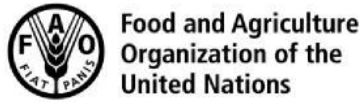


CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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

CL 2022/59-FICS
September 2022

TO: Codex Contact Points
Interested International Organisations

FROM: Secretariat, Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme

SUBJECT: **Request for Comments on a New Work Proposal for the Development of Principles and Guidelines on the Use of Remote Audit and Verification in Regulatory Frameworks**

DEADLINE: **14 October 2022**

COMMENTS: **To:** Australian Codex Contact Point
Email: codex.contact@agriculture.gov.au

Copy to: Codex Secretariat
Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme
E-mail: codex@fao.org

1. The 25th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS25) considered a paper, [CRD06](#), prepared by Australia on the use of information and communication technologies (ICT) tools in regulatory frameworks. The purpose of this proposal was to consider the need for Codex guidance on the use of ICT tools for alternative verification as part of modern regulatory frameworks. It was noted the issue had become ever more important during the COVID-19 pandemic which had altered the trading landscape and accelerated the development and utilization of alternative verification measures and an increased uptake of new technologies.
2. CCFICS25¹ agreed to establish an Electronic Working Group (EWG), chaired by Australia and co-chaired by Singapore and Canada, to develop a discussion paper on "Use of remote audit and verification in regulatory frameworks" with the possibility of also developing a new project document based on the input from CCFICS25.
3. To assist with the development of the discussion paper, the EWG chairs sought input from EWG members on the scope of the potential new work through a series of targeted questions seeking to gather information on members' experiences, objectives and priorities in relation to remote audit and verification, with two rounds of consultation on the discussion paper and a round of consultation on the project document.
4. Further, on 21 June 2022, Australia hosted a thematic session under the World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) Committee, which focused on the Use of Remote (Virtual) Audit and Verification in Regulatory Frameworks. The CCFICS Chairperson, Nicola Hinder PSM, delivered an update on the EWG work and moderated two panel sessions which focused on the benefits, challenges and opportunities for the use of remote audits. There was strong support from participants at the thematic session for the development of guidance under CCFICS. Recordings of the thematic session are available from the WTO website: https://www.wto.org/english/tratop_e/sps_e/thematic_session_21jun22_e.htm.

¹ REP21/FICS paragraphs 107-109, and 114(iv)

5. On 28 June 2022, the CCFICS Chairperson distributed a letter to Codex Members and Observers that outlined an expedited process for submitting the proposal for new work on remote audits in line with Codex procedures. The letter outlined that the discussion paper and project document for the new work proposal would first be circulated to all Codex Members and Observers via a Circular Letter (CL) for comments. The project document, amended as need be, would then be submitted for critical review by CCEXEC83 (November 2022), with a view to approval of the new work by CAC45 (November 2022).
6. The outcomes of the EWG are provided for Codex members and observers' consideration, the discussion paper in **Appendix A** and the project document in **Appendix B**.

REQUEST FOR COMMENTS

7. Codex Members and Observers are invited to consider **Appendix A** (discussion paper) and **Appendix B** (new work proposal) and provide comments on the following:
 - Whether Codex should undertake new work to develop principles and guidelines on the use of remote audit and verification in regulatory frameworks.
 - Provide comments on the project document (Appendix B) in line with the Codex Procedural Manual, pages 31 and 43 (Criteria for the Establishment of Work Priorities).
8. Comments should be submitted to the email addresses indicated above by **14 October 2022**.

DISCUSSION PAPER ON GUIDANCE ON THE USE OF REMOTE AUDIT AND VERIFICATION IN REGULATORY FRAMEWORKS

(Prepared by an Electronic Working Group (EWG) chaired by Australia, and co-chaired by Singapore and Canada)

1. Introduction

Discussion on the use of alternative tools for assessment activities for international trade and within National Food Control Systems (NFCS) occurred during the 25th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS25) (Virtual, May 31 – June 8, 2021). The Delegation of Australia presented Conference Room Document CRD 06 which described the uptake of alternative technologies to support the conduct of audits and inspections during the COVID-19 pandemic to allow competent authorities to conduct food safety assessment activities within NFCS. It was also identified that importing countries were starting to use technology to conduct remote audits or inspection of food facilities within exporting countries due to the international travel restrictions associated with the COVID-19 pandemic.

Given this rapid uptake, Australia suggested there was a need for Codex to consider developing guidance for application by competent authorities in situations where it was agreed that the use of technology would support and enable the use of alternative assessment tools (such as remote audit or inspection). Guidance would support the consistent application/use of alternative tools in assessment activities that protect the health of consumers and at the same time promote fair practices in the food trade.

During the discussion of CRD06, Members suggested there may be a problem with the consistent application of alternative assessment, with particular reference to remote audit and verification. There may be gaps within current Codex texts, which if resolved could help Members in their use of these assessment and assurance tools. Given the current uptake of remote audit and verification by several importing countries and application to exporting countries, it was agreed this work was timely and urgent to fulfil the Codex mandate.

