

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda item 7

CX/FICS 23/26/7 Add.1

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (CCFICS)

Twenty-Sixth Session

Hobart, Tasmania, Australia

1 – 5 May 2023

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

Comments in reply to CL 2023/12/OCS-FICS

Comments of Brazil, Chile, Colombia, European Union, Honduras, India, Indonesia, Iraq, Japan, Kenya, Malaysia, Mauritius, New Zealand, Norway, Republic of Korea, Uruguay, USA and FAO

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2023/12/OCS-FICS issued in March 2022. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the Annex

2. The comments submitted through the OCS are hereby attached as **Annex I** and presented in table format.

ANNEX I

GENERAL COMMENTS	MEMBER / OBSERVER
<p>The United States supported expedited initiation of this work and appreciates the significant progress made by the EWG as reflected in the Draft Principles and Guidelines (Appendix I). There remain some important issues that could benefit from further discussion and review, however, to increase understanding and improve the clarity of the guidelines for potential users.</p> <p>Notably, the scope and applicability of the text needs clarification throughout. Paragraph 2 and the Purpose/Scope section in Paragraphs 4-5 appear to indicate that the intent is to provide guidance both to countries conducting remote audits and inspections internally (“within their regulatory frameworks”) as well as to importing countries conducting remote audits and inspections of exporting countries.</p> <p>If so, that should be clearly stated and the wording throughout should be reviewed to make sure that both circumstances are adequately taken into account and reflected in all sections. (For example, in Section 4 under Paragraph 7—7(a) is not clear on which “competent authority” is directing/guiding, 7(e) seems only applicable to importing country interviews of exporting countries’ FBOs or authorities, etc.) If the intent is limited to guidance for import/export situations, that should be made clearer.</p>	USA
<p>Kenya appreciates the work done by the EWG chaired by Australia, and co- chaired by Singapore, Canada and China and supports advancement to Step 5 taking note of the comments raised. Kenya also proposes EWG to continue with this work to address the issues raised.</p>	Kenya
<p>India appreciate the work done by the eWG chaired by Australia and Co-chaired by Singapore, Canada and China. We would like to submit following general comments on the document under consideration:</p> <ul style="list-style-type: none"> • Provisional agenda (CX/FICS 23/26/1) indicated title of the Agenda Item 7 as “Proposed draft Principles and Guidelines on the Use of Remote Audit and Verification in Regulatory Frameworks” whereas the actual document (CX/FICS/23/26/7) title is “Proposed draft Principles and Guidelines on the Use of Remote Audit and Inspection in Regulatory Frameworks”. The document title needs to be uniform to avoid any confusion among members. • In case of Remote Audit and Inspection, the role of Information and Communication Technologies (ICT) is quite crucial. Therefore, the members need to be careful while using remote audit and inspection to ensure that cost of technology is not burdensome to Food Business Operators (FBOs), particularly in reference to small FBOs, justify the risk involved and user-friendly. • Verification activities are not specifically defined in the CCFICS text. Therefore, if we are considering to include verification also in the scope of the document, it would be more appropriate that agreed definition should be included. • The remote audit and inspection activities may be carried out in case of pandemic and other emergency situations since physical verification gives much clearer and factual picture as compared to remote audit. 	India
<p>New Zealand supports the development of this guideline acknowledging that undertaking regulatory activities remotely has been increasing, driven by a range of factors, and can be a practical way for regulatory functions to protect the health of consumers and ensure fair trade practices to be undertaken when circumstances dictate. Having supported the accelerated process for the</p>	New Zealand

commencement of new work as set out in the Project Document endorsed by CAC45 New Zealand is concerned at the change from 'audit and verification' to 'audit and inspection' and does not support either the change in the title or the global replacement throughout the entire text from 'verification' to 'inspection'. New Zealand therefore has proposed amendments throughout the text with rationale to address this.	
The European Union and its Member States (EUMS) would like to thank Australia, Singapore, Canada and China for leading the work on remote audits and inspections. The EUMS support the proposed draft Principles and Guidelines on the Use of Remote Audit and Inspection in Regulatory Frameworks as presented in Appendix 1 of CX/FICS 23/26/7 with the following comments.	European Union
Indonesia would like to express her appreciation to Australia as chair and Singapore, Canada and China as Co-Chairs of EWG for their efforts to prepare draft principles and guidelines on the use of remote audit and inspection in regulatory frameworks. Please find below Indonesia specific comments on the draft guidelines.	Indonesia
agree with no comments.	Iraq

SPECIFIC COMMENTS	MEMBER / OBSERVER
<p>DRAFT PRINCIPLES AND GUIDELINES ON THE USE OF REMOTE AUDIT AND INSPECTION VERIFICATION IN REGULATORY FRAMEWORKS</p> <p>New Zealand does not support the title change and suggests it revert to the use of 'verification' for the following reasons:</p> <ul style="list-style-type: none"> • Including the word 'inspection' shifts the scope considerably into the territory of end point product testing which was not as outlined in the Purpose and scope of the Project Document accepted by CAC45. • Although 'inspection' may be used by some to apply to a whole business or system it still implies the old fashion continuous and detailed observation of products and process which is at odds with modern thinking and practices. • The term 'Verification' is the modern and accepted term and is used extensively throughout Codex and CCFICS text. 	New Zealand
<p>DRAFT PRINCIPLES AND GUIDELINES ON THE USE OF REMOTE AUDIT AND INSPECTION IN REGULATORY FRAMEWORKS</p> <p>Mauritius thanks the Chair and Co-chairs of the EWG for the efforts towards progression of work on the Proposed Draft Principles and Guidelines on the Use of Remote Audit and Verification in Regulatory Frameworks. The EWG can pursue this work to address issues raised and to promote wider participation of Members. Mauritius also supports the advancement of the draft principles and guidelines to Step 5 in Codex step process, taking note of its comments in the document.</p>	Mauritius

