CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



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Agenda Item 5
CRD2

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Twenty-Sixth Session

REPORT OF WORKING GROUP ON CONSOLIDATION OF CODEX GUIDANCE RELATED TO EQUIVALENCE

(Prepared by Co-Chairs of EWG on Equivalence New Zealand, United States of America and Kenya)

A working group meeting was held on 30 April 2023 in Hobart Australia. The meeting was fully hybrid with participants present in Hobart and others attending via Zoom, and was conducted in English, French, Spanish. New Zealand, as lead for the working group chaired the meeting, the USA and Kenya, as co-chairs were also present. The meeting was informed that a CRD would be prepared reflecting the discussions of the meeting and because of this it would be proposed to move the discussion of this agenda item in the plenary to Wednesday in order for all delegates to be able to read the CRD and potentially allow the tracked changed version to be used by the plenary if agreed.

The objectives of the meeting of the working group were to:

- Consider the comments received in response to CL 2023/10/OCS-FICS, and in particular going paragraph by paragraph for the scope/purpose, preamble and principles sections of CX/FICS 23/26/5, in order to facilitate discussion under Agenda Item 5 of the Plenary,
- Help to inform the future development of the consolidated guidelines

Report

Following a welcome to all participants attending both physically and online, the Chairperson noted that the co-chairs were under no illusion over the size of the task given to the working group. Accordingly, the working group had been approaching the task in stages. The first stage had been to get general agreement on the broad design and likely headings of the sections, the scope/purpose, and the principles. The preamble also closely reflected the progress made in developing the preamble of the equivalence of NFCS – noting that the scope of this consolidation was slightly wider. Accordingly, after general comments the working group focussed on going paragraph by paragraph on the scope section first, with an intention, if time allowed, to just more generally summarise some of the comments received on the other sections. A summary of the general comments discussed are briefly provided below.

The delegations noted the importance of the consolidation work for CCFICS recognising it is bringing together the two existing equivalence specific texts (CXG 34-1999 and CXG 53-2003) and importantly the proposed Guidelines on the Equivalence of NFCS text, that is to be considered by CCFICS26 under Agenda item 4. Several delegations also sought clarification on the intended outcome of the consolidation, would it be a single text and replace all other equivalence text, or would it be a new main text with the others potentially in whole or in part as appendices. After some discussion the general view was that a single text would be preferrable, but it was premature to make a final determination in respect of the other text while the process of consolidation and updating was occurring. The importance of finalising the equivalence of NFCS text was also emphasised as a prerequisite to the working group being able to fully undertake this task.

A further point of general comment was the scope of the consolidation as it related to the inclusion of technical measures as well as sanitary measures, and the equivalence of NFCS. Delegations were reminded the scope of the consolidation needed to cover the use of equivalence potentially covering all trade issues associated with countries implementing their NFCS, noting that these spanned the full mandate of Codex. It was noted that while there was no specific guidance on the equivalence of technical measures

these were explicitly recognised as part of the Committees foundational guidance's, and importantly in the Guidelines on NFCS, Guidelines on Equivalence Agreements and the current work on the Equivalence of NFCS.

There was some discussion on the importance of ensuring the working group captured as much of the language and concepts from existing guidance, while also noting that the mandate for this work was to consolidate, rationalise and modernise the Codex guidance on Equivalence. Several members expressed the importance of both ensuring a consistency of terms and harmonising with the modernisation of language as used in the draft guidelines on the Equivalence of NFCS. The chairperson concluded this discussion by noting that while the work on a consolidation will be challenging this was a task that with the good will and support for each other can be achieved.

The working group then proceeded to consider the comments received in response to the circular letter. Detailed paragraph by paragraph suggested changes were proposed for the three sections considered – up until principle f (bis) when the time allocated ran out. As a result of the discussion the following changes were proposed and are presented in Annex 1 for the consideration of CCFICS26.

