For background information, please see CL 2023/50/OCS-FICS

Codex Members and Observers are invited to submit comments at Step 5/8 on the proposed Draft Principles and guidelines on the use of remote audit and inspection in regulatory frameworks. Comments should address whether the text is <u>ready for adoption or not</u>; and if not, provide the rationale and proposals to facilitate adoption. Comments should be provided in conformity with the Procedure for the Elaboration of Codex Standards and Related Texts (Part 3 – Uniform Procedure for the Elaboration of Codex Standards and Related Texts, Procedural Manual of the Codex Alimentarius Commission.

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 inspection¹ 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 supplements 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.

¹ Includes verification activities by competent authorities.

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.
 - 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:
 - i. 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.