CODEX ALIMENTARIUS COMMISSION





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REP23/FICS

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX ALIMENTARIUS COMMISSION

Forty-sixth Session
27 November - 2 December 2023

REPORT OF THE 26th SESSION OF
THE CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION
SYSTEMS

Hobart Tasmania, Australia, 1 - 5 May 2023

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SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para(s)
Members CCEXEC84 CAC46	Adoption	Proposed draft guidelines on recognition and maintenance of equivalence of National Food Control Systems (NFCS)	N25-2017	5/8	44 and App. II
Members CCEXEC84 CAC46	Adoption	Proposed draft principles and guidelines on the use of remote audit and inspection in regulatory frameworks	N07-2022	5/8	104 and App. III
CAC/CCEXEC Chair CCFICS	Advice and guidance	Write to the CAC Chairperson /CCEXEC Chairperson to seek advice on Geographical Indication (Gis) and the mandate of CCFICS	**	-	71
CCEXEC84 CAC46	Approval	roject document for the on review and update of the Principles for Traceability/Product tracing as a tool ithin a food inspection and certification system (CXG 0-2006)"		1/2/3	117 (a) and App. IV
EWGs	Drafting,	Proposed draft consolidated Codex related to equivalence	Guidelines	2,3 and 4	68 and App. V
CCFICS27 and Member (s)	Discussion, and/or comments	Proposed Draft guidance on the pre control of food fraud	vention and	2/3	93 (b)
		Review and update of the "Pri Traceability/Product tracing as a tool v inspection and certification system (CXG		2/3	117 (b)
United Kingdom CCFICS27	Comments Drafting Discussion	Review and update, Appendix A - the list of emerging global issues		120	
India and Nigeria Drafting CCFICS27 Discussion		Preparation of a discussion paper and project document on guidance on appeals mechanism in the context of rejection of imported food			125
Brazil, Australia, New Zealand, Spain and USA Drafting Discussion		Preparation of a discussion paper and project document on the standardization of sanitary requirements		128	

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LIST OF ABBREVIATIONS

AMR	Antimicrobial resistance
CAC	Codex Alimentarius Commission
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCFICS	Codex Committee on Food Import and Export Inspection and Certification Systems
CL	Circular Letter
CRD	Conference Room Document
CXG	Codex Guidelines
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
FBOs	Food Business Operators
NFCS	National Food Control Systems
OECD	Organisation for Economic Cooperation and Development
SMEs	Small and Medium Enterprises
SPS	Sanitary and Phytosanitary
STDF	Standards and Trade Development Facility
TBT	Technical Barriers to Trade
PWG	Physical Working Group
UNIDO	United Nations Industrial Development Organization
WCO	World Customs Organization
WHO	World Health Organization
WOAH	World Organization for Animal Health
WTO	World Trade Organization

INTRODUCTION

1. The Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) convened its twenty-sixth session on 1-5 May 2023, in hybrid form, at the kind invitation of the Government of Australia, Ms Nicola Hinder PSM, Australian Government chaired CCFICS26. The session was attended by 69 Member Countries, one Member Organization and seven Observers organisations and United Nations agencies. The full list of participants is contained in Appendix I.

OPENING OF THE SESSION

- 2. Auntie Brenda Hodge, Tasmanian Palawa Elder, welcomed delegates in Palawa Kani language - the language of her origin.
- 3. Senator the Hon. Murray Watt, Minister for Agriculture, Fisheries and Forestry, Australia, opened the meeting and welcomed participants to CCFICS26. Minister Watt highlighted the importance of the work of CCFICS in promoting free and open global trade through harmonisation of inspection and certification methods and procedures based on science and evidence to both protect the health of consumers and ensure fair practices in the food trade.
- 4. Mr. Diego Varela, Vice-Chairperson of the Codex Alimentarius Commission (CAC), Ms. Catherine Bessy, Senior Food Safety Officer, Food Systems and Food Safety Division of the Food and Agriculture Organization of the United Nations (FAO), Dr Akio Hasegawa, Technical Officer of the World Health Organization (WHO) and Mr Tom Heilandt, Codex Secretary also addressed the Committee.

Division of competence¹

5. CCFICS26 noted the division of competence between the European Union (EU) and its Member States, according to paragraph 5, Rule II, of the Rules of Procedure of the Codex Alimentarius Commission.

ADOPTION OF THE AGENDA (Agenda item 1)2

- 6. CCFICS26 adopted the Provisional Agenda as the Agenda of the Session with the following additions under Agenda Item 9 (Review and update of Appendix A - the list of emerging global issues):
 - Development of guidance on an appeals mechanism in the context of rejection of imported food proposed by India (CRD4); and
 - Standardization of sanitary requirements proposed by Brazil (CRD15).

MATTERS REFERRED TO CCFICS26 BY THE CODEX ALIMENTARIUS COMMISSION AND ITS SUBSIDIARY BODIES (Agenda item 2)3

7. CCFICS26 noted that all matters referred were for information only.

INFORMATION ON ACTIVITIES OF FAO AND WHO AND OTHER INTERNATIONAL ORGANIZATIONS RELEVANT TO THE WORK OF CCFICS (Agenda item 3)4

- 8. The representatives of FAO and WHO introduced CX/FICS 23/26/3, and emphasized the following points:
 - The constantly expanding use of the FAO/WHO food control system assessment tool as an instrument to evaluate in an evidence-based manner the status of national food control systems (NFCS); and define priorities and allow measurement of progress. The tool is also being used successfully as a foundation for investments by development banks and technical development partners.
 - The adoption by their respective governing bodies of the WHO Global food Safety strategy, as a guide for countries towards the reduction of the burden of food borne diseases, and the FAO Strategic Priorities for Food Safety, as guide for FAO action and support to its Members.
 - The global efforts towards the reduction of antimicrobial resistance (AMR).
 - Recent and ongoing capacity development initiatives regarding food fraud and risk-based inspection.

¹ Division of competence between the European Union and its Member States (CRD1).

² CX/FICS 23/26/1, CRD4 (India); CRD15 (Brazil)

³ CX/FICS 23/26/2

⁴ CX/FICS 23/26/3; CRD13 (Mauritius)

9. The Committee also noted the information provided by the United Nations Industrial Development Organization (UNIDO); the Organisation for Economic Cooperation and Development (OECD); the World Organization for Animal Health (WOAH), the World Trade Organization's (WTO) Committee on Sanitary and Phytosanitary Measures ("SPS Committee"), and the Standards and Trade Development Facility (STDF); the World Customs Organization (WCO) on their activities relevant to its work, as presented in CX/FICS 23/26/3 Add.1 and CX/FICS 23/26/3 Add.2.

Conclusion

10. CCFICS thanked FAO and WHO for their updates, noted the information provided and expressed gratitude for their technical support towards capacity development in the developing countries.

PROPOSED DRAFT GUIDELINES ON RECOGNITION AND MAINTENANCE OF EQUIVALENCE OF NATIONAL FOOD CONTROL SYSTEMS (Agenda item 4)⁵

- 11. The CCFICS Chairperson recalled that the work for the elaboration of the guidelines on recognition and maintenance of equivalence of NFCS had been under consideration since CCFICS21 (2014).
- 12. The Chairperson of the Electronic Working Group (EWG), New Zealand, supported by the Co-chairpersons the United States of America and Kenya, informed the Committee that after extensive work in the EWG, the guidance was well advanced. The terminologies in the guidelines had been carefully developed and agreed over the last few years to address issues and appealed to the Committee not to reopen discussions on them. The recommendation of the EWG to forward the proposed guidelines to CAC46 for adoption at Step 5/8 was noted, as it would allow work, as a priority, on the consolidation of equivalence text to progress.

Discussion

13. CCFICS26 noted the progress made in the EWG and agreed to consider the proposed draft guidelines section by section, made editorial corrections, endorsed the different provisions and took additional decisions on the following:

SECTION 1 - PREAMBLE

- 14. It was proposed to delete the list of examples under paragraph 1, noting that while they may be useful for facilitating understanding during discussion, they should not be retained in the guidelines as the main text was clear.
- 15. The EWG Chair clarified that elements listed in the brackets had arisen as Members had asked for some clarification between a systems approach as opposed to when a focus was on a specific measure. Accordingly, examples had been provided to help all members present and future understand the differences.
- 16. A proposal was put forward, to assist readability, that a footnote be included explaining that the document related to "the whole or a part of the NFCS", instead of repeating the same phrase whenever NFCS was used.
- 17. The EWG Chair explained that with regards to the use of the phrase "the whole or a part of the NFCS" that there were several different constructs of 'NFCS' within the guidance. As such, inserting a footnote as suggested, would inappropriately change the meaning of the relevant text.
- 18. A proposal was made to update paragraph 3 to either include (or list) all references contained in the draft guidelines or, simply indicate that the document references 'other relevant CCFICS texts' while listing, in an annex.
- 19. The EWG Chair clarified that the examples provided (i.e. Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CXG 26-1997); Guidelines for Food Import Control Systems CXG 47-2003)) had been highlighted because they were directly related to the process associated with approval and implementation of import measures. As such, these guidelines were identified as specifically appropriate to the guidance being developed.

Conclusion

20. Based on the explanations provided, CCFICS26 agreed to amend paragraph 1 to replace the words "for example" with "which could include, but is not limited to". The Committee also agreed to several editorial corrections to

⁵ CX/FICS 23/26/4; CX/FICS 23/26/4 Add.1; CRD5 (Burundi, Ghana, Morocco, Republic of Korea, Thailand and Uganda); CRD13 (Mauritius); CRD14 (Ecuador); CRD17 (Nigeria); CRD18 (Honduras) CRD20 (Morocco); CRD 21 (Panama), CRD22 (Senegal); CRD23(India)

paragraph 2 relating to the correct designation of the codex texts i.e. CXG instead of CAC/GL. The remainder of the text remained unchanged.

