

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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Organization

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Agenda item 7

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CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

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

(Report prepared by the Electronic Working Group chaired by Australia and co-chaired by Singapore, Canada and China¹)

(At Step 3)

Codex Members and Observers wishing to submit comments, at Step 3, on Appendix 1 of this proposed draft should do so as instructed in CL 2023/12/OCS-FICS available on the Codex webpage/Circular Letters 2023: <https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

INTRODUCTION & BACKGROUND

1. At its 20th Session in 2013, the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS20) recognised that emerging global challenges were impacting approaches and technologies relating to food safety controls and these trends were likely to continue.
2. The COVID-19 pandemic served as a catalyst for remote audit and inspection to support the continuity of the food supply chain. It also highlighted that these tools are likely to continue to be relevant to competent authorities and food businesses in the post-pandemic world.
3. During this time, national competent authorities adopted remote audit and inspection activities to gain necessary assurances that their National Food Control System (NFCS) operated in accordance with domestic requirements. Similarly, importing country competent authorities and auditing bodies have adopted these remote tools to undertake audits of the NFCS of trading partners.
4. At CCFICS25 in 2021, Australia presented a Conference Room Document (CRD) to the Committee on the use of information and communication technologies (ICT) 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. Australia recommended that the Committee consider new work and to establish an Electronic Working Group (EWG) to develop a discussion paper and the possibility of a new project proposal. Australia's proposal received strong support by the Committee, and it was agreed to establish an EWG chaired by Australia and co-chaired by Canada and Singapore, 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 for consideration by CCFICS26.
5. To assist with the development of the discussion paper, the Co-Chairs sought input from EWG Members on the scope of new work through a series of targeted questions to gather information on experiences, potential objectives and priorities in relation to remote audit and verification.

¹ Electronic Working Group participants/contributors: Argentina, Australia, Brazil, Canada, China, Chile, European Union, FIVS, France, Honduras, India, Islamic Republic of Iran, Japan, Malaysia, Mexico, Morocco, New Zealand, Norway, Peru, Republic of Korea, Saudi Arabia, Singapore, Spain, Sweden, United States of America.

6. There have been a series of developments on remote audit and verification in the international fora, which included the 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. There was strong support from participants at the thematic session for the development of guidance under CCFICS.²

- a. The Vienna Food Safety Forum was jointly hosted by the United Nations Industrial Development Organization (UNIDO), the Standards and Trade Development Facility (STDF) and the Australian Government. Here, UNIDO presented on survey data collected from the food industry and food safety authorities to build a stronger understanding on the use of remote audit and inspection.
- b. Similarly, the Organisation for Economic Co-Operation and Development (OECD) recently conducted a survey on the use of remote SPS auditing and inspection of food system and establishments in international trade.
- c. Across these forums, it was clear that various Governments and industry participants were strongly supportive of guidance to be development through CCFICS.

7. In light of the strong support for guidance across forums, on 28 June 2022 the CCFICS Chairperson distributed a letter to Codex Members and Observers that outlined a proactive 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, which was circulated on 12 September 2022.

8. Following feedback via the CL process, the Co-Chairs submitted the discussion paper and project document for critical review by the 83rd Session of the Executive Committee of the Codex Alimentarius Commission (CCEXEC83, November 2022). The 45th Session of the Codex Alimentarius Commission (CAC45, November 2022) approved the new work.

TERMS OF REFERENCE

9. CAC45:

- a. approved the new work proposal on the development of principles and guidelines on the use of remote audit and verification in regulatory frameworks by CCFICS;
- b. established an EWG under CCFICS, chaired by Australia and co-chaired by Canada and Singapore and working in English, French and Spanish, to prepare at Step 2 the Proposed draft principles and guidelines on the use of remote audit and verification in regulatory frameworks; and

10. Australia (the proponent) informed the committee that the scope of work would be further defined by the EWG as the work progressed.

11. Since CAC45, China has also joined as a Co-Chair of the EWG.

SUMMARY OF DISCUSSION

12. The Co-Chairs of the EWG on “Proposed draft principles and guidelines on the use of remote audit and inspection in regulatory frameworks” met virtually to discuss an initial draft document prepared by Australia. The draft document was discussed in depth with a focus on elements that required additional clarification over and above an audit or inspection conducted in situ.

13. The title of the document was considered, including whether audit and inspection was a more appropriate title than audit and verification. The EWG agreed that the proposal to change the title to “Draft principles and guidelines on the use of remote audit and inspection in regulatory frameworks” better captured the intent of the work proposal.

14. As a consequence of the name change, the Co-Chairs asked whether verification and assessment should also be included in the text with the EWG agreeing that the terminology was relevant and should be included carefully to avoid confusion in the use of such terminology.