<p>DRAFT PRINCIPLES AND GUIDELINES ON THE USE OF REMOTE AUDIT AND INSPECTION IN REGULATORY FRAMEWORKS</p> <p>We suggest that the committee reflects on the use of "regulatory frameworks" in this context.</p>	<p>Norway</p>
<p>Section 1 Preamble/Introduction</p>	
<p>Para 1. Not all activities performed as verification activities may fall within the scope of "audit and inspection activities." If the text is meant to include verification and assessment activities, the title should reflect this and the verification and assessment activities should be separated from inspection activities.</p>	<p>USA</p>
<p>Para 1. Remote audit and inspection-verification activities, including verification and initial 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-verification regulatory activities when physical visits are not practical.</p> <p>Replace 'inspection' with 'verification'. The key concept in paragraph 1 is oversight which is consistent with both audit and verification. Inspection can imply an individual item sorting/inspection type of activity such as occurs with meat inspection and is a significantly different concept.</p>	<p>New Zealand</p>
<p>Para 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 <u>complement to physical audit and inspection activities and also</u> ensure continuity of audit and inspection regulatory activities when physical <u>visits-activities</u> are not practical.</p> <p>Indonesia proposed to re-phrase this para and add the underlined sentences. This para is a preamble, therefore we need to emphasize that remote audit and verification can be useful for competent authorities as a complement to physical/onsite audit/inspection activities that have been practicing.</p>	<p>Indonesia</p>
<p>Para 1. Remote audit and inspection activities, including verification and assessment activities, while presenting some challenges, <u>activities</u> can offer significant benefits to competent authorities and food businesses whilst also providing an appropriate level of effective national competent authority oversight. <u>businesses.</u> Such tools can also ensure continuity of audit and inspection-regulatory activities when physical visits are not practical.</p> <p>FAO would like to propose a simplification in the text to ensure clarity.</p>	<p>FAO</p>
<p>Para 2. The last sentence appears to limit the intended scope of the document in the context of audits and inspections performed by the competent authorities of importing countries to "systems audits" of exporting countries' competent authorities' oversight programs. If the intent is broader, this should be clarified, for example, by replacing "or audits of competent authority oversight on [of] food business operators performed in the context of systems audits by importing country competent authorities" with "audits and inspections</p>	<p>USA</p>
<p>Para 2. Comment: The words "and auditing bodies" should be deleted.</p>	<p>India</p>

<p>Rationale: The document is talking about remote audit and inspection in the context of regulatory framework therefore the word "competent authorities" will cover all authorities which are competent to take such audit or inspection. It could be national competent authorities in the context of NFCS or the competent authority of the importing country in the context of audit or inspection of the export country as clearly specified in second part of the paragraph 2 and paragraph 4 under Purpose/Scope. The Private Auditing Bodies or Inspection Bodies may not fall in the scope of this document.</p>	
<p>Para 2. As technology continues to develop and offers increasing potential to undertake regulatory activities remotely, it is important for the use of such technology by competent authorities and auditing bodies to be transparent and negotiate agreed with the use of such tools within the food supply chain relevant parties. This remains true whether this concerns inspections or audits verification 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.</p> <p>For clarity and completeness - agreement between the parties on the use of technology is a key aspect - not just the process of negotiation - and also to align with paragraph 1 and using verification not inspection.</p>	New Zealand
<p>Para 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.</p> <p>We suggest deleting or redrafting the second paragraph as it is difficult to understand.</p>	Norway
<p>Para 2. As technology continues to develop and offers increasing potential to undertake regulatory assessment 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.</p> <p>In our view the term "regulatory activities" are linked to setting regulations and legal framework, and not the activity of performing inspection and audits remotely, we therefore suggest this amendment.</p>	
<p>Para 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 with the food supply chain. This remains true whether producers and reflect 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. <u>audit protocol.</u></p> <p>FAO believes that a simplified text will ensure clarity with members</p>	FAO

Para 3. Brazil wonders if the "Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations" (CXG 19-1995) and the "Guidelines for the Exchange of Information between Countries on Rejections of Imported Foods" (CXG 25-1997) would be useful as a reference.	Brazil
Para 3. Comment: The words "and auditing bodies" should be deleted. Rationale: The document is talking about remote audit and inspection in the context of regulatory framework therefore the word "competent authorities" will cover all authorities which are competent to take such audit or inspection. It could be national competent authorities in the context of NFCS or the competent authority of the importing country in the context of audit or inspection of the export country as clearly specified in second part of the paragraph 2 and paragraph 4 under Purpose/Scope. The Private Auditing Bodies or Inspection Bodies may not fall in the scope of this document.	India
Section 2 Purpose / Scope	
El objetivo debería ir en una sección independiente del ámbito de aplicación. Se considera que este documento debe llevar el mismo desarrollo de los demás documentos del Comité.	Colombia
Para 4. The purpose of this guidance is to assist competent authorities in the use of remote audit and inspection-verification activities within their regulatory frameworks. To align with our general comment that inspection should be replaced with verification, which is a well understood modern term widely used in Codex and CCFICS text.	New Zealand
Para 5. Is the intent to limit use of remote audit and inspection to NFCS/systems equivalence?	USA
Para 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 as well as the assessment of an exporting country's NFCS, or a relevant part thereof.	Norway
Para 5. The scope of the guidance is the use of remote audit and inspection as an optional <u>a complement</u> 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. Indonesia proposes to replace "an optional" to be "a complement". In conducting an audit, a physical audit is certainly more able to have thorough assessment. Remote audits can only be considered as optional if there are certain conditions such as a pandemic. Therefore, in this guidance remote audit is more appropriate as a complement rather than an option. Because there are several assessments that cannot be done remotely at all, such as organoleptic assessments.	Indonesia
Para 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. <u>controls.</u> FAO would like to propose a simplified sentence:	FAO