SECTION 2 - PURPOSE

21. Footnote 2: The Committee agreed to retain footnote 2 noting that it would enhance the readability of paragraph 4, but agreed to the deletion of the word "example".

SECTION 3 - DEFINITIONS

- 22. It was proposed to include a definition for "level of protection" based on the definition in the WTO/SPS Agreement. It was stressed that this term had been cited many times in the text and while it is used with the term "outcome", different meanings were implied.
- 23. The EWG Chair explained that the phrase "objectives, and related outcomes or level of protection" had arisen out of different views by Members wanting to use one of these terms over the other, noting that all three were used in both WTO Agreements. The inclusion of the phrase had been the subject of debate, but consensus around the use of the longer phrase had allowed the guidance to progress. It was noted that the definition of "appropriate level of protection" in the SPS agreement included animal and plant health which were outside the mandate of Codex. It was noted that 'level of protection' addresses both SPS and Technical Barriers to Trade (TBT) requirements. Any further changes at this stage would require a review of the document.
- 24. It was proposed that terms defined in the draft guidance be harmonised with those in the proposed draft guidelines consolidating codex guidance on equivalence.
- 25. The EWG Chair confirmed that through the completion of ongoing work relating to the consolidation of equivalence, that harmonisation of definitions would be considered.
- 26. It was proposed that in the definition of "Decision Criteria", the use of the word "objectively" be clarified, to ensure that it would not limit the use of the guidelines to SPS matters only.
- 27. The EWG Chair clarified that the use of the word "objectively" emphasised the need for evidence-based criteria to be considered.

Conclusion

28. Following the explanations, CCFICS26 agreed to retain the terms as proposed. CCFICS26 noted that it would consider ongoing work relating to the consolidation of texts on equivalence in Agenda item 5, and noted that it would consider the harmonisation of definitions at that point.

SECTION 4 - PRINCIPLES

- 29. It was proposed that a new principle on transparency be included noting that the process for recognition and maintenance of equivalence of NFCS was a complex issue.
- 30. The EWG Chairperson clarified that transparency was already explicitly mentioned in the principle on "Assessment". Further, under the "Principle Final Documentation", was another principle that would ensure transparency, as it required all aspects of recognition to be documented.
- 31. It was mentioned that the term 'international organizations' was vague and that the principles should either be explicit and mention FAO/WHO or use the words 'relevant' international bodies. If not, then the statement "or international organizations" should be deleted from paragraph 6(b).
- 32. The EWG Chairperson agreed that the addition of the word 'relevant' before 'international organizations' provided more flexibility.
- 33. It was proposed that the words 'level of protection' be deleted from paragraph 6(c), or alternatively an explanation should be included on its use.
- 34. The EWG Chairperson clarified that the words 'objectives' and 'level of protection' were used with the term 'outcomes as the guidelines apply both to TBT and SPS measures. The combination of words was a precise formulation ('objectives, and related outcomes or level of protection') used extensively in the text.

Conclusion

35. CCFICS26 amended the "Principle - Experience, Knowledge and Confidence" in paragraph 6(b) by inserting the word "relevant" before international organizations. The principles were endorsed.

SECTION 5 - PROCESS STEPS

36. CCFICS26 noted that there were no significant technical issues and agreed to endorse the proposed seven steps with the following changes:

- In various paragraphs, it was clarified that consultations after initial discussions should be formal;
- In paragraph 9 "matters for initial discussion", it was clarified that importing countries/markets may have rules/legislation regulating the procedures and steps of the equivalence recognition process and these should be understood by both importing and exporting countries during the initial discussions. This was added on the list of relevant matters for initial discussion.
- In footnote 5, the word "example" was deleted and the possibility of using other mechanisms beyond those listed in the footnote was included.
- The title for step 7 both in the chapeau (paragraph 7) and heading of section 5.7 was corrected to read "Final documentation".
- In paragraph 15 the statement reading "Alternative mechanisms to address the matters discussed could be considered" was deleted.
- 37. The EWG Chair explained the meaning of qualitative claims, in paragraph 11 of the guideline, these can include the claims on quality grading of food products or similar quality claims.

Conclusion

38. CCFICS26 endorsed all process steps with the above-mentioned technical and editorial changes.

Figure 1

- 39. There was a proposal to include in Step 1 the 'decision whether to commence'. There was also a proposal to amend 'Step 7' to align the language with the headings used in the 'process steps' (final documentation).
- 40. The EWG Chairperson explained that the decision whether to commence was captured in Step 1.
- 41. CCFICS26 endorsed Figure 1 taking into account the changes to Step 7.

Other issues

- 42. It was agreed that the references cited in the document would be hyperlinked to the original documents, as this would ensure ease of use.
- 43. The Chairperson noted that all technical issues had been resolved and proposed to forward the text to CAC46 for adoption at Steps 5/8.

Final conclusion

44. CCFICS26 agreed to forward the proposed draft *Guidelines on Recognition and Maintenance of Equivalence of NFCS* to CAC46 for adoption at Step 5/8 (**Appendix II**).

PROPOSED DRAFT CONSOLIDATED CODEX GUIDELINES RELATED TO EQUIVALENCE (Agenda item 5)6

- 45. New Zealand, as chair of both the EWG and Physical Working Group (PWG), supported by co-chairs United Stated of America and Kenya, introduced the EWG and PWG report and highlighted that a broad agreement was reached on the potential structure of the consolidated guideline.
- 46. CCFICS26 agreed to the proposal of New Zealand to consider the updated version of the document, as amended by the PWG (CRD2) to facilitate the discussion and further agreed, to review the document paragraph by paragraph.

⁶CX/FICS 23/26/5; CX/FICS 23/26/5 Add.1, CRD2(Report of Physical Working Group), CRD6 (Burundi, Ghana, Morocco, Thailand and Uganda), CRD13(Mauritius), CRD17 (Nigeria), CRD21 (Panama), CRD22 (Senegal), CRD26 (Morocco)

Discussion

SECTION 1: PREAMBLE

47. It was proposed that once consolidation was completed that the existing documents, the referenced documents in paragraph 4, should be revoked.

48. The EWG chair explained that it was premature to decide on the replacement of either part or all of the existing documents. This would be an issue for further discussion depending on the outcome of the consolidation process. However, it was clarified that the goal of the work remained to have a single and unified document that would replace all existing Codex documents on equivalence, and that the words 'and replaced' are kept in square brackets was intended for reference to remind CCFICS during the consolidation work that this issue needed to be considered.

SECTION 2: PURPOSE

Paragraph 6

49. It was proposed and agreed to delete the words "information and recommendations" as the wording "provides practical guidance" was considered sufficient.

Paragraph 7

- 50. It was noted that the term "conditions of trade" had been used in the text several times, and it was proposed that alternative language could be used at various places in the guidelines or the term should be defined.
- 51. The EWG Chair explained that the term "conditions" was used in WTO in association with various aspects of trade, and that while the alternative term was "measure", it was considered too broad. The issue would be reviewed by the EWG.

SECTION: DEFINITIONS

52. It was noted that the definitions had been inadvertently omitted in CRD2. It was agreed not to consider definitions at this session, but to reintegrate them in the current draft for consideration at a later stage.

SECTION 4: PRINCIPLES

- 53. There was a discussion whether sanitary and technical measures need to be specified throughout the document, if there is an understanding that these are considered as part of NFCS and thus would be covered when we qualify an NFCS as 'the whole or part of'. EWG to discuss further on this subject.
- 54. It was stressed that it would be necessary to compare the different guidelines to ensure that the relevant concepts or critical text from existing guidelines are not lost, and to allow Members to identify new concepts/text.
 - Scope of the request and assessment
- 55. Paragraph 8.b: The Committee inserted the words "and related outcomes or level of protection" to provide more clarity.
- 56. There was an objection to a proposal to delete the term "specific measure" as it had been taken from the "Guidelines on the Judgement of Equivalence of Sanitary Measures associated with Food Inspection and Certification Systems" (CXG 53-2003) and it allowed for the differentiation between TBT and SPS measures.
- 57. The EWG Chair clarified that the term "specific measure" was discussed extensively in the EWG. The EWG had agreed that it fell within the mandate of Codex and is intended to cover both the SPS and TBT obligations and therefore it should not be deleted.
 - Transparency and co-operation
- 58. Paragraph 8.f: The Committee agreed to replace "cooperate in working" with "work", added the words "in good faith", and replaced "timely" with "reasonable timeframe" to provide more clarity.
 - Demonstration of Equivalence
- 59. Paragraph 8.f(bis) and f(bis bis) were merged into one and rephrased to enhance clarity, remove duplication and ensure that the obligations of both exporting and importing parties were articulated in one paragraph. The paragraph was kept in square brackets for further consideration by the EWG as it did not fall under the category of principles.

Documentation and maintenance

- 60. Members agreed to editorial corrections and to delete the word "agreement" in 8(g).
- 61. The CCFICS Chair drew the attention of Members and observers to the limited time available to consider the entire document, and proposed that for Sections 6 and 7 that discussions should focus on the questions posed by the EWG, with a view to provide direction on the issues to be taken into account during the next EWG round.

SECTION 6: PROCESS STEPS

- 62. It was proposed that the process steps be separated into those that are applicable to equivalent systems and those for equivalence measures as they were different concepts. It was also mentioned that consolidation of the process steps was needed to enhance clarity and efficiency.
- 63. It was agreed that the EWG would continue discussions on this issue, taking into account that comparison with other documents had already been carried out extensively.
- 64. It was proposed to add an eighth step on maintenance of equivalence.