The Committee agreed to establish an EWG, chaired by Australia and co-chaired by Singapore and Canada. This EWG was tasked to develop a discussion paper on “Use of remote audit and verification in regulatory frameworks” with the possibility of also developing a new work proposal based on the input from CCFICS25 for consideration by CCFICS26.

To assist with the development of the discussion paper, the EWG chairs sought input from Members on the scope of the potential new work through a series of targeted questions seeking to gather information on Members’ experiences, objectives and priorities in relation to remote audit and verification. The set of questions asked of Members is included at **Appendix one**.

Responses to these questions were received from 14 members of the EWG.¹

Key learnings and experiences outlined by Members in their responses have been incorporated and summarised throughout the discussion paper below.

2. Background

The COVID-19 pandemic has altered the trading landscape, with the closure of international and national borders. In some countries there has been a need to accelerate the development and uptake of alternative tools to carry out assessments of NFCS. The use of information and communication technologies (ICT) have been critical in the application of these tools and competent authorities have begun to experiment with a range of technologies to assist them in undertaking assessments of NFCS.

These alternative tools will be equally critical to regulators and food business operators in the post-COVID19 pandemic world and the pace at which these developments are occurring necessitates the importance of the Codex members working together to ensure consistency in understanding and approaches. Risk analysis must be applied when considering how to regulate for food safety and the use of alternative or traditional practices with targeting of resources to higher risk aspects allowing efficient allocation of resources, whilst minimising impacts to trade.

¹ Canada, China, the European Union, Japan, Malaysia, Mexico, Morocco, New Zealand, Peru, the Republic of Korea, Spain, United Kingdom, the United States of America and Uruguay.

Analysis and learnings from shared experiences

Discussions at CCFICS25 and responses to the survey questions circulated amongst the EWG Members, highlighted that there is a broad range of experiences amongst countries in the use of alternative tools, such as remote audit and verification as well as the use of ICT. Whilst a number of countries had some experience using alternative tools for assessment and verification activities prior to the COVID-19 pandemic, it is evident that the pandemic provided a catalyst for most countries to move in this direction. Of 14 EWG Members that responded to the survey questions, 9 (64%) had not used alternative tools in this context prior to the pandemic. However, all respondents had begun to use, or had been requested to use, alternative tools in this context in response to movement restrictions imposed in response to COVID-19.

EWG members outlined that there are a number of benefits available from the use of alternative tools as well as several challenges.

Benefits identified from the use of remote audit include: reduced costs and time from travel, reduced impacts from COVID-19 movement restrictions, easy to share evaluations and documents among stakeholders, more participants are able to be involved, ability to record audits to be able to re-watch, ability to divide audits into several sessions rather than devoting entire days, more privacy for auditors to have discussions, lowered exposure risk to contracting COVID-19 and environmental benefits such as reduced use of paper.

Challenges identified from the use of remote audit and verification include: network/connection issues, compatibility of different ICT platforms, time zones, language barriers and added time inefficiency when consecutive translation is used versus simultaneous, communication interference such as loud background noise or wind, IT security policies, increased preparation required in terms of presenting documentation, some countries lack a specific regulatory framework/don't have flexibility within their existing regulatory framework, lack of specific training for remote audits, inability to use all senses e.g., smell to detect pests or instincts to read body language, and a limitation of information when compared to physical inspections/audit i.e. not able to access the same level of detail/areas as auditors may be dependent on what the person holding the camera shows.

Responses to the questions also highlighted that EWG Members do not believe that the use of remote audit and verification should replace conventional procedures but should be considered in the context of a supplemental tool in verification practices. Some responses also outlined the need to distinguish between the use of remote audit and verification in a countries' NFCS versus the use for third country assessments of a trading partner's NFCS.

Scope

The discussions at CCFICS25 considered the use of alternative assessment tools within NFCS and across borders for the verification of assurances about food being traded between countries. While tools to support remote audit may be similar for both cases, there are additional considerations required when applied to cross border trade.

It was identified that the scope of the discussion paper and proposal for new work needs to acknowledge that remote audits should not be approached as a replacement for conventional procedures but should be considered as an additional tool in verification practices, depending on the circumstances.

Given this feedback from the EWG, the scope of the new work should include the use of remote audit and verification in regulatory frameworks for both domestic assessments of NFCS as well as assessments of a third country's NFCS (i.e. cross border trade). However, there may be a need to differentiate between the two scenarios as there are unique characteristics in each.

Considerations

This discussion paper recognises the importance of remote audit and verification in supporting regulatory frameworks, whilst also acknowledging the benefits and barriers to uptake. Considering the increased use of alternative assessment tools, it is important to have agreed principles and guidance for their application.