- Section 1: Preamble the inclusion of more positive statements in paragraphs 1 & 2. The removal of 'unnecessarily restrictive'.
- Section 2: Purpose and Scope has been divided into two section, noting that clarifying this section would help to set the framework for the entire document.
- Section 4: Principles -
- o Principle a added 'relevant' before 'of parts of NFCS'.
- Principle b replace 'take into account' with 'consider'.
- Principle c amend subheading to 'Scope and the request for assessment' and align wording to that in the Agenda item 4 text.
- Principle d incorporate 'timely' into Principle f.
- o Principle e replace the entire text with the wording in the Agenda item 4 text.
- Principle f add 'timely' before 'transparent'.
- Principle f(bis) was placed in square brackets as there was divided opinion if it should be included as a separate principle or be addressed in the main text, in both the response to the circular letter and also those participating in the WG.
- Principle f (bis bis) Opinion was divided on the need for a further principle to balance f(bis). Possible wording to address this was also placed in square brackets.

The working group was not able to complete consideration of the comments received on the remaining principles in Section 4. Due to time constraint the working group did not consider the comments on Definitions (Section 3), or on the remaining sections (5, 6 & 7) of the draft.

Recommendation

It is the recommendation of the Working Group that the Plenary use Annex 1 of this report when considering Section 1, 2, and 4 of CX/FICS 23/26/5.

The committee may also like to consider whether at the end of its deliberations whether these three sections, or any combination of these, could be considered for progression to step 5 so as to allow the working group to focus its time on the rest of the sections of this very large task, noting that such an action would still allow further changes to be made to these sections in association with the next circular letter requesting formal comments.

Annex I

DRAFT

Please note that the boxed comments are provided only as an explanation to assist drafting and will be removed prior to finalization.

PROPOSED CONSOLIDATED TEXT ON THE:

PRINCIPLES AND GUIDELINES FOR THE RECOGNITION OF THE EQUIVALENCE OF SPECIFIED MEASURES OR THE WHOLE OR A PART OF NATIONAL FOOD CONTROL SYSTEMS

(STEP 3)

SECTION 1: PREAMBLE

Please note that this section will remain under review until the rest of the sections have completed at least one round of comments at step 3.

1. The recognition of equivalence is not generally required for most trade. However, where applied it can provide an effective means for further ensuring the conditions of trade between two countries are the least trade restrictive to ensure the importing country's relevant objectives, and related outcomes or level of protection are achieved. The recognition of equivalence, when it occurs, should result in positive changes to the conditions of trade, and facilitate the more efficient and effective use of resources in the importing and exporting countries.

2. Requests for the recognition of equivalence can cover those conditions of trade that relate to both the protection of the health of consumers and fair practices in the food trade and can cover a specified measure, or the whole or a part of an exporting country's National Food Control System (NFCS). Requests for the recognition of equivalence normally relate to changes that would improve conditions of trade or proposed trade. just those conditions of trade an exporting country considers are unnecessarily restricting their existing or proposed trade.

3. The recognition of equivalence may facilitate trade through reducing the need for exporting countries to implement unnecessary additional controls over and above those already effectively being delivered by its NFCS and may also result in resource savings for importing countries. The recognition of equivalence may lead to efficiencies in approval, audit, inspection, and certification processes especially as these may relate to food control systems, establishments, products, and processes.

4. These guidelines bring together<u>consolidate and update [and replace]</u> the guidance on equivalence set out in the Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CXG 34-1999), Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CXG 53-2003) and Draft Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems (CX/FICS 23/26/4) [reference to be updated when finalized].

5. These guidelines are intended to also be read in conjunction with other existing Codex text including <u>Principles and Guidelines for National Food Control Systems (CXG 82-2013)</u> the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CXG 26-1997), the *Guidelines for Food Import Control Systems* (CXG 47-2003), and the *Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food* (CXG 89-2016).

SECTION 2: PURPOSE/SCOPE (of guideline)

6. ____This consolidated text provides practical guidance, information and recommendations for importing and exporting countries on the process that may be applied for the <u>assessment</u>, <u>recognition and</u> <u>maintenance of assessment of requests for the recognition of the equivalence of a specified measure, or the whole or part of a NFCS, as well as what should be covered in any resulting agreement<u>and associated documentation.</u></u>

SECTION 3: SCOPE (of guideline)

6.7. The guidance covers requests for the assessment, recognition and maintenance of equivalence that relate to either the protection of the health of consumers or ensuring fair practices in the food trade, or both, as relevant to the trade in foods and the conditions of trade covered by the request.

SECTION 4: PRINCIPLES

7.8. The consideration, assessment, recognition, and maintenance of equivalence should be based on the following principles.