SECTION 7: DOCUMENTING THE AGREEMENT AND IMPLEMENTING THE DECISION

- 65. There was a discussion on whether the term 'agreement', which has treaty connotations, may be replaced with appropriate language. It was agreed that the EWG would continue discussion on this subject.
- 66. Members agreed to include a section on "maintenance of equivalence recognition", which could also include the extension of an existing equivalence recognition. It was noted that this would be appropriate as part of the update for the consolidation document.
- 67. To reflect progress in the work of the EWG, CCFICS agreed to hold at step 4: Section1 Preamble; Section 2 Scope; Section 3 Purpose; and Section 4 Principles (**Appendix V**). Members were reassured that they would still be able to provide comments on these sections.

Conclusion

- 68. CCFICS26, noting the importance of proceeding with the consolidation and updating of Codex guidance on equivalence, agreed:
 - i. The aim of the work was to produce a single consolidated text ensuring that all critical matters in the existing CCFICS texts were appropriately captured, with revocation of the existing texts to be confirmed at the time the consolidation was finalised by CCFICS.
 - ii. To hold at step 4 the text under "Section 1 Preamble"; "Section 2 Scope", "Section 3 Purpose" and "Section 4 Principles" found in **Appendix V**, noting that these provisions remain open for comment.
 - iii. To return the rest of the draft principles and guidelines as presented in Appendix 1 of CX/FICS 23/26/5 to Step 2 for further drafting, taking into account the discussion at CCFICS26, and written comments received.
 - iv. To establish an EWG open to all Members and Observers, chaired by New Zealand, and co-chaired by the United States of America and Kenya working in English only, with the following terms of reference:
 - to prepare revised draft consolidated Codex guidelines related to equivalence taking into account written comments received and set out in CX/FICS 23/26/5 Add 1, CRDs 6, 13, 17, 21, 22, 26 and the comments made and discussed at CCFICS26, for circulation of the entire text for comments and for consideration at CCFICS27.
 - to submit the report of the EWG at least three months in advance of the next session.
 - v. To keep open the option to hold a physical working group session immediately prior to the next CCFICS session and/or a virtual intersessional meeting, to address any outstanding issues.

PROPOSED DRAFT GUIDELINES ON PREVENTION AND CONTROL OF FOOD FRAUD (Agenda item 6)7

69. The United States of America as Chair of the EWG introduced this item. The CCFICS Chairperson opened the discussion on this item, inviting first comments on footnote 3 related to the consideration of geographical indications (GI) in the scope of the guidelines.

- 70. Different opinions were voiced by Members on this question, including:
 - a. Gls are within the mandate of Codex and CCFICS as it is an issue related to food and food quality requirements, and therefore falls under fair practices in food trade.
 - b. Gls are outside the mandate of Codex and CCFICS because they are related to matters of intellectual property and are not within the scope of these guidelines; further, Gls are not accepted on a global basis.
- 71. The CCFICS Chairperson advised that she would write to the CAC Chairperson/CCEXEC Chairperson to seek advice about the extent to which GIs could be considered within the mandate of CCFICS and would share the correspondence with CCFICS. It was further agreed to continue discussion on the inclusion of GI in the guidelines in the EWG and to maintain all text currently in square brackets for consideration by the EWG.
- 72. CCFICS proceeded to consider the proposed draft guidelines section by section, made editorial corrections and/or changes to bring clarity and took the following decisions on respective sections.

SECTION 1 - PREAMBLE/INTRODUCTION

Paragraph 3

73. It was proposed to replace "good manufacturing practices" with "good hygienic practices", or whether to mention the latter in addition. It was clarified that "good manufacturing practices" included "good hygienic practices" and it was therefore agreed to keep the text unchanged.

Paragraph 7

- 74. The merit of retaining the reference to the list of existing Codex documents addressing food fraud (contained in Annex 1) was discussed and whether it was important that they be included, as is done in other Codex documents.
- 75. The Chair of the EWG explained that in the EWG the majority view had been in favour of deleting Annex 1.
- 76. It was agreed to delete paragraph 7 including the reference to Annex 1, as it was deemed unnecessary in the introductory section, and already covered in paragraph 9 of section 2 (Purpose/Scope). It was also agreed that the inclusion of reference to Annex 1 should be further discussed in the EWG.

Paragraph 8

77. It was agreed: to delete the reference to Annex 2, and the annex itself as the list of international organizations working in food fraud was not exhaustive, and it was sufficient to maintain a general reference to leave it to members to use the work of other organizations.

SECTION 2: PURPOSE/SCOPE

Paragraph 9

- 78. It was decided to replace "food safety authorities" with "competent authorities" as food fraud is not necessarily related to food safety and that a more general term would take into account different situations in countries.
- 79. It was further discussed if the guidelines were directly intended to address Food Business Operators (FBOs). As section 6 (roles and responsibilities) included a paragraph on FBOs, it was considered appropriate to mention FBOs.
- 80. Some Members stated that feed for food producing animals was outside the scope of these guidelines and required wider consultation and also with WOAH, whereas others thought that it should be kept, as there could be a risk for human health. It was decided to continue the discussion on this issue in the EWG.

⁷ CX/FICS 23/26/6; CX/FICS 23/26/6 Add.1; CRD 07 (Australia, Burundi, El Salvador, Ghana, Iran, Mauritius, Morocco, Republic of Korea, Thailand and Uganda), CRD14 (Ecuador); CRD17 (Nigeria); CRD21 (Panama); CRD22 (Senegal); CRD24 (Morocco); CRD25 (United Kingdom)

81. Paragraph 9 – bis and bis bis

bis: It was considered that the prosecution of food fraud would be handled by countries under their respective laws and was outside the scope of the guidelines. Consequently, paragraph 9 bis was amended to reflect this, but remained in square brackets for further discussion in the EWG.

- **bis bis**: It was noted that this paragraph as already covered in sections 1 and 4, but the matter was referred to the EWG for further consideration.

SECTION 3: DEFINITIONS

- 82. Food integrity: It was proposed to delete this definition as it was considered too broad and not specific to food fraud alone. However, after consideration the definition was kept as it was referenced in the guidelines several times.
- 83. It was further proposed to add "commercial and regulatory seals" and "composition" to the characteristics in the definition. After consideration Composition was retained, however, it was clarified that seals were tools to prevent fraud and should thus not be part of the definition.
- 84. Food authenticity: It was proposed to delete this definition, however after consideration it was kept, as it included references to food labelling which could also include the mislabelling of food products.
- 85. Food fraud vulnerability and food fraud vulnerability assessment: It was proposed to delete these definitions as the terms are not used in the guidelines. After consideration, both definitions were deleted.

SECTION 4: TYPES OF FOOD FRAUD

- 86. The chapeau of the types of food fraud was simplified and it was clarified that the list was not exhaustive.
- 87. Substitution: It was suggested that the references to values should be deleted, as fraud can happen with ingredients with different characteristics but not necessarily higher or lower value. Product substitution in food fraud was referred to the EWG for further consideration.
- 88. Dilution: The reference to water as an example was deleted as dilution can also occur with other substances.

SECTION 5: PRINCIPLES

89. To avoid duplication with other Codex texts, it was proposed to consolidate principles 1, 2 and 3 in one principle. This was agreed and it was decided to continue discussion on the proposed text at the EWG, in particular, on the level of prescription.

SECTION 6: ROLES AND RESPONSIBILITIES

- 90. The chapeau of paragraph 11 was amended; to reflect the roles and responsibilities of competent authorities (rather than government); to reflect risk; and the circumstances in their territories or associated with imports.
- 91. It was agreed that the EWG would review this section and ensure consistency with the *Principles and Guidelines* for National Food Control Systems (CXG 82-2013), paragraph 13.
- 92. There was no additional time left to finalise the review of the document.

Conclusion

- 93. CCFICS26 agreed to:
 - a. Return the proposed draft guidelines on the prevention and control of food fraud to Step 2 for redrafting, using the edited version from the plenary.
 - b. Establish an EWG open to all Members and Observers, chaired by the United States of America and cochaired by the United Kingdom, the Peoples Republic of China, the European Union, and the Islamic Republic of Iran, working in English only, with the following terms of reference:
 - to prepare revised draft guidelines on the prevention and control of food fraud, taking into account all discussions and the comments (including text found in square brackets) submitted at CCFICS26, for consideration at CCFICS27.
 - ii. to submit the report of the EWG at least three months in advance of the next session.
 - c. To keep open the option to hold a physical working group session immediately prior to the next CCFICS session and/or a virtual intersessional meeting, to address any outstanding issues.

PROPOSED DRAFT PRINCIPLES AND GUIDELINES ON THE USE OF REMOTE AUDIT AND VERIFICATION IN REGULATORY FRAMEWORKS (Agenda item 7)8

94. Australia as Chair of the EWG, supported by co-Chairs Canada, China and Singapore provided the background to the item noting that CCFICS25 had recognised the challenges COVID-19 posed to inspection and verification systems and had agreed on the development of Codex guidance on the use of the ICT tools for alternative verification as part of a modern regulatory framework.

- 95. CCFICS25 had tasked the Electronic Working Group (EWG), to develop a discussion paper on the Use of remote audit and verification of regulatory frameworks. In a bid to respond in a timely manner to the challenge, the CCFICS Chairperson had sent the new work proposals to CCEXEC83/ CAC45 (2022) for critical review/ approval as explained in FICS/23/26 INF01. This approval by CAC45 allowed the EWG to develop draft guidelines for consideration at CCFICS26.
- 96. The EWG Chair and Co-Chairs reported that they had reviewed the comments submitted in response to the Circular letter and prepared CRD16 containing an updated draft. CCFICS26 agreed that CRD16 be used as basis for the discussion.