In undertaking this work and recognising that different countries will have different needs and capacities, some of the considerations associated with the use of remote audit and verification, which could be addressed include:

- the need for agreement on principles for use of alternative/additional assessment tools to provide assurances for importing countries and to ensure predictability for the exporting countries and facilitate international trade in food, including that the frequency of such audit or inspection should be no more than that required to provide the relevant assurances.
- the level of ICT infrastructure and connectivity available to food business operators.

- the need to consider Intellectual Property (IP) and staff privacy concerns or legal requirements relating to the identification of individuals. These could result in limited exchange of data between two countries during foreign audits of NFCS, thereby limiting the overall scope.
- communication and interpretation/translation issues, especially where different languages are used.
- ensuring all auditors sufficiently understand the broader NFCS context in the exporting country.
- the need for an agreed scope or interpretation of standards, especially with respect to how a required outcome may be achieved.
- getting the balance right between the exporting country providing an appropriate overview of its NFCS controls, followed by the importing country reviewing a selection of national and establishment records, coupled with a selection of ICT enabled (photographs, recordings or live streaming) checks where needed.
- ensuring that practices and considerations for food business operators and competent authorities adapt with technology as it evolves over time.
- the need for an agreed plan and audit scope between parties, including timeframes, requirements, and logistical considerations.

Some of these considerations are not unique to alternative assessment methods and Codex already has some guidance and principles that partially cover some of these aspects.

Members of the EWG were in general supportive of these considerations. They also highlighted that these considerations serve an important purpose of ensuring that remote audit and verification activities are conducted in a transparent and consistent manner and not unnecessarily restrictive to trade. The use of remote audit and verification should facilitate trade and may contribute to a reduction in compliance costs for industry and government.

Members also reiterated that a number of principles and considerations applied equally to physical audits and remote audits, specifically that auditors should have an understanding of the NFCS context in the exporting country and the difficulties faced through language barriers.

3. Scope for preliminary assessment of CCFICS texts

The scope of the preliminary assessment of CCFICS texts included all principles and guidelines developed by CCFICS, in line with the mandate of the EWG. Existing CCFICS texts that were reviewed by the Co-Chairs of the EWG included the following documents:

Principles for Food Import and Export Inspection and Certification (CXG 20-1995)

Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems, including the Annex: Principles and Guidelines for the Conduct of Assessments of Foreign Official Inspection and Certification Systems (CXG 26-1997)

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

Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to support the trade in food (CXG 89-2016)

Principles and Guidelines for Monitoring the Performance of National Food Control Systems (CXG 91-2017)

Guidelines for Food Import Control Systems (CXG 47-2003)

Comments solicited through the first draft of the discussion paper demonstrated that the Co-Chairs had captured most applicable CCFICS texts that should be included for review by the EWG, with the additional inclusion of Guidelines for Food Import Control Systems (CXG 47-2003). The Co-Chairs note the request to include the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CXG 53-2003). At this stage, it was not considered appropriate to include CXG 53-2003 in the analysis of texts as there is existing work in CCFICS which will result in review of this guidance. The Co-Chairs acknowledge the recommendation to include the World Health Organization (WHO) and Food and Agricultural Organization of the United Nations (FAO) revised 'COVID-19 Guidance for preventing transmission of COVID-19 within food businesses (updated guidance). However, noting that the scope of the assessment was Codex texts it was not considered appropriate to include review of this guidance as it was developed outside the scope of Codex. The Co-Chairs also do not consider the recently adopted Guidance on Paperless Use of Electronic Certificates (Revised Guidelines for Design, Production, Issuance and Use of Generic Official Certificates (CXG 38-2001) to be within scope or relevant to this work.

4. Preliminary analysis of existing CCFICS texts

Existing texts may require minor amendments for where a specific reference to application of remote audit and verification, may improve clarity that the same guidance or principles apply in these situations, for example, where the term “on-site” is used in the context of audits.

To address the use of alternative assessment tools within a NFCS and for cross border trade, the EWG considers that development of specific guidance will complement the existing Codex texts. Such guidance would assist with consistent application and use of alternative verification tools and clarify when it is appropriate to utilise them.

Members of the EWG supported the inclusion of examples of CCFICS texts in this discussion paper. These are included in **Appendix two**. The Co-Chairs agree that principles in existing texts should generally not require updating and any amendments to existing texts could be considered further once the guidance was further developed.

5. Development of complementary guidance to CCFICS texts

While some of the existing CCFICS texts may only require minor amendment, if required at all, to satisfactorily capture the use of remote audit and verification, it would be valuable to develop complementary guidance on the application of alternative assessment tools.

As alternative assessment tools may be used for two situations, within a country's NFCS and/or the assessments of an exporting country's NFCS, some of the considerations that need to be taken into account may differ. Development of specific guidance could include principles and/or guidelines for how these tools are applied both within NFCS and for cross border trade, where use of these tools is appropriate.

The main pieces of existing CCFICS texts cover the activities of assessment, such as audit or inspection procedures and assessment of National Food Control Systems.

Nevertheless, there is a need for CCFICS to initiate new work in this area to provide guidance on the use of remote audit and verification by competent authorities to keep pace with emerging technologies and practices.