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.	
Section 3: Definition	
New Zealand suggests that consideration is given to developing definitions for 'Verification' and for 'Assessment' in the context of CCFICS, to be potentially included in this guideline as well as possibly to be proposed for inclusion in one of CCFICS foundation document.	New Zealand
Remote audit or inspection activities: The auditor or inspector is not physically present at the site <u>but use communication technology to be audited/inspected</u> support the assessment. We propose to have definition about "remote audit or inspection activities" than just "remote". We need to have same definition regarding the remote audit itself.	Indonesia
Remote: The auditor <u>auditor(s) or inspector</u> is <u>inspector(s) are</u> not physically present at the site to be audited/inspected. FAO proposes this change to allow for the possibility of a team of auditors/inspectors to operate.	FAO
Modificar el nombre de la definición: Auditoría o inspección... a distancia. No es claro el título de A distancia para la definición incluida	Colombia
Section 4: Types of remote audit or inspection:	
Comment: Kenya proposes an amendment to the title and of section 4 by restructuring it to read as 'Methods of remote audits' Justification: The listed are examples of methods and not types of audit.	Kenya
This section provides a very good oversight.	Norway
Consultamos sobre la fuente u origen de los 5 tipos de auditorías o inspecciones incluidas. Se requiere para mayor claridad en el documento y para continuar con su construcción.	Colombia
Uruguay sugiere cambiar el título de la sección 4 tipo de auditorías o inspecciones a distancia por actividades que pueden formar parte de una auditoria o inspección a distancia.	Uruguay
Para 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 <u>Examples of audit or inspection activities which can that may be conducted remotely, may remotely include, but would are not be restricted to, the following:</u> Suggest including language that the remote audit can include any or all of these and change language to clarify that this is simply a list of examples of remote audit activities:	USA

<p>Para 7. Remote audit and inspection-verification 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-verification activities which can be conducted remotely, may include, but would not be restricted to:</p>	New Zealand
<p>Para 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 <u>Types of audit</u> or inspection activities which can be conducted remotely, may include, but would not be restricted to:</p>	Mauritius
<p>Para 7. Honduras sugiere incluir texto mencionando que una actividad de auditoría o inspección a distancia podría realizarse a través de uno o mas de los elementos de esta lista.</p>	Honduras
<p>Para 7. Se sugiere agregar un nuevo literal “f”, con el siguiente texto: “f. Diferida: auditoria que se realiza con acciones in situ presencial y a la vez a distancia, puede ser de forma sincrónica o asincrónica. Las acciones que se realizan son las mismas de evaluación en terreno y documental que se realizan para una auditoria normal.” Esta definición recoge la idea que actividades presenciales y a distancia pueden permitir una adecuada auditoría.</p>	Chile
<p>Para 7. Las actividades de auditoría o inspección a distancia a pueden considerarse ya sea ‘en parte’ cuando solo se realiza parcialmente a distancia ya sea “en su totalidad” cuando todas las partes se finalizan-realizan a distancia. Las actividades de auditoría o inspección pueden efectuarse a distancia y pueden incluir, entre otras cosas, lo siguiente: Sugerencias editorial en español</p>	Uruguay
<p>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. MY is of the view that the text in Section 4: Types of remote audit or inspection should be consistent in addressing the auditor / auditee</p>	Malaysia
<p>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 <u>service provider, such as a laboratory,</u> as directed and guided by a competent authority representative to observe real-time operating conditions. To the best of our knowledge “official facility” is not a term commonly used within CCFICS guidance? The key concept here is a place where some form of business or service activity is occurring (as opposed to offices).</p>	New Zealand
<p>Live video-streaming: Where a Food Business Operator (FBO) and/or exporting country competent authority representative will stream live video footage <u>and data sharing</u> from a business facility and/or official facility as directed and guided by a competent authority representative to observe real-time operating conditions. We propose to add “ .. data sharing” because sometimes data is required to be provided directly during a live streaming audit</p>	Indonesia

<p>Video en vivo y en directo: Cuando un operador de empresas alimentarias (OEA) y/o el representante de la autoridad competente de país exportador transmiten en vivo y en directo desde un establecimiento comercial y/o un establecimiento oficial, tal como fuera indicado y guiado por un representante de la autoridad competente encargado de observar las condiciones operativas en tiempo real.</p> <p>Suprimir la expresión establecimiento oficial. El establecimiento oficial ya está representado por la autoridad competente, para ser coherente con el ámbito de aplicación.</p>	Colombia
<p>Pre-recorded video: Where a pre-recorded video is taken at the request of an auditor or inspector <u>verifier</u> and electronically submitted to them for assessment.</p>	New Zealand
<p>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.</p> <p>FAO would like to propose to delete this is this is part of "traditional audits"</p>	FAO
<p>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 <u>might (could) include</u> by photographic and/or video footage and are typically sent by electronic means such as email. <u>footage.</u></p> <p>Suggest deleting "and are typically sent by electronic means such as email." This is unnecessary and technology restrictive.</p>	USA
<p>Off-site desktop review of documentation: Where a FBO and/or <u>or</u> exporting country's competent authority will submit <u>submits</u> documentary evidence for review by a <u>the relevant national or international</u> 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.</p> <p>In system audits the focus is on the competent authority being audited submitting the requested evidence be it their records or the relevant records from the FBO that corroborates the competent authority records.</p> <p>There are two situations being talked about in this paragraph so New Zealand suggests there is reference to the "relevant national or international competent authority". Identifying down to the level of an audit team is not necessary for this paragraph.</p>	New Zealand
<p>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 <u>email and cloud storage.</u></p> <p>We propose to add " .. and cloud storage" as the example of electronic means, since it also a common electronic means being use.</p>	Indonesia
<p>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</p>	FAO