Discussion

SECTION 1: PREAMBLE/INTRODUCTION

- 97. CCFFICS26 agreed to:
 - a. Include a new paragraph 3 to highlight the potential improvement in effectiveness and efficiency of official controls and the need to ensure that the cost of delivery of new services would not increase.
 - b. Replace "guidance" with "principles and guidelines" to align with the title of the document.
 - c. Insert a footnote "Includes verification activities by competent authorities", associated it to the term "inspection" noting that the term "verification", was widely used in Codex and CCFICS text, and that its use would also reference the relevant Codex texts:
 - d. Insert the following four codes of hygienic practices after paragraph 4(d): General Principles of Food Hygiene (CXC 1-1969); Code of Hygienic Practice for Meat (CXC 58-2005); Code of Practice for Fish and Fishery Products (CXC 52-2003); Code of Hygienic Practice for Milk and Milk Products (CXC 57-2004).
 - Additional editorial and linguistic changes to ensure readability and clarity.

SECTION 2: PURPOSE AND SCOPE

- 98. CCFICS26 agreed to:
 - a. Replace "guidance" with "principles and guidelines" in accordance with the decision taken under the section on the preamble.
 - b. Delete the words "within their regulatory framework" at the end of paragraph 5, to ensure consistency with other CCFICS texts.

SECTION 3: DEFINITIONS

99. CCFICS26 agreed the definition for "remote audit or inspection" and made further editorial changes to ensure the readability and clarity of the definition.

SECTION 4: TYPES OF REMOTE AUDIT AND INSPECTION

Examples of remote audit or inspection activities

- 100. All proposed changes in CRD16 for this Section were agreed, and made the following changes/clarifications:
 - a. Clarified that remote audit and inspection may be undertaken using one or a combination of tools as elaborated under section 4.
 - b. The terms "audit" and "auditor" should respectively be accompanied with the terms "inspection" and "inspector", in the entire guidelines/principles.

⁸ CX/FICS 23/25/7; CX/FICS 23/25/7 Add.1; CRD 8 (Burundi, Ghana, Morocco and Uganda); CRD11 (The Consumer Goods Forum), CRD16 (Revised proposed draft principles and guidelines on the use of remote audit and inspection), CRD19 (Thailand), CRD21(Panama)

c. For virtual interviews, (paragraph 8 (e)) it was clarified that these are conducted between either, competent authorities and FBOs or between competent authorities themselves; and such virtual interviews are intended to assess compliance and understand systems and processes.

SECTION 5: PRINCIPLES

- 101. CCFICS26 agreed the amendments proposed in CRD16 and made the following additional changes:
 - a. Title to Principle 1: was amended to read "Principle 1: Remote audit and inspection activities complement and may in some cases replace physical audits or inspections". Whether remote audits and inspections are intended to replace physical audits and inspections was discussed; it was agreed that while they are not intended to replace physical audits and inspections, circumstances may exist where they can replace them.
 - b. Principle 5: was amended to put emphasis on the need for protecting the privacy of individuals, and preventing any unauthorised access to use of personal data and confidential information.

SECTION 6: ROLE AND RESPONSIBILITIES

102. CCFICS26 agreed the editorial changes and amendments as highlighted in CRD16.

SECTION 7: PLANNING AND IMPLEMENTATION

- 103. CCFICS26 agreed all editorial and linguistic changes proposed in CRD16 and:
 - Deleted the provision on frequency for conducting remote audits and inspection, noting that this depended on the identified risk prevailing at a particular time;
 - b. Clarified the concept of timing of remote audits and inspection by competent authorities, highlighted in paragraph 19 (a), that Competent authorities should give reasonable advance notice to allow for planning of activities, and that the time for the audit should also be agreed between the competent authorities and entities to be audited or inspected.

Conclusion

104. CCFICS26 agreed to forward the proposed draft "Principles and Guidelines on the Use of Remote Audit and Inspection in Regulatory Frameworks" to CAC46 for adoption at Step 5/8 (**Appendix III**)

DISCUSSION PAPER ON REVIEW AND UPDATE OF THE "PRINCIPLES FOR TRACEABILITY/PRODUCT TRACING AS A TOOL WITHIN A FOOD INSPECTION AND CERTIFICATION SYSTEM" (CXG 60-2006) (Agenda item 8)⁹

- 105. The United States of America and the United Kingdom as co-chairs of the EWG introduced the report of the EWG highlighting identified gaps in CXG 60-2006 as outlined in document CX/FICS 23/26/8.
- 106. CCFICS26 agreed that it was timely to undertake new work to update and revise CXG 60-2006 which should:
 - a. be outcome based, and not overly prescriptive;
 - b. retain the traceability/product tracing principle of "one step back, one step forward";
 - c. define roles and responsibilities of different stakeholders and promote the exchange of information between them:
 - consider cost implications, and that the implementation would not put an additional burden on FBOs and competent authorities;
 - e. take into account the needs of developing countries and their Small and Medium Enterprises (SMEs);
 - f. promote the use of traceability/product tracing as a tool in a NFCS in whole or in part, as appropriate; and
 - g. not restrict trade.
- 107. CCFICS agreed to review the project document and made the following decisions.

⁹ CX/FICS 23/26/8; CRD9 (Burundi, European Union, Ghana, Mauritius, Morocco and Uganda); CRD12 (United Kingdom); CRD19 (Thailand)

Purpose and Scope of the Standard

108. The purpose of the work was revised to clarify that it should foster harmonization and help manage food safety risk, ensuring fair practices in the food trade.

- 109. In the scope of the work, the first bullet was revised to replace "interoperability between systems" to "exchange of information between systems of different stakeholders". This was done to take into account differences in technology and not to restrict differences to solely the availability of technology.
- 110. In the second bullet, it was clarified that traceability may be relevant to the whole and/or parts of the NFCS, as appropriate.
- 111. The third bullet point was revised to add consideration to SMEs.

Relevance and Timeliness

112. CCFICS made editorial changes to the text.

Main aspects to be covered

113. The second bullet point on scope was amended to reflect the changes made under scope in section 1 (purpose and scope). Similarly, the last bullet point was amended to reflect the exchanges of information between different stakeholders.

An assessment against the Criteria for the Establishment of Work Priorities

114. The general criterion language was simplified, adding reference to fair practices in the food trade, and taking into account the different maturity levels of NFCS.

Criteria applicable to general subjects

- (a) Diversification of national legislation and apparent resultant or potential impediments to international trade.
- 115. The reference to NFCS was removed to take into account different settings, while emphasizing the need to identify harmonized approaches.

Information on the relation between the proposal and other existing Codex documents as well as other ongoing work

116. The work in other international standard setting bodies was deleted and the reference to data standards was moved to the section "Criteria applicable to general subjects, letter (c).

Conclusion

- 117. CCFICS26 agreed:
 - To forward the project document on the revision and updating of the Principles for Traceability/Product
 Tracing as a Tool Within a Food Inspection and Certification Systems (CXG 60-2006) to CAC46 for
 approval as new work (Appendix IV);
 - b. To establish an EWG, open to all Members and Observers, chaired by the United States of America and co-chaired by the United Kingdom, Australia, Ecuador, and Honduras, working in English and Spanish, subject to approval of the new work, to prepare a proposed draft revision of the *Principles for Traceability/Product Tracing as a Tool Within a Food Inspection and Certification Systems* (CXG 60-2006) for consideration at CCFICS27;
 - To inform other Codex Committees about this work;
 - That the report of the EWG should be submitted at least three months before the next session of CCFICS;
 and
 - e. To keep open the option to hold a physical working group session immediately prior to the next CCFICS session and/or a virtual intersessional meeting, to address any outstanding issues.

REVIEW AND UPDATE OF APPENDIX A - THE LIST OF EMERGING GLOBAL ISSUES (Agenda item 9)10

118. Australia introduced the discussion paper, prepared in cooperation with Kenya, highlighting that emerging global issues continue to be important for CCFICS to consider, particularly in relation to new approaches and technologies applying to national food control systems. Based on the responses to the CL, Appendix A (Emerging Issues) had been revised to ensure clarity and consistency, consolidating the list to five key areas.

119. Following consideration, CCFICS26 agreed the recommendations in CX/FICS 23/26/9, paragraph 17. The importance of holding an intersessional workshop was stressed, noting that during the plenary meeting there was often not sufficient time to discuss this agenda item.

Conclusion

120. CCFICS26:

- a. Acknowledged the current list of emerging issues identified in Appendix A;
- b. Agreed for the list of emerging issues to continue as a standing Agenda Item for future CCFICS meetings, and that custodianship would continue to be rotated through Members on a meeting-by-meeting basis;
- c. Agreed to request the Codex Secretariat to issue a CL requesting inputs from members on emerging global issues to be included in Appendix A;
- d. Noted that as a result of consultations with the CCFICS Chairperson, the UK had agreed to be the next custodian for Appendix A of the Emerging issues paper (for CCFICS27), and that Australia was prepared to support the next custodian;
- e. Agreed that the responsibility of the Custodian would remain to prepare an updated document taking into account discussions at the current session, as well as the comments solicited through the CL; and submitting a report, including an updated and prioritised list of emerging issues, to CCFICS27 for consideration;
- f. Agreed to hold an intersessional workshop ahead of CCFICS27 to further discuss the emerging issues under Appendix A; and
- g. Agreed to retain Appendix B (as amended) as an internal document for CCFICS that may be updated based on experience gained from its use.

Discussion papers on potential new work proposals

Development of guidance on appeals mechanism in the context of rejection of imported food (CRD4)

- 121. India introduced CRD4 on development of guidance on appeals mechanism in the context of rejection of imported food. This proposal is aimed at addressing the challenges and requirements of the evolving food trade and it is aligned with the Codex Strategic Plan 2022-25.
- 122. The proposed guidelines would focus on the processes to be followed by the exporting and importing countries in the form of an appeal mechanism, covering the roles and responsibilities of the competent authorities.

Discussion

123. There was general support for the proposal, and it was recognised that the subject was within the scope of the CCFICS, and there was value in progressing the work.