Comments received from the EWG overall supported the need for complementary guidance on remote audit and verification within NFCS. Two Members raised that the core principles and processes already exist with respect to conducting assessments of an exporting country's NFCS and remain valid to both remote and onsite assessments. One Member questioned whether standalone guidance is needed or whether concepts could be incorporated into existing guidance. It was noted by several Members that the need for guidance was accelerated by the COVID-19 pandemic, however there are future benefits to developing guidance, including more efficient use of competent authority resources. It was also noted that international guidance will support consistency and harmonisation of practices and implementation.

Members also raised the importance of emphasising that remote techniques are one tool available to competent authorities in a modern food control system and it does not eliminate nor replace the option for physical assessment activities.

6. Conclusion

- i. The new work proposal will be presented to CCEXEC83 and CAC45 for consideration to develop complementary guidance and principles where necessary on the use of technology to support remote audit and verification, within NFCS and for verifying the performance of a NFCS, or its parts, for cross border trade.
- ii. CCEXEC83 and CAC45 to consider establishment of an electronic working group to:
 - prepare the proposed draft Codex guidance and/or principles on remote audit and verification, for discussion at Step 2/3 at CCFICS26.

Questions posed to EWG Members to inform development of the discussion paper**QUESTION 1:**

- A) *Did you use ICT to undertake assessments of national food control systems (NFCS) before COVID-19?*
- B) *Have you used, or been requested to use, ICT to enable the conduct of assessments in response to the COVID-19 environment (restrictions of movement)?*
- C) *If you use ICT, is it applicable to:*
 - a. *Inspection/audit of the NFCS only, i.e., at the domestic/national level; or*
 - b. *Inspection/audit of exporting country controls only; or*
 - c. *Both NFCS and assessment/verification of exporting controls?*
- D) *What benefits have been identified for the use of ICT?*
- E) *What challenges/problems have you identified with the use of ICT? For example, were there challenges with legislation to support these approaches*

QUESTION 2:

- A) *Do the EWG Members see value in having the scope of the document focus on the use of ICT for:*
 - i. *Assessment of the NFCS, or part thereof, at the domestic/national level only; or*
 - ii. *Assessment of exporting country controls only, or*
 - iii. *Both NFCS and assessment of exporting controls?*

Please include a rationale with your response to i, ii and iii.

Are there any other considerations on the scope of this document, related to the use of remote audit and verification in food regulatory systems?

QUESTION 3:

- A) *Does the EWG consider there to be additional CCFICS texts that should be included or should any of the above be excluded? Please include your suggested additional texts and a rationale for exclusion/inclusion of any texts.*

QUESTION 4:

- A) *Does the EWG agree that the discussion paper include examples of CCFICS texts that identify gaps or potential contradictions such as the following example? If you agree, do you have any additional content/texts to add? If you disagree, please explain why?*

Please note: The co-chairs will develop the preliminary analysis of Codex texts for the EWG's endorsement during the second round of consultation.

QUESTION 5:

- A) *Do these paragraphs make a strong enough case for the development of guidance? If not, what additional justification should be given?*

QUESTION 6:

- A) *Do you agree with the general content and steps outlined below? Are there any important aspects that should be added to the conclusion? If so, please explain.*

Placeholder for recommendations/conclusions – will be modified based on EWG feedback

Co-Chairs' note: Draft recommendations are presented below and will be revised based on the feedback from EWG Members.

QUESTION 7:

- A) *Do EWG Members have any additional comments on this discussion paper?*

Appendix 2

Preliminary analysis of CCFICS text

In undertaking the analysis of these texts the EWG took into consideration whether there would be a need to amend the definitions for *audit* and *inspection* to add specific reference to remote or physical – the EWG is of the view that the issue of definitions should be encompassed in the development of the principles and guidelines once the new work has been approved and work has commenced. This would be in line with previous practice of the committee to not waste time deliberating over definitions until such time as the guidance is sufficiently well developed and a more detailed understanding of the context of the guidance is in hand.

CCFICS Text	Section/Paragraph	Current Wording	Revised Wording	Comment/consideration
Principles for Food Import and Export Inspection and Certification (CXG 20-1995)	Section 1 - Introduction	<p>2. Inspection of food may occur at any stage in the production and distribution process. For some foods, inspection oversight of harvesting, processing, storage, transport, and other handling of product may be the most appropriate means of ensuring food safety. According to the methods of preservation used, it may be necessary to maintain inspection oversight on a continuous basis up to the time of retail sale. Inspection systems may be focused on the foodstuffs themselves, on the procedures and facilities employed in the production and distribution chain, on the substance and materials which can be incorporated into or contaminate foodstuffs.</p> <p>3. Inspection should be carried out at the most appropriate stages (e.g. control of refrigeration at every stage of the cold chain). For some requirements, eg those pertaining to product description, it may be possible to limit inspection to the distribution process and prior to final sale.</p>	N/A	Amendments to this text are not recommended since the text as written would not contradict with any guidance on remote audit.
	Section 2 – Definitions	Audit is a systematic and functionally independent	N/A	Co-chairs recommend that CCFICS consider the definition in the context