Equivalence

a. Countries should recognize that different measures, NFCS, or <u>relevant</u> parts of NFCS although designed and structured differently, may achieve the same objectives, and can therefore be recognized as equivalent.

Experience, Knowledge and Confidence

b. Importing countries should take into account<u>consider</u> relevant experience, knowledge and confidence in the exporting country's NFCS, or relevant part, including appropriate assessments by other countries or international organizations.

Scope of the request and assessment

c. The scope of any request <u>or any and</u>-subsequent assessment should focus on those <u>products and</u> conditions <u>affecting of trade where the exporting country considers the specific measure, its NFCS, or</u> relevant part of NFCS already achieves the same objectives as achieved by the importing country to be unnecessarily affecting trade in the specified products.

Timeliness

d. Requests for recognition of equivalence should be made in writing by the exporting country and should be addressed in a timely manner.

Alignment with International Standards

e. <u>The use of or reference to Codex standards, guidelines and/or codes of practice, or other relevant</u> international standards by importing and exporting countries can facilitate the consideration, assessment and recognition of the equivalence of a specific measure, NFCS, or the relevant part. Recognition of equivalence may be facilitated by the use of Codex or other relevant international standards, recommendations and guidelines by both importing and exporting countries.

Transparency and co-operation

f. Importing and exporting countries should cooperate in working through the process in a <u>timely</u>, transparent, evidence-based and outcome-focused manner.

Demonstration of Equivalence

[f (bis) The obligation to objectively demonstrate equivalence rests with the exporting country.]

[f (bis bis) Considering the criteria defined in Section 5) Initial Discussions, the importing party should ensure their measure is only applied to the extent necessary to achieve their level of protection relative to the bilateral risks.]

Question to CCFICS26: The Committee is asked to provide a view on:

i) the appropriateness of f(bis) as a separate principle or whether it is better stated in the main text as a component of the assessment process; and

ii) is there also a need for a balancing statement / principle re the importing party's obligation to ensure their measure is only applied to the extent necessary to achieve their level of protection relative to the bilateral risks?

Documentation and maintenance

g. Importing and exporting countries should document in an agreement any recognition reached, including specifying the food products and measures covered or excluded, and how the recognition of equivalence will be implemented and maintained for the trade in products between the countries.

Technical assistance / Regulatory co-operation

h. Importing countries should, upon request, consider providing technical assistance to an exporting developing / less developed country, to facilitate the assessment and recognition of equivalence.

SECTION 5: INITIAL DISCUSSIONS

The section provides guidance on how countries should:

- Review the nature and relevance of any potentially trade constraining requirements (e.g. sanitary versus technical matters or a combination) and the potential existence of solutions or processes, other than an assessment of equivalence to address these.

- Identify the purpose and review what the scope of a consideration of equivalence could be if this is the most appropriate process to address the matters under discussion.

- Identify and then consider how existing knowledge, experience and confidence, or previously exchanged information or assessment may be used, including to simplify any process.

8.9. It is recommended that the competent authorities of importing and exporting countries have initial discussions prior to formalizing a request for a recognition of equivalence, noting that such a request may be made at any point during these discussions.

9.10. The initial discussions should review the nature and relevance of the conditions of trade that the exporting country considers to be unnecessarily restricting. The discussions should identify whether the measures of concern are sanitary or technical, or a potential combination of both. Both countries should consider whether there may be potential solutions or processes other than an assessment of equivalence to address these concerns.

10.11. The discussions should be used to refine both the scope of any consideration as well as to identify what additional information and / or objective evidence may be required for an assessment process. The discussions should identify how existing knowledge, experience and confidence, or previously exchanged information or assessments may be used, including to simplify any process.

Appropriateness of an equivalence process

11.12. Relevant matters for considerations as to whether an equivalence process may be the most appropriate for the conditions of trade under review may include discussions on:

- the nature and impact of the conditions of trade which the exporting country considers are unnecessarily restrictive;
- the importing country's relevant NFCS objectives, and the related outcomes or level of protection;
- what flexibility the importing country currently has within the existing conditions of trade and what other mechanisms may be available;
- what level and type of objective evidence the exporting country may have that its NFCS or specified measures achieve the importing country's NFCS objectives, and the related outcomes or level of protection; and
- whether a recognition of equivalence will likely further facilitate trade while still ensuring the importing country's relevant NFCS objectives, and the related outcomes or level of protection are met.

