and suitability):

Hygienic design of establishments and equipment is important to provide an assurance that food will not come into direct contact with pathogenic contaminants or extraneous matter at levels that could render the product unsafe or unsuitable for sale [as defined by end-product standards].

DECISION CRITERIA FOR OBJECTIVE 1:

The exporting country's NFCS has a documented standard, approval and verification process that ensures food in trade is processed in establishments that are constructed, maintained,

and operated in a manner that minimises potential sources of contamination and ensures appropriate temperature controls.

SLIDE 7

NFCS OBJECTIVE 2: TRAINING AND COMPETENCE

“All those engaged in food operations who come directly or indirectly into contact with food should have sufficient understanding of food hygiene to ensure they have demonstrable competence appropriate to the operations that they are to perform.”

How this contributes to the overarching goals of the NFCS (safety and suitability):

“Training is fundamentally important to any food hygiene system and the competence of personnel. Adequate hygiene training, and/or instruction and supervision of all personnel involved in food-related activities contribute to ensuring the safety of food and its suitability for consumption.”

DECISION CRITERIA FOR OBJECTIVE 2:

The exporting country's NFCS requires and verifies that food business operators (FBO) have appropriate training and experience in food safety relative to the tasks they perform.

SLIDE 8

NFCS OBJECTIVE 3: ESTABLISHMENT MAINTENANCE, CLEANING AND DISINFECTION, AND PEST CONTROL

To establish effective systems that:

- ensure appropriate establishment maintenance;
- ensure cleanliness and, when necessary, adequate disinfection;
- ensure pest control;
- ensure waste management; and
- monitor effectiveness of cleaning and disinfection, pest control and waste management procedures.

How this contributes to the overarching goals of the NFCS (safety and suitability):

Ensures confidence in the continuing effective control of food contaminants, pests, and other agents likely to compromise food safety and suitability.

DECISION CRITERIA FOR OBJECTIVE 3:

The exporting country's NFCS requires and verifies that FBOs maintain documented quality systems with appropriate records that demonstrate effective establishment maintenance, cleaning and pest control that assure these factors will not negatively impact the safety and suitability of the products that they process.

SLIDE 9

NFCS OBJECTIVE 4: PERSONAL HYGIENE

To ensure that those who come directly or indirectly into contact with food:

- maintain appropriate personal health;
- maintain an appropriate degree of personal cleanliness; and
- behave and operate in an appropriate manner.

How this contributes to the overarching goals of the NFCS (safety and suitability):

Personnel who do not maintain an appropriate degree of personal cleanliness, who have certain illnesses or conditions or who behave inappropriately, can contaminate food and transmit illness to consumers through food.

DECISION CRITERIA FOR OBJECTIVE 4:

The exporting country's NFCS requires and verifies that FBOs maintain documented quality systems with appropriate records that ensure the health of workers will not negatively impact product safety and suitability.

SLIDE 10**NFCS OBJECTIVE 5: CONTROL OF OPERATIONS**

To produce food that is safe and suitable for human consumption by:

- formulating design requirements with respect to raw materials and other ingredients, composition/formulation, production, processing, distribution, and consumer use to be met as appropriate to the food business;
- designing, implementing, monitoring and reviewing effective control systems as appropriate to the food business.

How this contributes to the overarching goals of the NFCS (safety and suitability):

If operations are not controlled appropriately, food may become unsafe or unsuitable for the purpose for which it is intended or for which claims are made.

DECISION CRITERIA FOR OBJECTIVE 5:

The exporting country's NFCS requires and verifies that requires FBOs maintain documented quality systems with appropriate records that ensures the composition and labelling of food is both accurate and compliant, and that there are appropriate controls to ensure no ineligible ingredients or products are substituted.