CCFICS Text	Section/Paragraph	Current Wording	Revised Wording	Comment/consideration
		examination to determine whether activities and related results comply with planned objectives.		of its discussion once the new work is at a more advanced stage.
		Inspection is the examination of food or systems for control of food, raw materials, processing, and distribution including in-process and finished product testing, in order to verify that they conform to requirements.	N/A	Co-chairs recommend that CCFICS consider the definition in the context of its discussion once the new work is at a more advanced stage.
	Section 3 - Principles	16. Upon request by the competent authorities of the importing countries, the exporting countries should provide access to view and assess the actual working of their relevant inspection and certification systems.	N/A	Amendments to this text are not recommended since the text as written would not contradict with any guidance on remote audit.
	Section 3 - Principles	18. Importing countries should complete without undue delay any procedures necessary to assess compliance with requirements. Information requirements and any fees imposed by importing countries should be limited to what is reasonable and necessary.	N/A	Amendments to this text are not recommended since the text as written would not contradict with any guidance on remote audit.
	Section 3 - Principles	19. Countries that certify exports of food and those importing countries which rely on export certificates should take measures to assure the validity of certification. Validation measures by exporting countries may include achieving confidence that official or officially recognised inspections systems have verified that the product or process referred to in the certificate conforms with requirements.	19. Countries that certify exports of food and those importing countries which rely on export certificates should take measures to assure the validity of certification. Validation measures by exporting countries may include achieving confidence that official or officially recognised inspections systems have verified that the product or process referred to in the certificate conforms with requirements. Measures by importing countries may include	Amendments to this text are recommended based on feedback through the EWG.

CCFICS Text	Section/Paragraph	Current Wording	Revised Wording	Comment/consideration
		Measures by importing countries may include point of entry inspection systems, audit of exporting inspection systems, and ensuring that certificates themselves are authentic and accurate.	point of entry inspection systems, audit of exporting inspection systems, and ensuring that certificates themselves are authentic and accurate. The validation measures by the exporting country should not preclude the use of remote audit or inspection to validate export certificates. The importing countries' measures should also consider, where appropriate, the use of remote audit of exporting inspection systems.	
Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems, including the Annex: Principles and Guidelines for the Conduct of Assessments of Foreign Official Inspection and Certification Systems (CXG 26-1997)	Section 5 – Equivalence	<p>12. The exporting country should provide access to enable the inspection and certification systems to be examined and evaluated, on request of the food control authorities of the importing country. Evaluations of inspection and certification systems carried out by the authorities of an importing country should take into account internal programme evaluations already carried out by the competent authority or evaluations performed by independent third-party bodies recognized by the competent authority in the exporting country.</p> <p>13. Evaluations of inspection and certification systems by an importing country for purposes of establishing equivalence should take account of all relevant information</p>	N/A	Paragraphs 12 and 13 do not preclude the use of remote access to facilitate the examination or evaluation and re-enforce the need to consider existing information held by either the importing or the exporting country.

CCFICS Text	Section/Paragraph	Current Wording	Revised Wording	Comment/consideration
	Annex – Section I – Introduction	<p>held by the competent authority of the exporting country.</p> <p>2. These assessment activities should concentrate primarily on evaluating the effectiveness of the official inspection and certification systems rather than on specific commodities or establishments in order to determine the ability of the exporting country's competent authority(s) to have and maintain control and deliver the required assurances to the importing country. A number of tools are available for the conduct of an assessment of an exporting country's official inspection and certification system these include, but are not limited to, audits, inspections and visits. The level of experience, knowledge and confidence the importing country has in the exporting country's official inspection and certification system is important in determining the appropriate tool to undertake the assessment, including whether a visit to the country is required.</p>	N/A	Amendments to this text are not recommended, the annex provides additional guidance on the conduct of assessments and is complementary to Section 9 of this guideline document. The annex is not intended to mandate the use of assessments but to provide guidance that should be taken into account when they are used.
	Section 5 – Assessment Process	Assessment Preparation 34. A plan for undertaking the assessments, including the assessment tool, timeframes and exchange of required information should be prepared and communicated to the exporting country's competent authority within a reasonable period of time. The plan should include the following:		The preamble might refer to a step in the planning process that will be used to determine the assessment tool to be used and whether it could include considering whether a remote audit would meet the objective of the assessment. Amendments to points g) and i) are shown below.