Initial scope discussions

12.13. Initial discussions on scope should focus on both the nature of the conditions of trade and why the exporting country considers these are unnecessarily restrictive.

13.14. The conditions of trade may relate to one or more additional controls that the exporting country may be required to implement but may also include any additional processes applied by the importing country. For example, they may relate to specific additional processes and inspections required to be applied by the exporting country prior to export or additional product, process or establishment approval processes, or the frequency or type of import inspection as applied by the importing country.

14.15. The discussions should also identify the range of products for which the exporting country is seeking equivalence. When considering scope, both countries should also discuss the resources likely to be necessary to undertake the process relative to the possible benefits.

Experience Knowledge and Confidence

15.16. The use of or reference to existing experience, knowledge and confidence can reduce the amount of additional information and evidence that needs to be provided by the exporting country. It can also substantially reduce the scope and associated resources and timelines for the importing country assessment and decision-making processes.

16.17. Initial discussions should consider how existing experience, knowledge and confidence may be used to refine the process so as to make it more efficient and less burdensome on both countries.

<u>17.18.</u> Existing experience, knowledge and confidence may take the form of, for example:

- previous assessments, audits, study tours, technical visits or other related interactions;
- the prior history in food trade between the importing and exporting countries;
- the level of compliance of the exporting country's food products with the importing country's requirements;
- the level of cooperation that exists between the NFCS competent authorities of the importing and exporting countries;
- the similarity in design, legislative underpinning and operational principles and practices between the importing and exporting country's NFCS;
- the similarity in design and operational principles and practices of the exporting country's measures or NFCS or relevant part with the relevant Codex standard, guidelines or codes of practice;
- the alignment with relevant ISO guidelines and conformity assessment practices; and/or
- relevant assessments performed by the importing country, by recognized conformity assessment bodies, by other countries, or by international organizations.

18.19. Importing and exporting countries should develop a clear understanding of what role and to what extent existing experience, knowledge and confidence will be used in any consideration or assessment of equivalence. This understanding needs to cover how existing experience, knowledge and confidence will affect:

- the process applied to aspects within the scope of the request;
- the amount, nature and scope of any additional information needing to be supplied; and
- the assessment and decision-making processes.

Outcome of initial discussions

19.20. Where the conclusion of the initial discussions between the exporting and importing countries is that an equivalence process is the appropriate mechanism, the request for consultations with the aim of achieving an agreement on the recognition of equivalence should be submitted in writing.

<u>20.21.</u> Where the initial discussions identify that an equivalence process may not be the most appropriate mechanism, the countries may wish to consider working jointly towards some other mechanisms to help facilitate the trade. Alternative mechanisms may for example include:

- the importing country may decide to provide some further flexibility or options within its specified conditions of trade on how its objectives, and related outcomes or level of protection, may be met;
- the exporting country may decide to adopt additional controls which more closely align with or better achieve the importing country's objectives, and related outcomes or level of protection; or
- the two countries may decide to engage in further cooperation and/or capacity building between them so as to better understand and address the relevant challenges negatively impacting trade between them.

SECTION 6: PROCESS STEPS

The section provides the logical flow of steps that can be followed when carrying out consideration of a request for a recognition of equivalence once a request has been formalized. A brief explanation of each step is included.

The section explores any differences in process relating to whether a request solely relates to parts of the NFCS which are sanitary in nature compared to those which may be solely technical in nature, or where the request covers a combination of both.

The section also explores whether any differences in process are required for the consideration of requests, or components of requests, which relate to the consideration of the effects of discrete procedures, as opposed to whether the wider NFCS or relevant part is delivering the outcome required.

21.22. Where the initial discussions identify that an equivalence process is an appropriate mechanism the

two countries should then agree on a plan for the exporting country to provide the appropriate submission and for the importing country to work through its assessment and decision-making process. This plan may also include anticipated timeframes and if necessary, priorities.

The process steps are:

- Step 1: Scope of request discussed and documented
- Step 2: Importing country describes the basis of its measures
- Step 3: Importing country discusses and documents the decision criteria
- Step 4: Exporting country documents its case for equivalence
- Step 5: Assessment process
- Step 6: Decision process and final decision
- Step 7: Documenting the agreement and implementing the decision

Step 1: Scope of request discussed and documented

<u>22.23.</u> The exporting country requesting consultations with the aim of achieving an agreement on the recognition of equivalence should discuss and document both the range of products and the conditions of trade that the request covers.