- 124. However, it was noted that an analysis is needed to be undertaken with regards to:
 - The placement of the new guidance: i.e. whether new principles and guidelines on appeal mechanisms were to be developed as a stand-alone document or these would be part of the existing guidelines, such as the *Guidelines for the Exchange of Information between Countries on Rejections of Imported Foods* (CXG 25-1997) or the *Guidelines for Food Import Control Systems* (CXG 47- 2003).
 - The process for appeal mechanisms should be drafted taking into account communication between the importer and exporter and competent authorities as regards to food import rejections. Further aspects related to rejections based on certification also need to be considered.

¹⁰ CX/FICS 23/25/9; CRD4 (India), CRD10 (Burundi, Ghana, Mauritius and Uganda); CRD15 (Brazil)

Members discussed the appeals mechanism being a process between the operator responsible for the
rejected consignment and the competent authority of an importing country, and not a process between
importing and exporting countries and the details of appeal mechanisms are subject to administrative
legislation of Codex Members and requested that this be considered when bringing forward the next paper
for CCFICS consideration.

Conclusion

125. CCFICS26 requested that India, assisted by Nigeria, to prepare an updated discussion paper and project document, prior to further consideration at CCFICS27, taking into account the comments made at the session. Other Members are also encouraged to come forward to assist.

The standardization of sanitary requirements (CRD15)

- 126. Brazil introduced the discussion paper and project document contained in CRD15. The proposal is based on the identification of issues with electronic certification, including non-unique requirements, repetitive information, and lack of consistency and transparency in communication. The proposed work would define criteria and methods to evaluate existing attestations and enable the creation of a harmonized requirement list. The proposal aims to promote the use of electronic certification which could improve food safety and simplifying and expediting clearance processes while maintaining the flexibility of countries to define specific requirements.
- 127. CCFICS26 welcomed the proposal, noted that the project was complex and supported undertaking a pilot project. It was suggested that the pilot project focus on a single commodity to assess the feasibility of the proposal, against other models.

Conclusion

128. CCFICS26 requested Brazil with the assistance of Australia, New Zealand, Spain and the United States of America to prepare an updated discussion paper and project document for further consideration at CCFICS27. Other Members are also encouraged to come forward.

OTHER BUSINESS (Agenda item 10)

129. There were no other business considered by the Committee.

DATE AND PLACE OF THE NEXT SESSION (Agenda item 11)

130. The Chairperson informed the Committee that CCFICS27 was tentatively scheduled to be held in approximately 18 months, subject to confirmation by Australia in consultation with the Codex Secretariat.

REP23/FICS Appendix I

Appendix I

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APPENDIX II

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

(For adoption at Step 5/8)

SECTION 1 - PREAMBLE

- Recognition of the equivalence of the whole or a part of an exporting country's National Food Control System (NFCS)¹¹, as relevant to the trade in foods under consideration, can provide an effective means for minimizing unnecessary duplication of controls, while protecting the health of consumers and ensuring fair practices in the food trade. The recognition of equivalence, where it occurs, should result in positive changes to the conditions of trade, and facilitate the more efficient and effective use of resources in the importing and exporting countries (which could include but is not limited to recognition of lists of eligible export establishments; alternative processing and inspection procedures; or a reduced intensity and frequency of routine port of entry inspection).
- These guidelines are intended to be read in conjunction with other existing Codex text including but not limited to <u>Guidelines for the Design</u>, <u>Operation</u>, <u>Assesment and Accreditation of Food Import and Export Inspection and Certification Systems (CXG 26-1997)</u>, and the <u>Guidelines for Food Import Control Systems (CXG 47-2003)</u>.
- 3 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.

SECTION 2 - PURPOSE

- 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 part¹² of the NFCS at the system level.
- 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, as relevant to the trade in foods and the conditions of trade covered by the request.

SECTION 3 - DEFINITIONS

Equivalence of NFCS: The capability of different NFCS or parts of NFCS to achieve the same objectives.

Outcome: Intended effects or results that contribute to achieving the relevant NFCS objectives.

<u>Decision Criteria</u>: Those factors used to objectively determine whether the exporting country's NFCS or the relevant part achieve the objectives of the importing country's NFCS or the relevant part for the products under consideration.

SECTION 4 - PRINCIPLES

6 Consideration of the recognition of the equivalence of a NFCS should be based on the application of the following principles:

Equivalence of National Food Control Systems (NFCS)

a. Countries should recognize that NFCS's, or the relevant parts thereof, of importing and exporting countries, although designed and structured differently, may be capable of achieving the same objectives, and related outcomes or level of protection, with respect to protecting the health of consumers and ensuring fair practices in the food trade and can therefore be found to be equivalent.

¹¹ Principles and guidelines for National Food Control Systems (CXG 82-2013)

¹² An equivalence request could be limited to assurances associated with a specified sector such as seafood, or further refined to a subsector such as aquaculture or a processing type such as canned seafood. A request for equivalence recognition could cover a horizontal process for providing assurances such as the recognition of regulatory controls for sampling protocols and/or laboratory or specific methodology approvals.

Experience, Knowledge and Confidence

b. Countries should consider relevant experience, knowledge and confidence and may consider appropriate assessments by other countries or relevant international organizations.

Alignment with International Standards

c. The use of or reference to Codex standards, guidelines, and/or codes of practice, or other relevant international standards by importing and exporting countries can facilitate the consideration, assessment and recognition of the equivalence of a NFCS, or the relevant part.

Assessment

d. The assessment process should evaluate whether the relevant objectives, and related outcomes or level of protection, of the importing country's NFCS are achieved and the process should be documented; transparent; evidence-based; outcome-focused; efficient; and be conducted in a cooperative and timely manner.

Final documentation

e. The importing and exporting countries should document any recognition reached, including how the recognition of equivalence will be implemented and maintained for the trade in food between the countries.

SECTION 5 - PROCESS STEPS

- The following process steps relate to the consideration, assessment, recognition and maintenance of the equivalence of NFCSs.¹³
 - Step 1: Initial discussions, scope and decision to commence
 - Step 2: Description of the importing country's NFCS and the relevant objectives
 - Step 3: The decision criteria for comparison
 - Step 4: Description of exporting country's NFCS or relevant part
 - **Step 5: Assessment process**
 - Step 6: Decision process
 - Step 7: Final documentation

5.1 STEP 1: INITIAL DISCUSSIONS, SCOPE AND DECISION TO COMMENCE

Initial discussions

- Prior to a country requesting formal consultations on the recognition of the equivalence of its NFCS or the relevant part, it is recommended that initial discussions take place between the relevant competent authorities of both countries¹⁴. These discussions can help identify if commencing an assessment of the equivalence of the exporting country's NFCS is the most appropriate approach or whether some other mechanism¹⁵ would be better to address the matters under discussion.
- 9 Relevant matters for the initial discussions may include ¹⁶:
 - regulatory and/or legislative frameworks, should they exist, establishing the procedures and/or steps to be followed when evaluating the recognition of equivalence of a NFCS;
 - 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;

¹³ The principles and processes described in CXG 89-2016 are also useful in informing the exchange of information.

¹⁴ Noting that countries may make a request for consultations on equivalence at any point during the initial discussions.

¹⁵ Other mechanisms may include but not be limited to: The exchange of information to support trade (CXG 89-2016); equivalence of a specific sanitary measure or group of measures; compliance with importing county requirements; harmonisation of requirements; mutual recognition; memoranda of understanding; or assurances based on some other means acceptable to both countries.

¹⁶ Paragraphs 9 and 11 of CXG 34-1999 and paragraph 3 of the Appendix of CXG 53-2003 provide additional guidance.

- the potential scope of an equivalence request;
- experience, knowledge and confidence derived from, for example: the history and level of trade between the countries; the history of compliance with the importing country's requirements; the level of familiarization and/or cooperation between the competent authorities; and the exporting country's trade in the same or similar products with other countries¹⁷;
- the different level of development between the countries NFCS¹⁸;
- the similarity of design of each country's NFCS in whole or the relevant part including the legislative framework and the relevant objectives, and related outcomes or level of protection;
- the similarity to or harmonisation of the whole or the relevant part of the NFCS with standards, guidelines, and/or codes of practice from Codex or other relevant international standard setting bodies; and
- the information exchanges and assessments that may have already occurred (e.g. in accordance with CXG 89-2016) or the existence of other relevant recognitions of equivalence between the two countries or with third countries.

Scope Considerations

- During the initial discussions exporting and importing countries should determine the appropriate scope for the assessment. The scope may relate to an entire NFCS or only to that part of a NFCS relevant to the foods and conditions of trade to be covered by the request.
- 11 Relevant considerations in determining the scope may include:
 - the range of products currently being traded between the countries and/or products proposed for future trade¹⁹;
 - identification of those requirements where recognition of the equivalence of the NFCS or the relevant part will allow better use of resources, including resolution of issues affecting trade;
 - the range of NFCS assurances to be addressed (e.g. food safety, qualitative claims, labelling, or other matters relating to technical regulations, conformity assessment procedures or standards);
 - the level of trust and confidence in the performance of the exporting country's NFCS in whole or the relevant part relating to those products already being traded or those proposed for future trade; and
 - the availability of resources likely to be necessary to undertake the process as it relates to the whole or the relevant part of the NFCS proposed to be considered and the possible benefits.
- 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 required²⁰.

Decision whether to commence

- Where the conclusion of the initial discussions between the exporting and importing countries is that a recognition of equivalence is the appropriate mechanism, the formal request for consultations should be made and submitted in writing including a description of the scope of products and conditions of trade to be covered.
- The two countries may then agree on a plan for undertaking the assessment which may include for example, timeframes and if necessary, priorities.²¹

¹⁷ Paragraph 10 of the Appendix to CXG 53-2003 provides some further possible examples which may or may not be relevant depending on the circumstance [active links – Codex secretariat to follow up].

¹⁸ See also paragraph 15.

¹⁹ Paragraph 5 of CXG 34-1999.

²⁰ See CXG 53-2003 paragraphs 11 and 12 and paragraphs 9-13 of the Appendix for additional guidance.

