

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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AGENDA ITEM 4

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CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Twenty-fifth Session

Hobart, Australia, 27 April – 1 May 2020

DRAFT PRINCIPLES AND GUIDELINES FOR THE ASSESSMENT AND USE OF VOLUNTARY THIRD-PARTY ASSURANCE (vTPA) PROGRAMMES (Updated Text)

(Report prepared by the Electronic Working Group chaired by the United Kingdom and co-chaired by Canada and Mexico)

(At Step 7)

Codex members and Observers wishing to submit comments on the updated text, of the draft should do so as instructed in CL 2020/26/OCS-FICS available on the Codex webpage/Circular Letters 2020:

<http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/?y=2020>

Executive summary

This EWG, established by the Codex Committee on Food Import and Export Inspection and Certification Systems (Brisbane 2018), was chaired by the United Kingdom with co-chairs from Canada and Mexico. Following a round of comments on the text retained in square brackets the co-chairs concluded that there continued to be broad support for the guidelines and that there were no fundamental differences of views amongst members in relation to the suggestions members put forward to resolve the outstanding issues.

The issues considered included: duplication and logical flow of the principles; need to clarify the scope of the guidelines in relation to contracted private standards and standards enforced by regulators; ensure clarity on the roles and responsibilities of the competent authority (confidentiality of data shared), vTPA owners (accountability and significant risk scenario), and FBOs (conflicts of interest); a need for more clarity on the governance arrangements in relation to accreditation arrangements and certification bodies, and streamlining of the chapeaux introducing section G (guidelines on regulatory approaches). In navigating the issues and considering members comments the co-chairs have suggested the addition of several explanatory footnotes to aid understanding and to act as reference points.

The co-chairs' analysis of members' comments and their proposed revisions to the draft guidelines can be found in Appendix 2. A revised draft taking account of the co-chairs' proposed revisions can be found at Appendix 1. The co-chairs' key recommendations for the next steps are:

The PWG scheduled for 25 April 2020 should base its discussions on the output from the EWG and use the revised "clean" draft of the guidelines.

- The EWG co-chairs to review comments submitted at Step 6 to assist the PWG chair.
- The PWG to consider the comments submitted at Step 6.
- The PWG to report on the outcome of its discussions at the 25th Session of CCFICS in Hobart Australia under agenda item 4.
- CCFICS 25 to review the revised draft guidelines and consider whether to recommend to CAC43 adoption at Step 8.

INTRODUCTION

1. The 24th session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) met in Brisbane 22 – 26 October 2018. The Committee reached a decision to recommend adoption at Step 5 of the "draft principles and guidelines for the assessment and use of voluntary third-party assurance (vTPA) programmes. The Codex Alimentarius Commission at its 42nd session subsequently endorsed this recommendation and adopted the Step 5 text along with the recommendation to establish an EWG to consider the outstanding issues, primarily the text held in square brackets, and assist with Step 6 comments.

EWG TERMS OF REFERENCE

2. The 24th session of CCFICS agreed to establish an EWG, with the possibility of convening a PWG immediately prior to CCFIC25, chaired by the United Kingdom and co-chaired by Canada and Mexico, working in English and Spanish. The EWG was asked to consider: i) All outstanding issues, including comments made at CCFICS24,

and, ii) Comments submitted at Step 6.

PARTICIPATION AND METHODOLOGY

3. The EWG conducted its business on the electronic platform. Membership¹ of the group totalled 58 which comprised of 34 member countries and 7 observer organisations. The co-chairs sought comments from the EWG members on 26 April 2019, primarily on the text that had been retained in square brackets. A template was utilised to facilitate transparency, consistency, and to aid understanding. The template provided a short summary of each outstanding issue and requested comments, revisions and justifications. The closing date for comments was 21 June 2019 which was extended for members that requested an extension due to the proximity of the deadline to CAC42 and the holiday period in some regions.
4. A total of 15 EWG members responded. The co-chairs posted a progress update to the Platform in both languages on 23 October 2019. This included a consolidated version of all of the comments submitted via the template and details of the proposed next steps.
5. Time did not permit the EWG to consider Step 6 comments as the closing date for CL/FICS 2019/93/OCS-FICS was 31 December 2019. This meant consolidated comments (in their original language) were not made available to the co-chairs until the end of January 2020 which was judged to be too late for a meaningful consultation and analysis to take place. The co-chairs will however review the Step 6 comments in advance of the PWG meeting scheduled for 25 April 2020.