<p>results achieved. These data may be supplemented by photographic and/or video footage and are typically sent by electronic means such as email.</p> <p>FAO would like to propose deleting this 7c as this is also part of "traditional" audits.</p>	
<p>Examen de la documentación ex situ: Deberia decir: Examen de la documentación ex situ: Cuando un OEA y/o la autoridad competente del país exportador presenta pruebas documentadas para ser evaluadas por el equipo de auditores/inspectores de la autoridad competente del país importador para confirmar (...)</p> <p>Comentario: Se sugiere incorporar el texto "del país importador", para mejor comprensión del documento.</p>	Peru
<p>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) authority.</p> <p>unclear why the parenthetical is needed. If the competent authority doesn't have jurisdiction, it is unclear why the CA would be requesting or accessing the data.</p>	USA
<p>Remote collection of measurement information: Where a competent authority can access <u>a sample or summary report of data</u> 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).</p> <p>For clarity and completeness.</p>	New Zealand
<p>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 <u>FBO</u>.</p> <p>Remove all text after "and/or the exporting country competent authority." It is unnecessary and could serve to restrict the use of interviews.</p>	USA
<p>Virtual interview: Comment: The words "an importing country" and "or auditing body" may be deleted.</p> <p>Rationale: The Word "Competent Authority" will cover all applicable authorities.</p>	India
Comments on Section 5: Principles	
<p>Para 8. •It would be helpful to acknowledge in this paragraph that many of the basic principles and considerations are the same for both in person and remote audits, but that the nature of remote audits brings additional considerations.</p>	USA
Principle 1: Remote audit and inspection activities complement and do not <u>and, in some cases, can replace</u> physical/in-person audits or inspections	Brazil

<p>Brazil understands that remote audit and inspection activities are a complement to physical/in-person practices. Nevertheless we also understand that in some cases, these practices can replace the on-site activities, if the authority determines so, based on a risk approach (Principle 3).</p> <p>We fully agree with paragraph 9 that describes Principle 1. However, it mentions that “remote audit or inspections activities may be used as the sole regulatory tool for verifying compliance...” we would like to call the attention of the committee if it wouldn't be more appropriate to amend the title of Principle 1 to clearly mention that “in some cases, it can replace physical activities”.</p> <p>In our opinion there is a contradiction between the title of Principle 1 and its description.</p>	
<p>Principle 1: Remote audit and inspection activities complement and do not replace physical/in-person audits or inspections</p> <p>the language of the principle seems to be inconsistent with the text and purpose of the document to allow for remote audit and inspection activities to replace in-person audit when appropriate and agreed by relevant parties (e.g., exporting and importing country competent authorities).</p>	USA
<p>Principle 1: Remote audit and inspection or verification activities complement and do not replace <u>can be complementary to physical/in-person audits or inspections verifications</u></p> <p>Replacing inspection with verification for the reasons noted in our earlier comments. Further Principles are statements of fact and New Zealand agrees with the statements in the following text (paragraph 9), there are situations where remote activities may in fact replace the need for physical / in person audits or verifications. It is therefore not appropriate to definitively state that they ‘do not’ replace physical / in-person verifications.</p>	New Zealand
<p>Principle 1: Remote audit and inspection activities <u>can</u> complement and do not <u>at times,</u> replace physical/in-person audits or inspections</p> <p>Title of Principle 1 alludes that remote audits cannot replace Physical audits. Para 9 under Principle 1 recognizes that remote audits may be the sole regulatory tool for verifying compliance. Therefore, there may be circumstances when a remote audit may replace onsite audits/inspections.</p>	Mauritius
<p>Principio 1: Las actividades de auditoría e inspección a distancia complementan, pero no reemplazan <u>se complementan con las auditorías o inspecciones in situ o en persona</u></p> <p>Se solicita aclarar este texto. El título del principio parece indicar que las auditorías e inspecciones a distancia, o las actividades que respecto de ellas se realicen a distancia, no reemplazan las auditorías e inspecciones in situ, es decir, que deberían realizarse de todas maneras in situ. En otras palabras, todo lo que se pueda hacer a distancia tendría que hacerse nuevamente de manera presencial. Una redacción posible podría ser la presentada.</p>	Chile
<p>Principio 1: Las actividades de auditoría e inspección a distancia complementan, pero no reemplazan las auditorías o inspecciones <i>in situ</i> o en persona</p> <p>Uruguay no entiende el concepto de “pero no reemplazan” las auditorías o inspecciones in situ. Uruguay entiende que una vez se defina este tipo de auditoría en la reglamentación para la efectiva realización de los controles oficiales del SNCA de un país y la</p>	Uruguay

<p>evaluación del SNCA, o de la parte pertinente de un país exportador la auditoria in situ/ inspección in situ o a distancia deberían ser equivalentes</p>	
<p>Para 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 <u>mutual</u> 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.</p>	<p>USA</p>
<p>Para 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 <u>system/inspected</u> facility.</p>	<p>USA</p>
<p>Para 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.</p> <p>Comment: the words "auditing bodies" should be substituted with "the FBOs"</p> <p>Rationale: It may not be appropriate to have unilateral discretion. The readiness of FBOs for remote audit/inspection is equally important to make it participative and efficient.</p>	<p>India</p>
<p>Para 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, <u>justification</u> 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.</p> <p>RATIONALE: To consider justification and rationality to conduct remote audit is necessary before applying them.</p>	<p>Japan</p>
<p>Para 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</p>	<p>Japan</p>

<p>authorities and the remote nature of the exercise may result in incorrect conclusions being drawn on the compliance of the audited system/inspection facility.</p> <p>Throughout this document, both "audit and inspection" and "audit or inspection" are used. Are there any difference? If not, just use a single term "audit and inspection".</p>	
<p>Para 9. Remote audit or inspection activities may be used as the sole regulatory tool are optional assessment 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.</p>	Malaysia
<p>Para 9. The applicability of remote audit either full or partial has already been mentioned in paragraph 4, Section 4. As such we suggest amendment to the text to indicate that it is an alternative, as follows:</p> <p>Remote audit or inspection activities are optional assessment tool for verifying compliance of a process, facility or NFCS or used in combination with physical/in-person practices.</p>	Malaysia
<p>Para 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 system or FBO.</p> <p>New Zealand is not sure what an inspection facility is. Suggest this principle be focused on the "system" or the FBO for consistency with the rest of the document.</p>	New Zealand
<p>Para 9. Remote audit or inspection activities may be used as the sole regulatory assessment 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.</p> <p>We would suggest replacing «regulatory tool» with "assessment tool" for the reason as described above</p>	Norway
<p>Para 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</p>	FAO