15. The EWG was asked to consider the need for definitions in the document. Most respondents agreed that both audit and inspection were well defined in Codex and so those definitions would suffice and would not be redefined in the document to ensure its longevity. The EWG did, however, agree that the word “remote” should be defined to ensure it was used appropriately throughout the text.

² 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

16. Regarding the Scope of the work, the EWG agreed that there was a need to avoid confusion between activities undertaken. While it is reasonable to conduct an audit or inspection in its entirety as a remote exercise, in the current environment in-situ audits will most likely predominate and the guidance provided should acknowledge this.

17. Additional considerations in the planning and implementation included the costs of audits and the use of interpreters and responsibilities with the provision of similar services. These were thought to be covered in existing CODEX documents on conducting an audit or inspection and their inclusion in this document were considered not necessary. Focus was given to those activities which had additional requirements or considerations because of the audit or inspection being conducted remotely.

18. There was consensus in the comments from EWG participants that brief descriptions of how technology might be used would be of assistance to Members, hence their inclusion in sections of the document. However, it was generally agreed that a case study would not necessarily be of use as it would be restricted to the information and technologies available at the time of writing and would reduce the resilience of the document in the longer term.

CONCLUSIONS

19. The Co-Chairs of the EWG would like to acknowledge and extend appreciation to Codex Members and Observer organisations for their ongoing and continued support for the expedited development of work on this topic.

20. It is the view of the EWG Co-Chairs that given the strong interest in the work and feedback to date through both EWG forums, that the tasks as prescribed by CCFICS and CAC have been completed, including to develop a draft framework and the scope of a guideline, and content for the use of remote auditing and inspection in regulatory frameworks in line with the terms of reference as identified.

21. The Co-Chairs believe it is appropriate for CCFICS to continue the trajectory and recommend progress to Step 5 or Steps 5/8 in the step process.

RECOMMENDATIONS

22. Noting the significant amount of work completed to date and the support for the completion of that work, the committee is invited to:

- a. note the work undertaken to date and the level of support for this work; and
- b. consider recommending the advancement to Step 5 OR accelerated advancement to Step 5/8 of the proposed *Draft principles and guidelines on the use of remote audit and inspection in regulatory frameworks*, Appendix 1; and
- c. consider next steps of the EWG for further work, if required.

APPENDIX I**DRAFT PRINCIPLES AND GUIDELINES ON THE USE OF REMOTE AUDIT AND INSPECTION IN REGULATORY FRAMEWORKS****(At Step 3)****Section 1: Preamble/Introduction**

1. Remote audit and inspection activities, including verification and assessment activities, while presenting some challenges, can offer significant benefits to competent authorities and food businesses whilst also providing an appropriate level of effective national competent authority oversight. Such tools can also ensure continuity of audit and inspection regulatory activities when physical visits are not practical.
2. As technology continues to develop and offers increasing potential to undertake regulatory activities remotely, it is important for competent authorities and auditing bodies to be transparent and negotiate the use of such tools within the food supply chain. This remains true whether this concerns inspections or audits of food business operators by the competent authority responsible for their oversight or audits of competent authority oversight on food business operators performed in the context of systems audits by importing country competent authorities.
3. This guidance supplements current Codex texts when competent authorities and auditing bodies consider undertaking the whole or part of an audit or inspection, remotely. Relevant current texts include:
 - a. *Principles and guidelines for national governments for National Food Control System (NFCS)* (CXG 82-2013);
 - b. *Principles and guidelines for monitoring the performance of National Food Control Systems (NFCS)* (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); and
 - 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.

Section 2: Purpose / Scope

4. The purpose of this guidance is to assist competent authorities in the use of remote audit and inspection activities within their regulatory frameworks.
5. The scope of the guidance 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 NFCS and the assessment of an exporting country's NFCS, or a relevant part thereof.

Section 3: Definition

6. **Remote:** The auditor or inspector is not physically present at the site to be audited/inspected.

Section 4: Types of remote audit or inspection:

7. 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. Audit or inspection activities which can be conducted remotely, may include, but would not be restricted to:
 - a. **Live video-streaming:** Where a Food Business Operator (FBO) and/or exporting country competent authority representative will stream live video footage from a business facility and/or official facility as directed and guided by a competent authority representative to observe 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.
 - c. **Off-site desktop review of documentation:** Where a FBO and/or exporting country's competent authority will submit documentary evidence for review by a competent authority audit/inspection team to confirm required activities have been undertaken or testing results achieved. These data may be supplemented by photographic and/or video footage and are typically sent by electronic means such as email.

- 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 (usually within a competent authority jurisdiction).
- e. **Virtual interview:** Where an importing country competent authority or auditing body will conduct remote interviews with a FBO and/or the exporting country competent authority to assess compliance, understand systems and processes, and/or evaluate regulatory verification requirements.