CCFICS Text	Section/Paragraph	Current Wording	Revised Wording	Comment/consideration
		<p>34. g) an indication of the type or where possible/relevant the identity of locations to be visited (e.g. offices, laboratories or other facilities) and the timing and responsibility for the notification to the sites where necessary (although this task may be completed at the assessment opening/entry meeting);</p> <p>i) travel schedules and other logistics, as necessary for an assessment visit; and</p>	<p>g) where it has been mutually agreed on the type of assessment required, an indication of the type or where possible/relevant the identity of locations to be visited (e.g. offices, laboratories or other facilities) and the timing and responsibility for the notification to the sites where necessary (although this task may be completed at the assessment opening/entry meeting);</p> <p>i) where relevant, the travel schedules and other logistics, as necessary for an assessment visit; and</p>	<p>Proposed wording to accommodate for circumstances where as mutually agreed by parties, remote audits may be considered as meeting the objective of the intended assessment.</p> <p>Amendments to this text are recommended based on feedback from the EWG.</p>
	Section 5 – Assessment Process	38. d) When an on-site visit is the assessment tool proposed a review of documents describing the system including legislative support should be conducted prior to commencement of the assessment visit. This is to allow the most efficient and effective use of time spent on-site i.e. to reduce the burden of assessments on the competent authorities of both countries.	38. d) Whether the assessment proposed is to be conducted as a remote or as an onsite visit, When an on-site visit is the assessment tool proposed a review of documents describing the control system including legislative support should be conducted prior to commencement of the assessment visit. This is to allow the most efficient and effective use of time spent during the assessment i.e. to reduce the burden of assessments on the competent authorities of both countries.	Amendments to this text are recommended based on feedback from the EWG.
	Section 5 – Assessment Process	42. In the case of an assessment involving a visit an opening or entry meeting should be held. a) The meeting should be held at a place designated by the competent authority of the exporting country.	42. In the case of an assessment involving a remote or on-site visit, an opening or entry meeting should be held. a) The meeting should be held at a time (and place if relevant) designated by the competent authority of the exporting country.	This should apply equally to a remote audit - an entry or opening meeting conducted virtually will ensure that both parties understand the manner in which the assessment will be conducted.

CCFICS Text	Section/Paragraph	Current Wording	Revised Wording	Comment/consideration
				Amendments to this text are recommended based on feedback from the EWG.
	Section 5 – Assessment Process	<p>43. In the case of an assessment involving a visit a closing or exit meeting should be held.</p> <p>a) The meeting should be held at a place designated by the competent authority of the exporting country.</p> <p>b) The assessment team should summarize main findings and preliminary conclusions. Any non-conformities should be identified and outline the objective evidence to support the conclusions. Correction of non-conformities should be left to the competent authority of the exporting country and verified by the competent authority of the importing country including a follow-up assessment if required.</p> <p>c) This meeting provides an opportunity for the competent authority of the exporting country to raise questions or seek clarification of the findings and observations provided at the meeting.</p>	<p>43. In the case of any type of assessment (involving a visit or conducted remotely), a closing or exit meeting should be held.</p> <p>a) The meeting should be held at a time (and place if relevant) designated by the competent authority of the exporting country.</p> <p>b) The assessment team should summarize main findings and preliminary conclusions. Any non-conformities should be identified and outline the objective evidence to support the conclusions. Correction of non-conformities should be left to the competent authority of the exporting country and verified by the competent authority of the importing country including a follow-up assessment if required.</p> <p>c) This meeting provides an opportunity for the competent authority of the exporting country to raise questions or seek clarification of the findings and observations provided at the meeting.</p>	<p>This should apply equally to a remote audit. Where the assessment is conducted remotely the closing or exit meeting may take place after the importing country has had sufficient time to review the documents/video etc and make its report.</p> <p>Amendments to points 43 and 43 a) are recommended based on feedback from the EWG.</p>
Principles and Guidelines for National Food Control Systems (CXG 82-2013)	Section 4.2 System Design	<p>53. Control programs should be designed to include the following elements but not limited to:</p> <ul style="list-style-type: none"> • Inspection, verification and audit including on-site visits; 	<p>53. Control programs should be designed to include the following elements but not limited to:</p>	<p>Minor amendment to account for remote audits.</p> <p>Amendments to this text are recommended based on feedback from the EWG.</p>

CCFICS Text	Section/Paragraph	Current Wording	Revised Wording	Comment/consideration
			<ul style="list-style-type: none"> • Inspection, verification and audit including remote and/or on-site visits; 	
	Section 4.2 System Design	59. <ul style="list-style-type: none"> • Reliable transportation systems and equipment to perform inspection, audit and verification services and transmission of samples to laboratories; and • Information, communication and technology (ICT) systems; 	N/A	
	Section 4.3 Implementation	71. <ul style="list-style-type: none"> • Operating procedures including methods of audit, verification, inspection and control, sampling plans, and testing; 	N/A	
	Section 4.3 Implementation	80. The competent authority should implement a range of food control activities, including inspections, audits, verification and surveillance to ensure that food business operators meet their responsibilities and are in compliance with requirements. Detailed procedures should be developed to articulate the key tasks and responsibilities of verification of compliance and the consequences of non-compliance, including repeated non-compliance.	N/A	Amendments to this text are not recommended since the text as written would not contradict with any guidance on remote audit.
	Section 4.3 Implementation	81. <ul style="list-style-type: none"> • Increased intensity of audits and/ or inspection and/or monitoring of products and/or processes; identified as being not in conformity and/or the undertakings concerned; and 	N/A	