<p>authorities and the remote nature of the exercise may result in incorrect conclusions being drawn on the compliance of the audited system/inspection facility. Periodic physical inspections and audits could be used as a means to verify accuracy of results.</p> <p>FAO considers that the first sentence of this paragraph sounds contradictory with Principle 1 as stated above. we propose some text to better highlight complementarities.</p>	
<p>Para 9. Las actividades de auditoría o inspección a distancia pueden utilizarse como una herramienta reglamentaria única para verificar el cumplimiento de un proceso, establecimiento o SNCA, o utilizadas en combinación con prácticas físicas o en persona. La utilización de esta herramienta queda a discreción de las autoridades competentes u organismos auditores que participan, en función de la evaluación de la aptitud, la compatibilidad y el apoyo técnico. Las autoridades competentes deben ser conscientes de que las auditorías o inspecciones a distancia pueden no ser adecuadas para todas las operaciones de comercio de alimentos o las autoridades competentes, y de que la naturaleza de un ejercicio a distancia puede dar lugar a conclusiones incorrectas sobre el cumplimiento del sistema/establecimiento de inspección auditados.</p> <p>Se sugiere suprimir la expresión reglamentaria única debido a que no es necesaria. El párrafo queda claro sin la expresión que se sugiere suprimir.</p>	Colombia
<p>Principle 2: Remote audit and inspection activity best practice aligned to physical audits and inspections</p> <p>•The heading for this principle, as written, is confusing. Perhaps change it to “. . . Remote audit and inspection activity best practices align with physical audit and inspection activities best practices”</p>	USA
<p>Principle 2: Remote audit and inspection activity best practice aligned to physical audits and inspections</p> <p>Comment: Kenya proposes a modification of the title of principle 2 to read “Remote audit and inspection activities should be aligned to physical audits and inspections best practices”</p> <p>Justification: Physical audits should be the bench mark for remote audits as indicated in para 10</p> <p>Kenya proposes EWG to continue with this work to address the issues raised.</p>	Kenya
<p>Principle 2: Remote <u>Alignment of remote and physical audit and inspection activity verification</u> best practice aligned to physical audits and inspections</p> <p>To clarify and focus the title on the core concept.</p>	New Zealand
<p>Principle 2: Remote audit and inspection activity best practice aligned to physical audits and inspections</p> <p>review the title. a word seems to be missing or review as "Best practice principles for physical audits and inspections are equally applicable to remote audit and inspection.</p> <p>Title of Principle 2 that seems to depict that physical audits should follow the best practice of remote audits. Remote audit is being bench marked against the physical audits as indicated in para 10 and not vice versa.</p>	Mauritius

<p>Para 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 <u>criteria</u> being applied, assessment preparations, entry and exit meetings, the <u>the</u> provision of feedback and draft reports for comment, and other activities as per best practice and international guidance.</p> <p>•For consistency with the systems equivalence document, replace “standards being applied” with “criteria being applied”</p>	USA
<p>Para 10. Relevant processes for conducting a physical audit or inspection <u>verification</u> 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.</p>	New Zealand
<p>Para 10. The period of notification before a remote audit or inspection should allow sufficient time for the auditee to prepare.</p>	European Union
<p>Para 10. Honduras sugiere revisar la traducción al español, quizá el concepto "criterios de la auditoría" sea más aplicable en este párrafo.</p>	Honduras
<p>Principle 3: Risk-based <u>Use of a risk-based approach</u></p>	Mauritius
<p>Para 11. Competent authorities should perform remote audit and inspection <u>verification</u> activities in a manner that is proportionate to <u>the performance of the system and or FBO and risks</u> posed. Consideration should be given to:</p> <p>Performance is a key concept to insert into this principle as the actual risk is ultimately a factor of how well the system or business is controlling the risks for its products and processes.</p>	New Zealand
<p>Para 11. Add new bullet as follows:</p> <p>- “Consideration of location facilities or production areas”</p> <p>Rationale: We propose to add new bullet since two bullets related to the risk assessment aspect are not adequate.</p>	Indonesia
<p>Para 11. Bullet 1</p> <p>Comment: The words "ensuring that any increase in frequency because of the remote nature of the audit is justified" should be substituted with "remains the same as if the physical audits or inspections were being conducted".</p> <p>Rationale: In the name of remote audit or inspection, it may not be appropriate/justifiable to increase to frequency. The others are editorial changes.</p>	India
<p>Para 11. Bullet 1</p> <p>the frequency of such audits or inspections ensuring that any increase in frequency <u>or urgency</u> because of the remote nature of the audit is and the risks posed are <u>justified</u>; and</p>	Japan

RATIONALE: to be risk based, frequency and urgency of the remote audit, nature of the risks posed should be considered.	
<p>Para 11. Bullet 1</p> <p>the frequency of such audits or inspections ensuring that any increase in frequency because of verifications is not greater than justified by the remote nature risk posed by the performance of the audit-FBO or NFCS regardless as to whether the activity is justified conducted remotely or in person; and</p> <p>New Zealand suggests the key concept to be captured here is that the frequency of any audit is performance and being risk driven, not by the type of audit conducted.</p>	New Zealand
<p>Para 11. Bullet 1</p> <p>the frequency of such audits or inspections ensuring that any increase in frequency because of the remote nature of the audit <u>or inspection</u> is justified; and</p> <p>to ensure consistency</p>	FAO
<p>Para 11. Bullet 2</p> <p>that the scope of remote audits or inspection <u>activities</u> remains the same as if the physical audit was being conducted.</p> <p>Second bullet appears to assume the audit or inspection is 100% remote. If the Guidance is intended to allow for partially remote and partially in person, replace “audits or inspection activities remains” with “audit or inspection activities remain”</p>	USA
<p>Para 11. Bullet 2</p> <p>Comment: After the words "physical audit" the words "or inspection" should be inserted.</p> <p>Rationale: In the name of remote audit or inspection, it may not be appropriate/justifiable to increase to frequency. The others are editorial changes.</p>	India
<p>Para 11. Bullet 2</p> <p>that the scope or intensity of remote audits or inspection remains the same as verifications is not greater than if the physical audit activity was being conducted undertaken physically / in person.</p> <p>Intensity is a key concept to capture in the principle as well. Similarly to the previous bullet, the key concept here is the scope and intensity should not be greater just because it is a remote audit.</p>	New Zealand
<p>the fact tthat the scope of remote audits or inspection remains the same as if the physical audit was <u>were</u> being conducted.</p>	Mauritius
<p>that the scope of remote audits or inspection remains the same as if the physical audit <u>and inspection</u> was being conducted.</p> <p>to ensure consistency</p>	FAO

