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

Agenda Item 8

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

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INFORMATION DOCUMENT ON THE DEVELOPMENT OF PRINCIPLES AND GUIDELINES ON THE USE OF REMOTE AUDIT AND VERIFICATION IN REGULATORY FRAMEWORKS

This document compiles the primary information that was presented to CAC45 (2022) for consideration when approving the new work for the development of the proposed Principles and Guidelines on the Use of Remote Audit and Verification in Regulatory Frameworks. For purposes of this work (See Agenda Item 7) the approved project document is attached as Appendix on page 7.

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX ALIMENTARIUS COMMISSION
Forty-fifth Session
FAO Headquarters, Rome, Italy
21 – 25 November and 12-13 December 2022

Other matters related to Codex Subsidiary Bodies

(Prepared by the Codex Secretariat)

A. New work proposal for the development of principles and guidelines on the use of remote audit and verification in regulatory frameworks

1. The 25th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS25) considered a paper, prepared by Australia on the use of information and communication technologies (ICT) tools in regulatory frameworks as one of the global emerging issues. 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. CCFICS25 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. The kick-off message for the EWG was circulated on 20 August 2021 with a deadline for registration as 9 September 2021. The EWG worked in English, French and Spanish.
4. 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.
5. 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 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.
6. 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. In the letter, it was 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 CL for comments. The project document, amended as need be, would then be submitted for critical review by CCEXEC83, with a view to approval of the new work by CAC45 (November 2022).
7. A CL was issued on 12 September 2022 with the deadline of 14 October 2022 inviting Codex Members and Observers provide comments on whether Codex should undertake new work to develop principles and guidelines on the use of remote audit and verification in regulatory frameworks, and provide comments on the project document in line with the Criteria for the Establishment of Work Priorities of the PM.
8. Comments were received from 19 Members and 1 Observer organization, all supporting the new work proposal. Specific comments were addressed, and a revised work proposal is contained as Annex III.
9. CAC45 is invited to decide whether to approve the new work proposal or not, taking into account the recommendation of CCEXEC83.
10. If approved, CAC45 is requested to consider establishment of an EWG to prepare the proposed draft principles and/or guidelines on the use of remote audit and verification in regulatory frameworks for discussion at Step 2/3 at CCFICS26.

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

(Prepared by an 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 CRD06 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 and can be accessed [here-questions](#).

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 summarized 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 minimizing impacts to trade.

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

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.

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 recognizes 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 recognizing 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 infrastructure, connectivity and access to ICT available to food business operators and competent authorities.
- 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.
- the need to provide technical assistance for food industry operators and competent authorities in relation to infrastructure, connectivity and access to ICT.

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 utilize them.

Members of the EWG supported the inclusion of examples of CCFICS texts in this discussion paper. These are included and can be accessed [here-CCFICS texts](#). 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 harmonization of practices and implementation.

Members also raised the importance of emphasizing 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 is presented to CCEXEC83 and CAC45 for consideration and possible approval (Appendix)
- ii. If approved, CAC45 is requested to consider establishment of an EWG to prepare the proposed draft principles and/or guidelines on the use of remote audit and verification in regulatory frameworks, for discussion at Step 2/3 at CCFICS26.

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 when it is used for the purpose of verification of compliance within regulatory frameworks. The guidance will include advice on the use of remote audit and verification as a complementary tool to support the effective delivery of official controls 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 approaches such as remote audit and verification 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 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, including on the terminology and definitions used.

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 ensuring 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 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. It will also cover, as needed, practical guidance on the implementation of the existing principles for the conduct of assessments of exporting country 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/on-site 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 guidance 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).