²¹ Paragraph 4(d) of Appendix to CXG 53-2003 and Paragraph 8 and 9 of CXG 34/1999 refers.

Where the initial discussions between the two countries conclude that an assessment of the equivalence of the exporting country's NFCS is not the most appropriate mechanism, the countries may wish to consider working jointly towards some other mechanisms to help facilitate the trade. CXG 34/1999 (paragraph 11) also identifies that amongst other things, information exchange, joint training, technical cooperation and support, and the development of infrastructure and strengthening of the food control systems can serve as building blocks for a future request for recognition of the equivalence of systems.

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

- As relevant to the scope of the request and to facilitate the exporting country in describing its own systems, the importing country should provide information to describe, with appropriate references, the related elements with the objectives, and relevant outcomes or level of protection, of its NFCS that are to be part of the assessment for example:²²
 - regulatory and legislative framework;
 - control and approval requirements (for example establishment, process and product programs);
 - verification or conformity assessment, and audit programs;
 - monitoring, surveillance, investigation and food safety incident response programs;
 - enforcement and compliance programs;
 - stakeholder engagement, communication and rapid alert systems;
 - system overview monitoring and evaluation programs, or existing conformity assessment procedures; or
 - any other elements directly relevant to the specific products or programs under consideration.
- 17 In describing its own NFCS or the relevant part, the importing country may include reference to relevant standards, guidelines, and/or codes of practice from Codex or other relevant international standard setting bodies.

5.3 STEP 3: THE DECISION CRITERIA FOR COMPARISON

- Once the formal request for consultations on a recognition of equivalence of a NFCS or the relevant part has been made, the importing country should document the decision criteria to be used to evaluate the exporting country's NFCS or relevant part associated with the scope of the request. The criteria should reference the relevant objectives, and related outcomes or level of protection, that should be shown to be achieved for recognition of equivalence. The decision criteria document should be provided to and discussed with the exporting country in a cooperative manner.
- The decision criteria should facilitate the importing country's assessment process being able to determine whether or not the exporting country's system design and implementation achieves the importing country's relevant objectives, and related outcomes or level of protection, associated with the scope of the request.²³
- The decision criteria may be qualitative or quantitative and may include for example:
 - the level of qualitative or quantitative evidence that is expected;
 - the indicators²⁴ of outcomes if these are to be used to facilitate comparisons;
 - the level of protection achieved by the importing country's NCFS or relevant part, and
 - how experience, knowledge and confidence are to be used.
- The decision criteria should focus on the performance of the NFCS in whole or the relevant part as opposed to individual procedures or measures.

²² ref: <u>CXG 34-1999</u>, Section 7; <u>CXG 82-2013</u>, paragraph 43 and <u>CXG 89-2016</u> Section 7

²³ One example of a possible decision criteria could be: Regulatory decisions are based on sound scientific analysis and evidence, involving a thorough review of all relevant information (e.g. historical regulatory decisions, published risk assessments, or compliance actions).

²⁴ See Appendix B of <u>CXG 91-2017</u> for some illustrative examples of outcomes and examples of potential indicators for those selected outcomes.

- Where the objectives of any part of the NFCS under consideration relate to the protection of the health of consumers the decision criteria should focus on whether the exporting country NFCS in whole or the relevant part achieves the level of protection as set by the importing country.
- Where the objectives of any part of the NFCS under consideration relate to matters set out in technical regulations, conformity assessment procedures, or standards, the decision criteria should focus on whether the exporting country's NFCS in whole or the relevant part adequately achieves the relevant outcomes associated with the objectives of the importing country's NFCS.
- 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.

5.4 STEP 4: DESCRIPTION OF EXPORTING COUNTRY'S NFCS OR RELEVANT PART

- The exporting country should make available appropriate information, including relevant references and evidence that describes the exporting country's NFCS or the relevant part and demonstrates how it achieves the objectives, and related outcomes or level of protection, of the importing country's NFCS or relevant part for the foods and conditions of trade covered by the request.
- 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 country.²⁵
- Taking into consideration the scope of the request for recognition of equivalence and existing experience, knowledge and confidence, additional information exchanges may be required for those matters or elements of the exporting country NFCS which need to be subjected to a more detailed assessment.

5.5 STEP 5: ASSESSMENT PROCESS

- Once 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 and evidence-based. The importing country should focus its assessment on determining whether the exporting country's NFCS in whole or the relevant part meets the decision criteria. There should be an effective communication mechanism between both countries, for providing feedback.
- 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 the particular modification to existing trade conditions being sought. In general, the importing country should:
 - consider whether the information submitted by the exporting country or otherwise available is sufficient to enable an appropriate assessment;
 - proceed with an assessment applying the decision criteria and requesting additional information if deemed necessary;
 - consider any additional information submitted by the exporting country at the request of the importing country that could facilitate the assessment process;
 - where appropriate, convey to the exporting country any information for the addition of one or more specific controls to their NFCS that could facilitate the assessment process;
 - consider any additional controls proposed by the exporting country to facilitate a positive determination.
- The importing country's assessment process should:
 - focus on whether the exporting country's NFCS in whole or the relevant part achieves the
 objectives, and related outcomes or level of protection, of the importing country's NFCS or the
 relevant part in accordance with the decision criteria (as opposed to whether specific procedures
 or functions, undertaken by certain parties in the importing country, are replicated);
 - consider the use of indicators of outcomes different to the importing country's to be used by the exporting country to demonstrate the performance of its NFCS in whole or the relevant part to achieve the importing country's objectives, and related outcomes or level of protection;

²⁵ See Paragraph 6 d) of CXG 89-2016

- weigh the outcome of the various elements of the exporting country's NFCS relative to their impact on achieving the objectives and related outcomes or level of protection of the importing country's NFCS or relevant part;
- be conducted in a cooperative and timely manner and may include the review of documents, and the use of in-country assessments / audits²⁶ where justified as necessary to demonstrate the NFCS in whole or relevant part:
- allow for regular discussion / consultations between the countries and the provision of clarifications and / or supplementary information as required; and
- appropriately protect commercially sensitive and confidential information.
- 31 Other overarching considerations relevant to the assessment process may include:
 - freedom from conflicts of interest;
 - transparency of decisions and actions;
 - how the exporting country NFCS maintains the three characteristics of: situational awareness proactivity and continuous improvement²⁷; and
 - the availability of resources and infrastructure to continue to implement the NFCS or the relevant
- 32 Meetings between the importing country assessors and the exporting country's competent authority may assist the assessment process and their potential use should be included in the planning for the equivalence of systems assessment, as appropriate. Countries are encouraged to communicate and conduct meetings electronically, where practicable. Where possible, the provision of technical assistance may also be used to support the assessment process.²⁸

5.6 **STEP 6: DECISION PROCESS**

- 33 The decision process should:
 - be transparent and conducted in a timely manner; and
 - focus on whether the exporting country's NFCS or the relevant part meets the decision criteria; and
 - not introduce a new objective or outcome in excess of what is being applied within the importing country without justification.
- 34 The importing country should document the draft assessment conclusion and the rationale and the exporting country should be given the opportunity to comment on the draft conclusions. In the case of an initial finding that the exporting country's NFCS or the relevant part is assessed as not equivalent, the exporting country should have the opportunity to provide additional information for consideration by the importing country prior to the finalization of the decision.
- 35 In the case where the exporting country's NFCS or the relevant part is assessed as not equivalent the two countries may, if they wish, agree to a plan and timeframe for the exporting country to provide any additional information or controls for the identified parts of the NFCS that were determined not to be equivalent. Subsequent additional information should be reviewed by the importing country without requiring all aspects of the assessment process to be repeated so long as the additional information is provided in a timely manner. The importing country should document the final assessment conclusions and the associated rationale.

²⁷ Paragraph 36, <u>CXG 82-2013</u>

²⁶ See the Annex to CXG 26-1997 for further guidance on the conduct of assessments

²⁸ Examples could include technical exchanges to help facilitate better understanding of each country's systems, or assistance with making changes to those parts of the NFCS that are identified during the assessment process as needing further development.

5.7. STEP 7: FINAL DOCUMENTATION

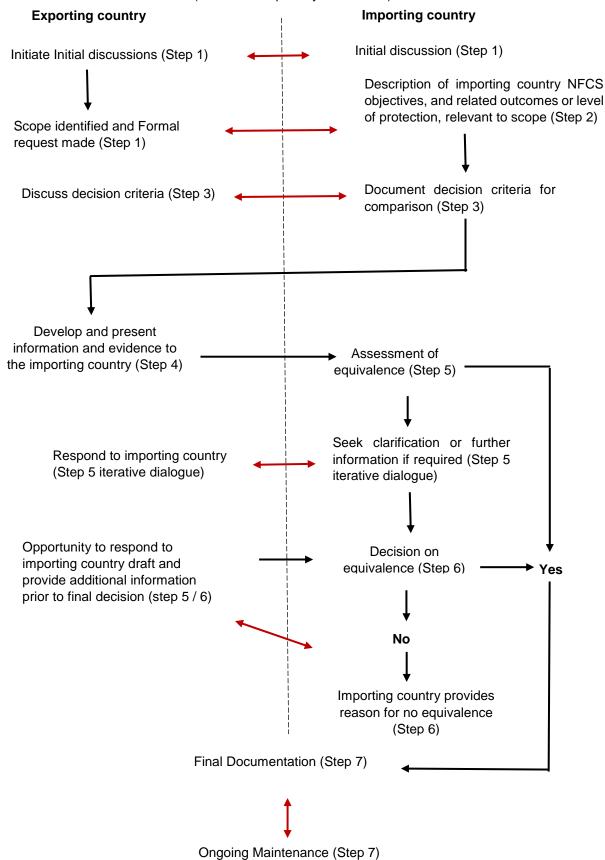
- The importing and exporting countries should document any recognition reached including how the recognition of equivalence will be implemented for the trade in food between the countries (e.g. recognition of lists of establishments; or modification to point of entry, or additional in-country process prescriptive requirements). Such documentation may be done for example, through an exchange of letters or through the negotiation of a more comprehensive equivalence agreement or arrangement²⁹.
- 37 The documentation of the recognition of the equivalence of systems should include provisions on maintenance and review of the recognition. Maintenance of recognition arrangements should allow regulatory frameworks, programs and oversight to evolve over time. The documentation should include what level of change to the exporting or importing country's NFCS or other changes in circumstance requires notification to the other country and when a review of the recognition of equivalence may be required.
- 38 The countries should document their expectations with respect to ongoing communication and cooperation.
- 39 Maintenance and review of recognitions of the equivalence of NFCS may include activities such as:
 - regular provision of summary information on the performance of the NFCS or the relevant part;
 - advice of and potential review of any proposed significant changes to the laws, regulations or performance measures underpinning the components of either country's NFCS covered by the recognition of equivalence arrangement;
 - regular technical discussions between relevant experts; and
 - intermittent country visits or technical exchanges so as to maintain the currency of experience, knowledge and confidence.³⁰

²⁹ Although this guideline refers to "countries" and "agreements," in many cases the relevant competent authorities will enter into agreements or other arrangements. <u>CXG 34-1999</u> Appendix A provides a list of information that could, as appropriate, be included in an equivalence agreement.