CCFICS Text	Section/Paragraph	Current Wording	Revised Wording	Comment/consideration
	Section 4.4 Monitoring and System Review	90. The results of the evaluations, including the results of self-assessment and audits should also be taken into account in further improvement of the system, and corrective actions should be taken into account as appropriate.	N/A	
Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to support the trade in food (CXG 89-2016)				The scope of the document is information exchange and assessment of the information required prior to the commencement of trade and in that context the 'assessment' is a paper-based process based on information provided to the importing country by the exporting country ie through submissions or questionnaires. Therefore, there is no need to amend or further analyse this text.
Principles and Guidelines for Monitoring the Performance of National Food Control Systems (CXG 91-2017)	Section 3 – Definitions	24. Monitoring and system review requires sufficient financial and human resources with relevant expertise to support the collection and use of data. The following questions can help the competent authority to assess existing resources and technical capacity: What resources (financial, human, technical and material) are available to support monitoring and system review? How can existing resources be leveraged if necessary?	N/A	The existing text would allow for the consideration of the circumstances in which the monitoring and system review were taking place. There is probably no need for specific text on the use of alternative verification tools. Noting this standard is for application by competent authorities in monitoring the performance of their own NFCS.
Guidelines for Food Import Control Systems (CXG 47-2003)				There are a number of cross-references to other CCFICS texts in this guidance document. The EWG or the committee may wish to consider if

CCFICS Text	Section/Paragraph	Current Wording	Revised Wording	Comment/consideration
				amending those texts will reduce the need for specific amendments to this text. In the interests of preserving the original intention of the guidance and for clarity.
	Section 3 General Characteristics of Food Import Control para 3 - 5	Requirements for imported food that are consistent with requirements for domestic foods.		<p>This could be interpreted to include where relevant the use of the alternative verification/assessment tools such as remote audit. There does not appear to be a need to make specific suggestions to amend the text of this guideline.</p> <p>The guidelines provide a framework for the development and operation of an import control system and states that audits of the facilities and procedures of the exporting country may be conducted for the requirements of imported food that are consistent with requirements for domestic food. Therefore, use of alternatives could be considered as already covered.</p>

CCFICS Text	Section/Paragraph	Current Wording	Revised Wording	Comment/consideration
	Section 4 – Implementation of the control system	23. Physical checks of imported product, preferably using statistically based sampling plans, should represent valid methods for the verification of compliance with requirements by the product as established by the importing country, or in the case of importing a product for the purposes of re-exportation, verification should be made on the requirements of the country of final destination and said requirements should be specified in the certificate of re-exportation. Inspection procedures should be developed to include defined sampling frequencies or inspection intensities, including for re-exported product.	N/A	EWG considered that there is no alternative to physical checks in this situation.
	Appendix – Principles and guidelines for imported food inspection based on risk	6. second dash point The adequacy of processing controls in place in the exporting country as evidenced by its laws, regulations, and other policies; its infrastructure; and its ability to effectively enforce food safety requirements, as may be verified by audits and on-site visits by the competent authority of the importing country.	N/A	The wording of this text already appears to recognise that an audit does not necessarily mean it is the same as an on-site visit.
Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification	Section 5 – The context of an equivalence determination	13. b. programme design, implementation and monitoring; including documentation of systems, monitoring, performance, decision criteria and action, laboratory capability,		At this stage, it is not considered appropriate to include CXG 53-2003 in the analysis of texts as there is existing work in CCFICS which will result in review of this guidance.

CCFICS Text	Section/Paragraph	Current Wording	Revised Wording	Comment/consideration
Systems (CXG 53-2003)		transportation infrastructure and provisions for certification and audit; and/or		

PROJECT DOCUMENT**NEW WORK PROPOSAL FOR THE DEVELOPMENT OF PRINCIPLES AND GUIDELINES ON THE USE OF REMOTE AUDIT AND VERIFICATION IN REGULATORY FRAMEWORKS****1. Purpose and Scope of the Standard**

The purpose of the work is to develop guidelines and principles where necessary to assist competent authorities in the use of remote audit and verification of regulatory frameworks activities for international trade and within National Food Control Systems (NFCS), which complement existing practices.

The intended scope of the guidance covers both the use of remote audits and verification within a country's NFCS and/or the assessments of an exporting country's NFCS, or a relevant part thereof. However, there will be a need to differentiate between the two scenarios as there are unique characteristics in each and principles for international audit already exist.

2. Relevance and Timeliness

The COVID-19 pandemic and associated movement and travel restrictions has resulted in national competent authorities using alternative mechanisms to gain the necessary assurances that their NFCS are operating in accordance with their own requirements, as well as being able to continue to provide agreed assurances to their trading partners. Similarly, importing countries have started using remote mechanisms to undertake audits of the NFCS of trading partners, where these are required.