<p>Principle 4: Remote audit and inspection activities must <u>should</u> be planned and conducted in a cooperative manner</p> <p>RATIONALE: Codex text usually uses “should” instead of “must”.</p>	Japan
<p>Principle 4: Remote audit and inspection-verification activities must be planned and conducted in a cooperative manner</p>	New Zealand
<p>Principle 4: Remote audit and inspection activities must be planned and conducted in a cooperative manner <u>especially related to technology capability</u></p> <p>Adding new sentence in the principle 4 title to make it more accordance with the explanation contained in para 12.</p>	Indonesia
<p>Para 11. Planning and implementation of remote audit and inspection activities should consider the level of technology <u>accessible to the FBO and/or exporting country competent authority has access to</u>, to support the proposed activities. The activities such as 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.</p> <p>•agree the planning and conducting of the remote audit should be cooperative; however, the mention of technology doesn't seem to be in alignment with the overall language of the principle.</p>	USA
<p>Para 11. 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<u>activities and based on agreement between relevant parties</u>. 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.</p> <p>RATIONALE: It is required relevant parties agree how to conduct audit in physical or remote approach taking into account availabilities of IT tools and confidentiality of protecting information of auditee.</p>	Japan
<p>Para 12. Planning and implementation of remote audit and inspection-verification 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.</p>	New Zealand
<p>Para 12. Planning and implementation of remote audit and inspection activities should <u>be conducted in a cooperative manner</u>. In particular, this step 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.</p> <p>While the title of the principle includes reference to cooperative manner, the actual paragraph only considers the technology. FAO proposes some text to better connect the title and the paragraph content.</p>	FAO

<p>Principle 5: Protection of confidential information</p> <p>while the technology is different, the idea of maintaining confidentiality is the same whether the audit/inspection is remote or in person.</p>	<p>USA</p>
<p>Principle 5: Protection of confidential information</p> <p>In order to keep this on a principle level, we would suggest some amendments to ensure that the following is clear: "CA should safeguard the data protection rights of the Citizens of exporting country when engaging in remote audits. Data and documentation disclosed in remote audit are only to be used in accordance with the agreed objectives of the audit. The Parties shall undertake all necessary precautions to prevent any unauthorized access to and use of personal data and confidential information." We understand the first sentence, however we do not consider it a part of a principle, and would suggest that it is deleted here.</p>	<p>Norway</p>
<p>Para 13. 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. 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.</p>	<p>USA</p>
<p>Para 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 <u>should</u> 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. <u>Have policies or written agreement in place to demonstrate adherence of information protection obligations, if necessary.</u></p> <p>RATIONALE: Agreement in information protection between both parties is essential to conduct remote audit due to remote nature.</p>	<p>Japan</p>
<p>Para 13. Information sharing during a remote audit or <u>and</u> 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.</p>	<p>Japan</p>
<p>Para 13. Information sharing during a remote audit or inspection is different to that during a physical audit or inspection verification and brings additional challenges. <u>The auditee's right to privacy and protection of intellectual property should be protected.</u> Video-streaming <u>comes with a potentially heightened risk that it can be captured and inappropriately shared, and as do</u> 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 electronically. 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</p>	<p>New Zealand</p>

<p>protections and assurances to the auditee regarding confidentiality, including security of ICT access and information collection, storage and handling processes.</p> <p>For clarity and to ensure the key concepts that are to be protected are clearly stated rather than just noted as something that can happen.</p>	
<p>Para 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-. <u>When such conditions cannot be guaranteed, the auditee may require a physical audit or inspection</u></p> <p>The guidelines should allow the possibility to require a physical audit or inspection when the security and protection of data cannot be guaranteed.</p>	<p>European Union</p>
<p>Para 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 CA should safeguard the risk to the auditee’s right to privacy and data protection rights of intellectual property. Competent authorities should ensure the confidentiality-Citizens of information/data exporting country when engaging in line with the relevant legal requirements in their countries-remote audits. Parties must agree to handle personal-Data and commercially sensitive material documentation disclosed in a manner that provides protections and assurances-remote audits are only to be used in accordance with the auditee regarding confidentiality, including security-agreed objectives of ICT-the audit. The Parties shall undertake all necessary precautions to prevent any unauthorized access to and information collection, storage-use of personal data and handling processes-confidential information.</p>	<p>Norway</p>
<p>Section 6: Roles and Responsibilities</p>	
<p>Para 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:<u>“However, stakeholders may face some additional responsibilities when conducting these activities remotely, notably the competent authority should:”</u></p> <p>To streamline the second sentence, see alternative text.</p>	<p>USA</p>
<p>Para 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<u>should</u>:</p> <p>Must is too strong</p>	<p>USA</p>

<p>Para 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:</p> <p>In second sentence, not clear who the “stakeholders” are.</p>	USA
<p>Para 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 mustshould:</p>	Japan
<p>Para 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;However, stakeholders may face some additional responsibilities in facilitating these activities to be undertaken remotely, notably the competent authority must:</p> <p>Recommend : (Delete 'notably the competent authority must')</p> <p>(rational) Remote audit is used as supplementary tool. Therefore, it is not appropriate to mandate the responsibilities and roles of the competent authorities because the timing and capabilities to reflect them vary depending on the situation of the Member States.</p>	Republic of Korea
<p>Para 14. The roles and responsibilities of the competent authorities and entities to be audited or inspected verifiedare similar in remote and physical audit and inspection-verification activities. However, stakeholders-all may face some additional responsibilities in facilitating these activities to be undertaken remotely, notably the competent authority mustshould:</p> <p>Substituting the word stakeholder as it is confusing. Also replacing ‘inspection’ with 'verification' in line with previous comments. Additionally, Codex refrains from using the terms must and shall except in exceptional circumstances, for this guideline ‘should’ is the appropriate terminology.</p>	New Zealand
<p>Para 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 mustshould:</p>	Norway
<p>Para 14. the second sentence is somewhat unclear: it starts with "stakeholders may face additional responsibility " and ends with "notably the Competent authority must". what would be the responsibilities of other stakeholders, or should directly replace "stakeholders" with Competent authorities?</p>	FAO
<p>Para 14. deveria decir: 14. (...) Particularmente, la autoridad competente del país importador debe:</p> <p>comentario: Se sugiere incorporar el texto “del país importador”, para mejor comprensión del documento.</p>	Peru