³⁰ See Section 1(2) of the Annex to <u>CXG 26-1997</u> (*Principles and Guidelines for the Conduct of Assessments of Foreign Official Inspection and Certification Systems*)

Figure 1: Equivalence of National Food Control Systems Process

Simplified flow chart for recognition and maintenance of equivalence of NFCS (Individual steps may be iterative)



APPENDIX III

PROPOSED DRAFT PRINCIPLES AND GUIDELINES ON THE USE OF REMOTE AUDIT AND INSPECTION IN REGULATORY FRAMEWORKS

(For Adoption at Step 5/8)

Section 1: Preamble/Introduction

- 1. Remote audit and inspection³¹ activities, while presenting some challenges, can offer significant benefits to competent authorities and food businesses whilst also providing an appropriate level of oversight by national competent authorities. These activities can also ensure continuity of audit and inspection related activities when physical visits are not practical.
- 2. As technology continues to develop, offering increased potential to undertake activities remotely, it is important for the use of such technology by competent authorities to be transparently applied and agreed.
- 3. Remote audit or inspection may improve the effectiveness and efficiency of official controls under the right conditions. Remote audit or inspection activities should not increase the cost to deliver official controls as it should consider availability of existing technology.
- 4. These principles and guidelines supplement current Codex texts when competent authorities consider undertaking the whole or part of an audit or inspection, remotely. Relevant current texts include but are not limited to:
 - a. Principles and Guidelines for National Food Control System (CXG 82-2013);
 - b. Principles and Guidelines for Monitoring the Performance of National Food Control Systems (CXG 91-2017);
 - c. Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to support the trade in food (CXG 89-2016);
 - d. Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export inspection and Certification Systems (CXG 26-1997), (and especially the Annex on Principles and guidelines for the conduct of assessments of foreign official inspection and certification systems).
 - e. General Principles of Food Hygiene (CXC 1-1969);
 - f. Code of Hygienic Practice for Meat (CXC 58-2005);
 - g. Code of Practice for Fish and Fishery Products (CXC 52-2003);
 - h. Code of Hygienic Practice for Milk and Milk Products (CXC 57-2004)

Section 2: Purpose / Scope

- 5. The purpose of these principles and guidelines is to assist competent authorities in the use of remote audit and inspection activities.
- 6. The scope of these principles and guidelines is the use of remote audit and inspection as an optional tool to support the effective delivery of official controls both within a country's National Food Control System (NFCS) and the assessment of an exporting country's NFCS, or a relevant part thereof.

Section 3: Definition

7. **Remote Audit or Inspection:** An audit or inspection when the auditor(s) or inspector(s) are not physically present at the site to be audited or inspected and their activities are undertaken remotely.

Section 4: Examples of remote audit or inspection activities:

- 8. Remote audit and inspection activities can be considered as either "partial", when only some parts are conducted remotely, or "full", when all parts are completed remotely. Examples of audit or inspection activities that may be conducted remotely, include, but are not restricted to one or a combination of the following:
 - a. **Live video-streaming**: When live video footage is streamed from an audit or inspection site guided by an auditor or inspector of the competent authority observing real-time operating conditions.
 - b. **Pre-recorded video**: Where a pre-recorded video is taken at the request of an auditor or inspector and electronically submitted to them for assessment.

³¹ Includes verification activities by competent authorities.

- c. **Off-site desktop review of documentation**: When documentary evidence or data is submitted for review by a competent authority audit/inspection team to confirm required activities have been undertaken or outcomes achieved. These data could include photographic and/or video footage.
- d. **Remote collection of measurement information:** Where a competent authority can access data relayed from measuring devices and equipment for example, temperature recordings, or other electronically captured data reported directly to that competent authority.
- e. **Virtual interview:** Where a competent authority conducts remote interviews with a FBO and/or other competent authority to assess compliance, and understand systems and processes.

Section 5: Principles

9. Many of the basic principles and considerations are the same for both physical and remote audits or inspections. Taking into account the nature of remote audits and inspections, in deciding whether and when to use remote audit and inspection tools, competent authorities should consider the following:

Principle 1: Remote audit and inspection activities complement and may in some cases replace physical audits or inspections

10. Remote audit or inspection activities may be used as the sole tool for verifying compliance of a process, facility or NFCS or part thereof, or used in combination with physical audits or inspections. The use of this tool is at the discretion of the participating competent authorities or FBOs depending on their agreement of the suitability, compatibility, and technological support. Competent authorities should be aware that remote audits or inspections may not be appropriate for all food business operations or competent authorities.

Principle 2: Remote audit and inspection activities should be aligned with physical audits and inspection activities

11. Relevant processes for conducting a physical audit or inspection will similarly apply to the remote process, such as sufficient notification of the need and planning for an activity, the scope, the audit criteria, assessment preparations, opening and closing meetings, the provision of feedback and draft reports for comment, and other activities referenced in relevant guidance.

Principle 3: Risk-based approach should be used when deciding upon a remote audit or inspection activity

- 12. Competent authorities should perform remote audit and inspection activities in a manner that is proportionate to risks posed, noting:
 - the frequency of such audits or inspections should not be greater than that justified by the risk posed and by the performance of the FBO or NFCS in whole or in part; and
 - the scope of remote audits or inspection should be clearly defined and agreed by both parties and will be determined by the risk.

Principle 4: Remote audit and inspection activities should be planned and conducted in a cooperative manner

13. Planning and implementation of remote audit and inspection activities should be conducted in a cooperative manner, considering the level of technology accessible to the FBO and/or exporting country competent authority to support the proposed activities. Considerations should include the technology available, the internet coverage, the bandwidth of the internet, wireless connectivity, impeding structural elements of buildings, and the quality of the handling and presenting of information, which are just a few elements that can impact the success of the remote activity.

Principle 5: Protection of confidential information

14. The mechanism used for information sharing during a remote audit or inspection is different to that during a physical audit or inspection and brings additional challenges. All necessary precautions should be taken to protect the privacy of individuals and to prevent any unauthorised access to, and use of personal data and confidential information. When such conditions cannot be guaranteed, a physical audit or inspection may be appropriate.

Section 6: Roles and Responsibilities

15. The roles and responsibilities of the competent authorities and entities to be audited or inspected are similar in remote and physical audit or inspection activities. However, all may face some additional responsibilities in facilitating these activities to be undertaken remotely.

- 16. Competent authorities conducting remote audits and or inspections should:
 - a. Review legislation to ensure it supports remote audit and inspection activities as appropriate;
 - b. Establish audit and inspection programs, policies and procedures which outline the conditions and scenarios for the use of remote versus physical audit and inspection activities as appropriate; and
 - c. Provide clear direction to the entities to be audited or inspected (e.g. FBO, and other competent authorities) on the information and communication technology requirements necessary for successful execution of the remote audit/inspection and determine whether such requirements are feasible.
- 17. Entities to be audited or inspected should:
 - Ensure they understand the availability of, and their access to necessary technologies to facilitate remote audit and inspection activities when there is a stipulated reasonable requirement from a competent authority; and
 - b. Clearly indicate their ability and commitment to engage in remote auditing or inspection, or whether a physical audit or inspection would be their preferred option.

Section 7: Planning and Implementation

18. While remote audit and inspection activities will generally follow steps that are similar to physical audit or inspection activities, there are important considerations that will contribute to their successful implementation.

Planning

- 19. The following points should be taken into consideration when planning remote audit and inspection activities:
 - a. Timing: Competent authorities should give notice, sufficiently in advance to allow a reasonable time for planning activities. The time or date of the audit should be agreed between the competent authorities and or entities to be audited or inspected. Where significant time zone differences exist between the location of the auditor or inspector and the competent authority or FBO, the hours of operation of the food business or competent authority being audited or inspected should be given priority when establishing a time for conducting a remote audit or inspection to ensure that remote audit and inspection activities are delivered during standard operating hours.
 - b. **Qualifications:** Auditors or inspectors conducting the remote audit or inspection should be as appropriately qualified and competent as if conducting a physical audit or inspection. There may be an additional need for proficiency in the application of any technologies used during the remote audit or inspection activity.
 - **c. Technology:** Consideration should be given to the technology required for a remote audit or inspection including:
 - Whether access to the relevant technology needed for a remote audit or inspection is a reasonable requirement;
 - ii. Whether the use of the proposed technology remains as the most appropriate approach or whether other types of remote audit or inspection would be able to provide the required level of assurance:
 - iii. Whether technical assistance or support is available to the food business operators and/or competent authorities in relation to the identified technology;
 - iv. Testing of connections and IT systems between competent authority and FBO, and between competent authorities to ensure a successful audit; and
 - v. Both sides agreeing on contingencies when planning remote audit and inspection activities to manage possible interruptions caused by technological failures.