23.24. The description of the scope of the request should include for example:

- the specific foods or group of foods, including any types of secondary processing;
- the conditions of trade considered to be unnecessarily restricting trade;
- the reasons the exporting country considers the conditions of trade to be unnecessarily restrictive; and
- a brief description of the exporting country's specified alternative measures, NFCS or relevant part that the exporting country is requesting a consideration of.

24.25. The request for consultations should also ask the importing country to describe in writing the basis for its measures as relevant to the scope of the request.

Step 2: Importing country describes the basis of its measures

<u>25.26.</u> The importing country should discuss and document the relevant NFCS objectives, and related outcomes or level of protection, for the conditions of trade and scope of products covered by the request. This should include as appropriate:

- the scientific or policy basis justifying the necessity for the specified measures under consideration, including risk assessment where appropriate;
- how the specified measures contribute to achieving the NFCS objectives, related outcomes or level of protection¹;
- where appropriate, an expression of the level of control of the hazard in a specific food or group of foods that is achieved by the sanitary measure;
- the identification of the specific risks as relative to the protection of the health of consumers or ensuring fair practices in the food trade that the specified measures are intended to address;
- the justification for the specified measures as relevant to the bilateral circumstances existing between the two countries; and
- any additional information that may assist the exporting country in presenting an objective demonstration of equivalence.

<u>26.27.</u> For further context and to help the exporting country better tailor its case for recognition of equivalence, the importing country should also describe², with appropriate references, how its own measures, NFCS or relevant part, achieves its specified NFCS objectives, and related outcomes or levels or protection.

¹ Including the quantitative or proportionate effect of their contribution.

² ref: CXG 34-1999, Section 7; CXG 82-2013, paragraph 43 and CXG 89-2016 Section 7.

Step 3: Discussing and documenting the decision criteria

27.28. The decision criteria provides the objective basis for comparison. Decision criteria should also further explain the type of evidence the exporting party should provide to demonstrate that its specified measures, NFCS or relevant part, achieves the importing country's relevant NFCS objectives, and related outcomes or level of protection.

28.29. Discussions should occur between the exporting and importing country to assist the development and better understanding of the decision criteria to be applied, which where possible should be agreed between both countries.

<u>29.30.</u> The development of the decision criteria should also involve the assessment of a relative weighting of how important each will be regarded when coming to a final conclusion.

<u>30.31.</u> Following the discussions, the importing country should document the decision criteria to be used to evaluate the request and provide these to the exporting country.

31.32. The decision criteria may be qualitative or quantitative and should include for example:

- the relevant importing country NFCS objectives, and related outcomes or level of protection;
- the type of evidence expected;
- how existing experience, knowledge and confidence are to be used;
- an indication of the amount or level of qualitative or quantitative evidence that is expected; and
- any indicators³ of outcomes required if these are to be used to facilitate comparisons.

<u>32.33.</u> The decision criteria should not apply a standard or level of performance that exceeds the performance the importing country's specified measures, NFCS or relevant part achieves.

Step 4: Exporting country documents its case for equivalence

<u>33.34.</u> The exporting country should submit or make available appropriate information, including relevant references and evidence that demonstrates how its specified measures, NFCS or relevant part, achieves the importing country's relevant NFCS objectives, and related outcomes or level of protection.

34.35. The detailed information provided in the submission should just cover those foods and conditions of trade covered by the request for a recognition of equivalence.

35.36. The submission should as far as possible be tailored to appropriately cover all aspects of the decision criteria and objectively demonstrate that the exporting country's specified measures, NFCS or relevant part, meets those criteria.

36.37. The submission should only cover that additional relevant information and evidence that the importing and exporting countries have agreed is not already covered by existing knowledge, experience, and confidence.

37.38. As far as practical, importing countries should allow flexibility in the format of the information submitted by the exporting country, and where appropriate allow reference to relevant international standards, guidelines, or codes of practice.

38.<u>39.</u> The exporting country may provide qualitative data in summary form or in a full data package, as appropriate to demonstrate performance of the exporting country's NFCS or relevant part.