<p>Para 14. Bullet 1</p> <p>Delete 14.a: (Rational) The principle applicable to remote audits is an aid to physical/in-person audits, and it is not appropriate for the competent authority to specify a review of the scheme as a role and responsibility to do so. Instead, it is desirable that the review of the country's system is applied according to the situation of the Member States.</p>	<p>Republic of Korea</p>
<p>Para 14. Bullet 1</p> <p>Honduras sugiere modificar el texto por revisar la legislación y además incluir el término "establecer", ya que en algunos casos, la legislación podría no estar plenamente establecida.</p>	<p>Honduras</p>
<p>Para 14. Bullet 2</p> <p>Establish audit and inspection-verification programs, policies and procedures which outline the conditions and scenarios for the use of remote versus physical audit and inspection-verification activities as appropriate; and</p>	<p>New Zealand</p>
<p>Para 14. Bullet 3</p> <p>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, <u>and determine whether such requirements are feasible.</u></p> <p>Paragraph 14c continues to disregard that resolving technology issues may be completely out of the hands of the FBO or competent authority.</p>	<p>USA</p>
<p>Para 14. Bullet 3</p> <p>Provide clear direction to the entities to be audited or inspected-verified (e.g. food businesses, and other competent authorities) on the information and communication technology requirements necessary for successful execution of the remote audit/inspection <u>audit or verification.</u></p>	<p>New Zealand</p>
<p>Para 14. Bullet 3</p> <p>Provide clear direction to the entities to be audited or inspected (e.g. food businesses, and other competent authorities) <u>and have capabilities</u> on the information and communication technology requirements necessary for successful execution of the remote audit/inspection.</p> <p>Adding "... and have capabilities" since point c explains that the competent authority should provide direction related to the ICT requirements needed for remote audits to the auditee, therefore it needs to be emphasized by adding "have capabilities".</p>	<p>Indonesia</p>
<p>Para 15.</p> <p>Entities to be audited or inspected have the role and responsibility to <u>verified should:</u></p>	<p>New Zealand</p>

<p>It is not necessary to repeat the phrase ' roles and responsibility'. New Zealand is not sure this is an obligation. It is only something they may need to do if they want or need to partake in remote audits as opposed to physical ones. Making it an obligation on all entities is heavy handed and overly prescriptive and therefore inappropriate for Codex guidance. .</p>	
<p>Para 15. Bullet a</p> <p>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 <u>the feasibility</u> to engage in remote auditing or inspection, otherwise physical audit or inspection would be the preferred option.</p> <p>Paragraph 15a continues to disregard that resolving technology issues may be completely out of the hands of the FBO or competent authority.</p>	USA
<p>Para 15. Bullet a</p> <p>Ensure they understand the availability of and have <u>an appropriate understanding of and</u> access to necessary those technologies <u>necessary</u> to facilitate remote audit and inspection-verification activities when there is a stipulated reasonable requirement from a competent authority; and b. They should clearly <u>Clearly indicate their ability and commitment to engage in facilitate a remote auditing audit or inspection-verification,</u> otherwise or whether a physical audit or inspection-verification would be the preferred option.</p> <p>Edits to address the concern raised in the preceding comment.</p>	New Zealand
<p>Section 7: Planning and Implementation</p>	
<p>Para 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.</p> <p>RATIONALE: redundant</p>	Japan
<p>Para 16. While remote audit and inspection-verification 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.</p>	New Zealand
<p>Para 17. The following points should be taken into consideration <u>by a competent authority</u> when planning remote audit and inspection verification activities:</p> <p>For clarity and completeness and to replace inspection with verification and align with our previously stated rationale.</p>	New Zealand
<p>Para 17. We would suggest including the need for an agreed plan which should include the timeframe, name of participants etc. The reason for this would be that planning and executing a remote audit is time consuming and require resources from both the importing and the exporting country. Remote controls should be notified well in advance to ensure sufficient time for planning and both countries must set aside enough time to execute the remote audits in an appropriate manner. Transparency is also a matter, and therefore the name etc of participants should be "open". This is based on our experience with remote audits over a period of time and we would appreciate for example that 30 days in advance is mentioned. We therefore suggest an initial bullet reflecting this</p>	Norway

Para 17. Bullet 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. This paragraph is repetitive with first bullet of Paragraph 11	USA
Para 17. Bullet a. Comment: The paragraph should be substituted with the following: "Frequency/ Duration: Competent authorities should not increase the frequency or duration of remote audit or inspection activities when compared to physical on-site audits or inspections. However, duration of remote audit or inspection may be longer in comparison to physical audit or inspection in view of technological challenges associated with such activities." Rationale: Frequency and duration cannot be looked into from the same yardstick. If competent authorities have the provision to justify the necessity of increased frequency of remote audit or inspection, the same is likely to be misused.	India
Para 17. Bullet a. Frequency or duration: 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.	Japan
Para 17. Bullet a. MY suggest to use physical on-site audits or inspections for consistent term.	Malaysia
Para 17. Bullet a. Frequency: Competent authorities should not unnecessarily increase the frequency or duration of remote audit or inspection-verification activities when compared to physical on-site audits or inspections verifications.	New Zealand
Para 17. Bullet a. repetition of similar point made under principles	Mauritius
Para 17. Bullet a. FAO would like to comment that generally remote audits and inspection take more time, so that could contradict the reference to duration in the paragraph above.	FAO
Para 17. Bullet a. Honduras sugiere revisar este texto ya que podría haber duplicidad con el texto en párrafo 11.	Honduras
Para 17. Bullet a. Frecuencia: Las autoridades competentes no deberían aumentar <i>ni disminuir</i> innecesariamente la frecuencia o duración de las actividades de auditoría o inspección a distancia con respecto a las auditorías e inspecciones <i>in situ</i> . Se sugiere agregar la expresión "ni disminuir", como se indica. Las frecuencias de las auditorías deben ser las necesarias para garantizar que los Sistema Nacional de Control de los Alimentos (SNCA) funcionan de acuerdo a los requisitos establecidos.	Chile
Para 17. Bullet 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. "prioritized" should be replaced with "priority consideration".	Japan