Implementation

- 20. The following should be considered during conduct of remote audit and inspection activities:
 - a. Protection of information: The competent authorities conducting the remote audit and inspection activities should only gather information that is necessary. When it is necessary to gather information that is confidential, information should be transferred over secure channels and should not be shared with any third party without the consent of the original owner and should be stored and destroyed in a secured manner when no longer required.

- b. **Feedback:** Depending on the actual conditions, both competent authorities may decide whether to include in the closing meeting a discussion and review of the remote audit or inspection process. The auditing or inspecting competent authority should provide its feedback in written form afterwards.
- c. Health and Safety: Workplace health and safety procedures applied for physical audit and inspection activities remain applicable, for example, for any person who may be instructed to take measurements or record activities during a remote audit or inspection Health and safety procedures should take into consideration the length of activity sessions, differences in time zones and need for breaks to maintain physical and mental wellbeing of all participants.

APPENDIX IV

PROJECT DOCUMENT

NEW WORK PROPOSAL FOR THE REVISION OF PRINCIPLES FOR TRACEABILITY/PRODUCT TRACING AS A TOOL WITHIN A FOOD INSPECTION AND CERTIFICATION SYSTEM (CXG 60-2006)

(For approval)

1. Purpose and Scope of the Standard

The purpose of the new work is to update CXG 60-2006 so that it takes account of developments since original work completed in 2006. The work will foster harmonization and help manage food safety risk, ensuring fair practice in food trade. The work will entail:

- Revision of the Principles for Traceability/Product Tracing as a Tool Within a Food Inspection and Certification System (CXG 60-2006)
 - to update to the text to take account of current and emerging regulatory and industry good practices and advances in supporting technology, while remaining technology neutral.
- A refreshed structure to allow for additional content to be added (see Section 3 below).

The scope of the new work is to:

- Provide good practice advice, including key considerations that would promote the exchange of information between systems of different stakeholders.
- Promote the use of traceability/product tracing in the context of the whole and/or parts of a National Food Control System (NFCS), as appropriate.
- Provide guidance on the roles and responsibilities of the different actors/stakeholders involved in the
 production, processing, distribution, transport, and retail sale of food or ingredients, taking into account
 the condition of small or medium enterprises.

2. Relevance and Timeliness

It is good practice for Codex Committees to review their standards to ensure they remain relevant and fit for purpose. The traceability guidelines were finalized seventeen years ago and reflect customs and practices prevalent at that time. The guidelines do not therefore fully reflect current thinking and modern approaches to traceability that have emerged since adoption. These new and emerging approaches are being driven by regulatory modernization programs and a desire from industry to innovate so that they have increased visibility along their supply chains which helps them better manage risks and meet consumer demands. The 2006 guidelines did not foresee these changes which means these new and emerging approaches to traceability are not fully accommodated in the current Codex text.

Traceability is recognized more so now than it was in 2006 as a component of a modern, well-designed NFCS alongside the good hygiene practices set out in *General Principles of Food Hygiene* (CXC 1-1969). This recognition became apparent during the development of the NFCS guidelines (i.e. *Principles and Guidelines for National Food Control Systems*, (CXG 82-2013)) which identify traceability as a main characteristic of an effective control system. As a tool, traceability provides valuable information to link the different stages of a product's journey from primary production to consumption. Traceability information, how it is kept, and ease of access is often critical when the food safety of a product is compromised. A critical characteristic of these new/modern systems is interoperability with existing systems and the use of common data standards. However, the value to control systems goes beyond just managing food safety recalls/incidents. Innovation and the availability of more affordable technology has seen businesses voluntarily implement enhanced traceability systems which are beneficial to public health and better serve the needs of businesses and regulatory authorities, by providing increased visibility along supply chains which in turn allows for the more efficient use resources. In reality, the better a traceability system is the more surgical the regulatory intervention can be, saving time, reducing waste, and minimizing costs to affected businesses.

In light of the changes that are already occurring in the food system, it would be timely for Codex to revise and update CXG 60-2006 to avoid the risk of fragmentation by providing a practical resource that can help foster harmonization. Further, increases in global trade, the complexity of supply chains, and digitization of information along with the emergence of more affordable technologies to facilitate the integrity and sharing of food chain information suggest now is the right time to revisit the 2006 text.

3. Main aspects to be covered

The revised guidance will be based on CXG 60-2006. The proposed structure and content will cover the following aspects:

- Preamble (new combine context and rationale text from CXG 60-2006)
- Scope (revise to promote use of traceability/product tracing as a tool within a NFCS, in whole or in part, as appropriate)
- Definitions (revisit and update, as appropriate, from CXG 60-2006)
- Principles (retain 1up/1down, revise/supplement, as appropriate from CXG 60-2006)
- Roles and responsibilities (new, Competent Authorities, FBOs)
- Regulatory frameworks (combine with "Design" paragraph from CXG 60-2006 and add "key considerations" to retain flexibility)
- Good practice (combine with "Application paragraphs from CXG 60-2006 and supplement to cover new/emerging approaches, including the exchange of information between different stakeholders

4. An assessment against the Criteria for the Establishment of Work Priorities

General Criterion

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

The proposed new work will support the development or advancement of traceability/product tracing systems that can more rapidly identify products that have an adverse impact on consumer health. It will also promote the fair practice in food trade. It will also promote consistency and harmonization of approaches between countries, thus facilitating communication about food safety concerns, while allowing for sufficient flexibility to consider different levels of capacity and development in different countries. Updated international guidelines will also provide greater clarity and certainty for food businesses.

Criteria applicable to general subjects

(a) Diversification of national legislation and apparent resultant or potential impediments to international trade.

Lack of standardization around traceability/product tracing can hinder rapid responsiveness, which is especially important in situations where public health can be impacted. Updating the Codex guidance so that it is inclusive of current and emerging traceability/product tracing practices would provide a common framework for harmonized approaches and in doing so help prevent fragmentation.

(b) Scope of work and establishment of priorities between the various sections of the work.

Refer to scope section above.

(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).

Work is being done in this area related to data standards by organizations such as U.N. Center for Trade Facilitation and Electronic Business (UNCEFACT) and World Customs Organization (WCO) (e.g. https://www.wcoomd.org/DataModel).

(d) Amenability of the subject of the proposal to standardization.

Codex currently has a principles document in this area. The proposed work would consider revisions to the existing guidance. Standardization in the area of traceability/product tracing that is inclusive of new and emerging approaches will help facilitate communication between trading partners.

(e) Consideration of the global magnitude of the problem or issue.

Increases in global trade, the complexity of supply chains, and digitization of information along with technologies to facilitate the integrity and sharing of such information suggest it would be timely to revisit the *Principles for Traceability/Product Tracing as a Tool Within a Food Inspection and Certification System* (CXG 60-2006) to ensure their scope and content are fit for purpose, e.g., contain relevant and up-to-date good practice considerations on regulatory and industry practices.

5. Relevance to the Codex strategic objectives

The proposed work is directly related to the purposes of the Codex Alimentarius Commission. Namely, goals one and five of the Codex Strategic Plan 2020-2025, to "Address current, emerging and critical issues in a timely manner" and to "Enhance work management systems and practices that support the efficient and effective achievement of all strategic plan goals." This work is relevant to Strategic Objective 1.2, "Prioritize needs and emerging issues."

6. Information on the relation between the proposal and other existing Codex documents as well as other ongoing work

In addition to the existing guidance, *Principles for Traceability / Product Tracing as a Tool Within a Food Inspection and Certification System* (CXG 60-2006), this work will consider existing Codex texts such as *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CXG 19-1995), *Principles and Guidelines for National Food Control Systems* (CXG 82-2013), and *Principles and guidelines for the exchange of information between importing and exporting countries to support the trade in food* (CXG 89-2016), and the *General Principles of Food Hygiene* (CXC 1-1969).

7. Identification of any requirement for and availability of expert scientific advice

Not required.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

Not required at this time

9. Proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

Subject to the Codex Alimentarius Commission approval at its 46th Session in 2023, the goal is to complete the new work in two CCFICS sessions or three years, depending on the future schedule of CCFICS meetings.

APPENDIX V

PROPOSED DRAFT CONSOLIDATED CODEX GUIDELINES RELATED TO EQUIVALENCE (HOLD AT STEP 4)

SECTION 1: PREAMBLE

- 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.
- 3. The recognition of equivalence may facilitate trade through reducing the need for exporting countries to implement 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 consolidate and update [and replace] 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 Principles and Guidelines for National Food Control Systems (CXG 82-2013) 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

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

SECTION 3: SCOPE

7. The guidance covers 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

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 relevant 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 consider 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 or any subsequent assessment should focus on those products and conditions affecting trade where the exporting country considers the specific measure, its NFCS, or relevant part of NFCS already achieves the same objectives, and related outcomes or level of protection as achieved by the importing country.

Alignment with International Standards

e. The use of or reference to Codex standards, guidelines and/or codes of practice, or other relevant international standards by importing and exporting countries can facilitate the consideration, assessment and recognition of the equivalence of a specific measure, NFCS, or the relevant part.

Transparency and co-operation

f. Importing and exporting countries should work through the process in good faith, in a reasonable timeframe and in a transparent, evidence-based and outcome-focused manner.

Demonstration of Equivalence

[f (bis) The obligation to objectively demonstrate equivalence rests with the exporting country, the importing party should ensure their specified measures are only applied to the extent necessary to achieve their level of protection.]

Documentation and maintenance

g. Importing and exporting countries should document 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, where feasible, providing technical assistance to an exporting developing and in particular least developed countries, to facilitate the assessment and recognition of equivalence.