Given the rapid uptake of remote audit and verification approaches during the pandemic and the likelihood of the ongoing use of these approaches, there is an important need for the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) to develop guidance for competent authorities on the use of remote audit and verification to promote harmonization of approaches, transparency, and consistency.

Such guidance would supplement and complement the existing CCFICS guidance on the conduct of physical audits and verifications and support the consistent application/use of such alternate mechanisms in the provision of assurances with respect to the protection of the health of consumers and the promotion of fair practices in the food trade.

Remote audit and verification practices, while presenting some challenges, can offer significant benefits to competent authorities and food businesses whilst also providing an appropriate level of national competent authority oversight. Such tools can also ensure continuity of verification and audit when physical visits are not practical for a range of reasons.

While the fundamental principles of audits and verification (as articulated in the Annex to CXG 26-1997) are likely to largely remain the same, practical guidance covering the specific implementation of these principles in remote situations will help national competent authorities adapt and continue to evolve their audit and verification systems as these practices and technologies continue to develop.

3. Main aspects to be covered

The new work is intended to provide guidelines and principles where necessary, on processes to guide competent authorities when conducting a remote audit and/or verification activity. The new work will cover the preparation and use of remote audits and verifications, including as appropriate practical guidance on the use of information and communication technologies (ICT) where this is needed. The guidance will not mandate the use of any specific type of ICT, taking into account the different ICT infrastructure and capabilities of food businesses and Codex members, but will provide guidance on selection of the most appropriate tool, taking into consideration the relevant circumstances.

The new work will also consider the differences that may be applicable to the remote audit and verification of a country's own NFCS versus the use of remote audits in the assessment of an exporting country's NFCS.

In developing this guidance CCFICS would include consideration of the use of ICT as a valid regulatory tool to enable remote audit or verification, noting that it is part of a range of tools available to a competent authority for verifying systems. The guidance will also aim to highlight that the use of remote audit and verification may contribute to a reduction in compliance costs for industry and national competent authorities and help to facilitate trade and improve the flow of goods across borders.

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 competent authorities in the implementation of NFCS, in particular to provide additional tools for audit and verification activities, both at the domestic level and in international trade. It would enable better targeting of resources to greater risk scenarios, thus meeting the general criterion of consumer protection and will also promote consistency and harmonization of approaches between countries, thus facilitating trade while enhancing food safety.

Criteria applicable to general subjects

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

The lack of international guidance on the use of remote audit and verification will lead to diverging approaches at the national level, and a degree of confusion as to what may be acceptable practices. Additional guidance by Codex might assist countries in amending their legislation to support the use of remote audit and verification approaches, when traditional practice has generally been focused on in person approaches.

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

Please refer section one which includes a reference to the scope of the work. During the development of the guidance, it may become necessary to prioritize development of harmonized guidance on use of remote audit and verification for international audits and to adjust timelines for development of guidance on the use of such approaches within a country's NFCS.

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

There is some work in the area of remote audit and verification within the International Accreditation Forum (IAF) and the International Organization for Standardization (ISO).

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

The subject is amenable to standardization and CCFICS25 has expressed strong support for the work. There are existing Codex guidelines on audit; however, there is a lack of international guidance that would support the use of remote audit and verification as an additional mechanism within the regulatory toolkit.

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

The COVID-19 pandemic has accelerated the uptake of remote audit and verification tools both at the domestic level and in support of international trade. The absence of international guidance on the use of remote audit and verification leads to variable approaches, inconsistencies and confusion as to what may be acceptable practices. Codex guidance on remote audit and verification is an essential contribution to global standardization of audit practices in NFCS.

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". In particular, this work is relevant to Strategic Objective 1.2 "Prioritize needs and emerging issues" where the outcome is "Timely Codex response to emerging issues and the needs of members". This work will address the gap in guidance on the use and consistent application of remote audit and verification systems.

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

The development of specific guidelines and principles where necessary, on the use of remote audit and verification in regulatory frameworks will complement existing CCFICS texts. This includes the *Principles for Food Import and Export Inspection and Certification* (CXG 20-1995) and the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems, including the Annex: Principles and Guidelines for the Conduct of Assessments of Foreign Official Inspection and Certification Systems* (CXG 26-1997). Specific guidance will assist with consistent application and use of alternative audit and verification tools and clarify circumstances where it is appropriate to utilize them.

Existing CCFICS documents may require minor amendments where, for example, they contain a specific reference to physical assessment, audit or inspection, in order to improve clarity that the same guidance or principles apply in circumstances where it can be agreed that an alternative to onsite audits or inspections would be appropriate. The Electronic Working Group has already completed an initial assessment of relevant texts to assist the committee in this part of the work.

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 45th Session in 2022, it is hoped that the new work can be expedited (i.e. within two sessions of CCFICS).