<u>39.40.</u> Any quantitative supporting data referenced by the exporting country should be appropriately summarized with relevant statistical analyses provided as appropriate. Fuller data packages should be made available on request where appropriate.

40.41. Subject to the nature and scope of any request for recognition, additional information exchanges may be required where a more detailed assessment is considered necessary.

Step 5: Assessment process

41.42. The aim of the assessment process is for the importing country to evaluate the information and evidence submitted by the exporting country so that the summary findings can be considered against the decision criteria.

³ See Appendix B of CXG 91-2017 for some illustrative examples of outcomes and examples of potential indicators for those selected outcomes.

42.43. The importing country and its assessment process should appropriately protect any commercially sensitive or confidential information as supplied by the exporting country.

43.<u>44.</u> Existing experience, knowledge, and confidence can reduce both the potential scope and intensity of the assessment process. Accordingly, appropriate use and reference to existing experience, knowledge, and confidence can reduce the resources required and facilitate a timelier assessment.

44.<u>45.</u> Prior to initiating the assessment process the importing country should assess whether the information submitted or otherwise available is likely to be sufficient to address the matters specified in the decision criteria.

45.46. If the importing country has any concerns with the submission as presented, it should notify the exporting country at the earliest opportunity and should detail the reasons for concern. If possible, the importing country should suggest how the concerns might be addressed.

46.<u>47.</u> The assessment process should then proceed in a timely and cooperative manner, including where any further clarifications or supplementary information is required.

47.48. The assessment process will normally comprise a number of steps which may vary depending on:

- the scope of the request including the range of foods and the conditions of trade for which equivalence is sort;
- the scope of assessment, e.g., whether it is restricted to certain specified measures or potentially requires a wider assessment of the NFCS or relevant part;
- the complexity of alternative controls needing to be assessed;
- whether additional information or clarifications are needed; and / or
- whether an in-country visit will likely be necessary.

48.49. The assessment process should normally start with a desktop review of the documents submitted, taking into account any existing knowledge, experience and confidence.

49.50. The importing country should contact the exporting country where it requires any clarifications or further information during this phase.

50.51. An in-country visit may be justified and required as part of an assessment, for example in situations where:

- existing knowledge, experience and confidence in the exporting country's NFCS is not sufficient to be able to conclude that the information and evidence submitted is sufficient to make a conclusion;
- the complexity of the consideration justifies additional verification as part of the assessment;
- where sufficient confidence may not be able to be ascertained through the analytical data itself, or through conformity assessment processes undertaken in accordance with international accreditation arrangements, or through cross reference to other relevant assessments.

51.52. Where an initial assessment identifies the lack of a specific control considered necessary to achieve the relevant importing country objectives, the importing country should, where appropriate, provide an opportunity to remedy the deficiency.

52.53. At the conclusion of the assessment process the importing country should summarise its assessment findings. The exporting country should be given the opportunity to correct any errors of fact before the importing country finalizes its assessment.

Step 5a: Assessment process – System equivalence

Question to CCFICS26

Do we need something different here?

Step 5b: Assessment process – Equivalence of measures

Question to CCFICS26

Do we need something different here?

Step 6: Decision process and final decision

53.54. The importing country should consider its summarised assessment findings against the documented

decision criteria with a view to producing a decision document.

54.55. The importing country's decision process should be:

- transparent, documented and conducted in a timely manner;
- focus on whether the exporting country's NFCS or the relevant part meets the decision criteria; and
- not introduce an objective, outcome, standard or process in excess of what is being applied within the importing country without justification.

55.56. The decision document should highlight whether and, where relevant, the degree to which, each of the decision criteria have been met along with the relative weighting each has have on the draft final decision. Where the importing country considers one or more of the decision criteria have not been met the importing country should clearly document why it has reached this conclusion.

56.57. The draft decision document should be consulted with the exporting country. The importing country should allow the exporting country to correct any error in fact, and in the case of a draft negative overall decision, the importing country should allow the exporting country to propose a remedy to any identified deficiency. The importing country should take any additional information provided by the exporting country into account when finalizing the decision document.

57.58. Where the importing country recognises the equivalence of the specified measures, NFCS or relevant part, both countries should then discuss how this recognition will affect the conditions of trade between the countries. The recognition of equivalence and how it affects the conditions of trade between the two countries should then be documented in an equivalence agreement / arrangement.