Section 5: Principles

8. In deciding whether and when to use remote audit and inspection tools, competent authorities and auditing bodies should consider the following.

Principle 1: Remote audit and inspection activities complement and do not replace physical/in-person audits or inspections

9. Remote audit or inspection activities may be used as the sole regulatory tool for verifying compliance of a process, facility or NFCS or used in combination with physical/in-person practices. The use of this tool is at the discretion of the participating competent authorities or auditing bodies depending on their assessment of 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 and the remote nature of the exercise may result in incorrect conclusions being drawn on the compliance of the audited system/inspection facility.

Principle 2: Remote audit and inspection activity best practice aligned to physical audits and inspections

10. Relevant processes for conducting a physical audit or inspection will similarly apply to the remote process, such as notification of the need for an activity, explaining the audit criteria, the scope, standards being applied, assessment preparations, entry and exit meetings, the provision of feedback and draft reports for comment, and other activities as per best practice and international guidance.

Principle 3: Risk-based approach

11. Competent authorities should perform remote audit and inspection activities in a manner that is proportionate to risks posed. Consideration should be given to:

- the frequency of such audits or inspections ensuring that any increase in frequency because of the remote nature of the audit is justified; and
- that the scope of remote audits or inspection remains the same as if the physical audit was being conducted.

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

12. Planning and implementation of remote audit and inspection activities should consider the level of technology the FBO and/or exporting country competent authority has access to, to support the proposed activities. 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 are just a few elements that can impact the success of the remote activity.

Principle 5: Protection of confidential information

13. Information sharing during a remote audit or inspection is different to that during a physical audit or inspection and brings additional challenges. Video-streaming can be captured and shared, and documents presented or sent can be distributed or copied, all increasing the risk to the auditee's right to privacy and protection of intellectual property. Competent authorities should ensure the confidentiality of information/data in line with the relevant legal requirements in their countries. Parties must agree to handle personal and commercially sensitive material in a manner that provides protections and assurances to the auditee regarding confidentiality, including security of ICT access and information collection, storage and handling processes.

Section 6: Roles and Responsibilities

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

- 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. food businesses, and other competent authorities) on the information and communication technology requirements necessary for successful execution of the remote audit/inspection.
15. Entities to be audited or inspected have the role and responsibility to:
- a. Ensure they understand the availability of and have access to necessary technologies to facilitate remote audit and inspection activities when there is a stipulated reasonable requirement from a competent authority. They should clearly indicate their ability to engage in remote auditing or inspection, otherwise physical audit or inspection would be the preferred option.

Section 7: Planning and Implementation

16. While remote audit and inspection activities will generally follow steps that are similar to the physical versions of those activities, there are important considerations that will contribute to the successful implementation.

Planning

17. The following points should be taken into consideration when planning remote audit and inspection activities:

- a. **Frequency:** Competent authorities should not unnecessarily increase the frequency or duration of remote audit or inspection activities when compared to physical on-site audits or inspections.
- b. **Timing:** Where significant time zone differences exist between the location of the auditor and auditee, the hours of operation of the food business should be prioritized when establishing a time for conducting a remote audit or inspection to ensure that remote audit and inspection activities are delivered during standard operation hours.
- c. **Qualifications:** Officials or officially recognized bodies conducting the remote audit or inspection should be as appropriately qualified and competent as if conducting a physical onsite audit. There may be a requirement for proficiency in the application of any technologies used during the audit or inspection activity.
- d. **Technology:** Where the level of access to the technology required for remote audit or inspection is not adequate e.g. poor or limited videoconferencing connectivity, consideration should be given to:
 - i. Whether the adequate access to the relevant technology needed for a remote assessment is a reasonable requirement;
 - ii. Whether the use of technology remains as the most appropriate approach or whether other types of remote audit (e.g. desktop review of documentation) would be able to provide the required level of assurance;
 - iii. Whether technical assistance or support is appropriate for the food business operators and/or competent authorities in relation to infrastructure, connectivity, and access to technology;
 - iv. Testing of connections and remote 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 (e.g. loss of connectivity).

Implementation

18. The following should be considered during conduct of remote audit and inspection activities:

- a. **Protection of information:** Parties conducting remote audit and inspection activities should strive to gather information that can be shared freely without the need for secure channels of transmission. When it is necessary to gather information that is personal or commercially sensitive, the parties who conduct remote audit and inspection activities should arrange for secure lines of transmission of that data. Personal or commercially sensitive information should not be shared with any third party without the consent of the original owner and should be stored and destroyed in a secure manner when no longer required.

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- b. **Feedback:** Depending on the actual conditions, both parties may decide whether to include in the closing/exit meeting a discussion and review of the remote audit or inspection process. The auditing or inspecting party should provide its feedback in written form afterwards.
 - c. **Health and Safety:** Best practice work 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. 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.