RATIONALE: improve readability.	
Para 17. Bullet b. Timing: Where significant time zone differences exist between the location of the auditor and auditee, the hours of operation of the food business <u>or competent authority</u> 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.	Malaysia
Para 17. Bullet b.the hours of operation of the food business or competent authority should	Malaysia
Para 17. Bullet 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-verification to ensure that remote audit and inspection-verification activities are delivered during standard operation-operating hours-. <u>Similar consideration is also needed when speaking with the competent authority or another regulatory agency, so that one party is not required to be available outside reasonable hours.</u> As drafted this is written to only apply to food businesses. Similar consideration should also be given to the competent authority so that personnel are not required to be interviewed in the middle of the night.	New Zealand
Para 17. Bullet b. Timing: Where significant time zone differences exist between the location of the auditor auditor, inspector 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. Ensuring consistency	FAO
Para 17. Bullet 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 <u>an additional need</u> for proficiency in the application of any technologies used during the audit or inspection activity.	USA
Para 17. Bullet 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. Comment: The paragraph should be substituted with the following: “Qualifications: Auditor or Inspector conducting the remote audit or inspection should be as appropriately qualified and competent as if conducting a physical onsite audit or inspection. There may be a requirement for proficiency in the application of any technologies used during the remote audit or inspection activity.” Rationale: In order to bring uniformity in the text (in line with definition in Paragraph 6).	India
Para 17. Bullet c. Qualifications: Officials or officially recognized bodies conducting the remote audit or inspection-verification should be as appropriately qualified and competent as if conducting a physical onsite audit audit or verification. There may be a requirement for proficiency in the application of any technologies used during the audit or inspection-verification activity.	New Zealand

Para 17. Bullet c. Honduras sugiere modificar el texto por: incluyendo las competencias en la aplicación de las tecnologías utilizadas durante la actividad de auditoría o inspección.	Honduras
Para 17. Bullet d. Technology: Where the level of access to the technology required for remote audit or inspection-verification is not adequate e.g. poor or limited videoconferencing connectivity, consideration should be given to:	New Zealand
Para 17. Bullet d.1 Comment: The words "assessment" should be substituted with "audit or inspection". Rationale: In order to bring uniformity in the text.	India
Para 17. Bullet d.1 Si un acceso adecuado a la tecnología pertinente necesaria para llevar a cabo una evaluación a distancia constituye un requisito razonable. — <u>Para completar el documento</u> Al final del documento se debería incluir información sobre la evaluación de la actividad de auditorías o una conclusión.	Colombia
Para 17. Bullet d.2 Whether the use of technology remains as the most appropriate approach or whether other types of remote audit (e.g. desktop review of documentation) <u>documentation or pre-recorded video</u>) would be able to provide the required level of assurance;	Norway
Para 17. Bullet d.2 Honduras sugiere modificar por documentación ex situ ya que sino no sería considerada una evaluación a distancia.	Honduras
Para 17. Bullet d.5 Both sides agreeing on contingencies when planning remote audit and inspection-verification activities to manage possible interruptions caused by technological failures (e.g. loss of connectivity).	New Zealand
Para 18. Implementation This section is detailed and prescriptive. New Zealand does not consider this level is necessary.	New Zealand
Para 18. The following should be considered during conduct of remote audit and inspection-verification activities:	
Para 18. 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 <u>secure-secured</u> manner <u>and destroyed</u> when no longer required. ; For clarity	USA
Para 18. a Protection of information: Parties conducting remote audit and inspection-verification activities should strive to gather information that can be shared freely without the need for secure channels of transmission. When-Where it is necessary to gather <u>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 be transmitted over secure channels and should</u> 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.	New Zealand

Suggested edits to simplify and focus on the key aspects.	
<p>Para 18. 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-. <u>National data protection legislation should be considered in these processes.</u></p> <p>FAO would like to propose to include a reference to data protection legislation in the country.</p>	FAO
<p>Para 18. a Debería decir: a. Protección de la información: (...) La información sensible personal o comercial no debe compartirse con ninguna tercera parte sin el consentimiento del propietario original y debe almacenarse y destruirse de manera segura cuando ya no se requiera y proporcionar evidencia de este hecho.</p> <p>Comentario: Se sugiere incorporar el texto "y proporcionar evidencia de este hecho" a fin que se cuente con evidencia de la eliminación de información, que ya no es necesaria.</p>	Peru
<p>Para 18. 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-verification process. The auditing or inspecting-verifying party should provide its feedback in written form afterwards<u>during or after the meeting.</u></p>	New Zealand
<p>Para 18. c Health and Safety: Best practice work health and safety-workplace 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.</p>	USA For clarity
<p>Para 18. c Health and Safety<u>Safety for auditor and auditee:</u> Best practice <u>for work health and safety</u> procedures applied for <u>both auditor and auditee of</u> 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.</p> <p>Rationale: improve readability</p>	Japan
<p>Para 18. c Health and Safety: Best practice work health and safety procedures applied for physical audit and inspection-verification activities remain applicable, for example, for any person who may be instructed <u>applicable to take measurements or record-remote</u> activities. Health and safety procedures-Consideration should take into consideration also be given to the length of activity sessions, sessions and differences in time zones and need for breaks to maintain physical and mental wellbeing of all participants zones.</p> <p>To simply and focus on the key aspects</p>	New Zealand
<p>Para 18. c Honduras sugiere revisar la traducción al español, el término más indicado quizá sea "seguridad ocupacional".</p>	Honduras