SECTION 7: DOCUMENTING THE AGREEMENT AND IMPLEMENTING THE DECISION

This section had been developed largely based on information contained in CXG 34-1999 and a review of the other text, updated as appropriate. This section contains information on:

- The purpose/use of an equivalence recognition
- The form in which an equivalence recognition could be documented
- The standard content/provisions for a document, included as an Appendix.

58.59. The importing and exporting countries should document any recognition reached. This agreement / arrangement should stipulate both the scope of recognition as well as how it changes the conditions of trade in the affected commodities or products exported to the importing country.

59.60. The agreement / arrangement should document expectations with respect to the future maintenance of the recognition. Such agreements / arrangements typically include expectations with respect to ongoing exchanges of information consistent with the maintenance of an appropriate level of experience, knowledge and confidence.

<u>60.61.</u> The importing and exporting country should also agree on what level of substantive change will necessitate a reassessment in whole or in part of the recognition. Generally, recognition agreements / arrangements continue to apply while any such reassessments are progressed. Such changes may for example include:

- a change to the importing country's level of protection;
- a drop in the level of protection achieved by the exporting country; and / or
- a substantive change to the exporting country's NFCS or relevant part.

61.62. The agreement / arrangement should also address situations where more urgent actions may be justified, such as associated with individual exporter performance failures or new or emerging issues threatening the safety of the foods traded.

62.63. Where appropriate, the agreement / arrangement may also cover expectations with respect to the type and frequency of any ongoing audits. Generally, such audits should be mutually agreed and jointly undertaken. These audits should focus on how the exporting country's NFCS is continuing to ensure the specified measures, NFCS or relevant part, as recognized as equivalent are continuing to be effectively applied.

Note: The Annotated outline previously circulated contained a proposed Section 8: Maintenance of Equivalence Recognitions with the following note:

It is suggested that this is a new section which provides some guidance (for inclusion in the documentation) on how countries can maintain the ongoing currency of equivalence recognitions through:

- The use of regular information exchanges
- Agreeing criteria for when some level of reassessment may be appropriate
- · How recognitions may affect in-country audits etc

Question to CCFICS26

Does the information relating to maintenance of an equivalence recognition currently in Section 7 provide sufficient guidance OR should it be set out in a separate section as initially suggested?

APPENDIX 1:

To be determined:

Question to CCFICS26

Is a flow diagram useful?

If so are additional flow diagrams for different types of equivalence assessment required?

APPENDIX 2:

CONTENT OF AN EQUIVALENCE RECOGNITON DOCUMENT

[Adapted from Appendix A of CXG 34-1999]

Note: the specific language used will depend on whether the equivalence agreement is a cooperative arrangement between the relevant competent authorities or a treaty level agreement between the governments of the two countries.

- (a) *Title:* The name given to the agreement may vary, depending on the preferences and legal requirements of the parties to the agreement/arrangement.
- (b) Parties / Participants: The name of the entities entering into the agreement.
- (c) **Purpose:** A brief statement of the specific purpose of the agreement.
- (d) Scope: Identification of the products and measures that are the subject of the agreement.
- (e) Definitions: Definitions of terms used in the agreement, as needed.
- (f) **Principles:** The collectively agreed principles that will apply to the administration of the agreement.
- (g) Equivalence finding: A statement of the specified measures, NFCS or relevant part that have been found to be equivalent and the effect this has on the conditions of trade for the exporting country for products / measures within the scope of the agreement.
- (h) Administrative Provisions / Intentions: A comprehensive description of each participant's intentions and specific responsibilities with respect to the ongoing implementation and maintenance of the agreement. These may include, for example:
 - i. Liaison channels
 - ii. Information exchange
 - iii. Meeting and consultation provisions
 - iv. Audit and verification
 - v. Notification provisions
 - vi. Reassessment criteria
- (i) **Emergency measures:** The notification, cooperation and cooperation provisions that will apply should one Party / Participant need to adopt an emergency measure.
- (j) **Review, modification and termination:** The methods for the review, modification and termination of the agreement.
- (k) Entry into effect: The date on which the provisions of the agreement enter into effect.
- (I) **Signature panel:** Dates, signatures, names, titles and country / competent authority committing the respect governments or competent authorities to the agreement.