ANALYSIS AND NEXT STEPS

6. The co-chairs carried out a thorough analysis of the comments submitted and noted that members did not express particularly strong views either way on the range of issues they were asked to provide comment on. The comments submitted could be summarized as constructive and generally supportive in that they provided a range of suggested revisions and fixes. Where there were differences, for example some members supporting deletion and a majority retention the analysis tended to show that the suggested revisions often addressed the reason for deletion. By way of an example, a majority of members supported retention of the text in square brackets relating to the scope and exclusion of contracted private buyer standards whereas some members favoured deletion on the basis the sentence was overly long and generally well understood without the additional text. The suggested revisions addressed the point about the length and clarity of the sentence. On this issue, the co-chairs also considered the views expressed at CAC42 about the need to ensure clarity on the exclusion of contracted private buyer standards from the scope of the guidelines. A similar pattern emerged for other issues under consideration, and the co-chairs took the view that there were no fundamentally different views held by members which meant it was possible to propose revisions to address all of the outstanding issues.
7. However, the co-chairs' proposals to revise, merge, re-title and re-order the principles would benefit from further discussion at the PWG. This section is critical to the guidelines given what follows flows from the principles. And whilst members did not express particularly strong views, their comments were again helpful and constructive, and it would be useful to verify and confirm with members the proposed new language, for example the new title "avoiding burdens on business" which replaced the title "proportionality" as members suggested this was better suited to another principle.
8. Another issue worth flagging is the continued sensitivity around the confidentiality of data that may be shared with the competent authority by the vTPA owner. A few members supported retention of the text in square brackets whilst most felt it to be redundant.
9. A clean version of the draft guidelines was produced that incorporated all of the co-chairs' proposed changes and this new draft is attached at Appendix 1. The co-chairs' analysis and supporting rationale for their proposals can be found at Appendix 2.

CONCLUSIONS

10. Based on the analysis of the comments submitted by the members of the EWG (See Appendix II), the co-chairs concluded that there continued to be broad support for the text and that there were no fundamental differences of views amongst members. As a result, the co-chairs were able to propose revisions to the draft guidelines to resolve all of the outstanding issues and produce a clean text without square brackets.
11. Whilst not being able to consider the Step 6 comments (CX/FICS 20/25/4 Add.1) due to time constraints, the co-chairs take the view that these can be considered during the PWG that will be held immediately before the next CCFICS session in Hobart, Australia on the afternoon of 25 April 2020.

¹Membership of EWG

Australia, Belgium, Brazil, Canada, Chile, Colombia, Costa Rica, Dominican Republic, Egypt, EU, France, Guatemala, Honduras, India, Indonesia, Ireland, Jamaica, Japan, Kazakhstan, Malaysia, Mexico, Morocco, Netherlands, New Zealand, Nigeria, Norway, Peru, Republic of Korea, Singapore, Switzerland, Thailand, UK, Uruguay, USA, GFSI, CGF, FIA, FAO, ICBA, NSF, SSAFE

RECOMMENDATIONS

12. The co-chairs' recommendations for next steps are as follows:

- The PWG scheduled for 25 April 2020 should base its discussions on the output from the EWG and use the revised "clean" draft of the guidelines as attached in Appendix I.
- The EWG co-chairs to review comments submitted at Step 6 to assist the PWG chair.
- The PWG to consider the comments submitted at Step 6.
- The PWG to report on the outcome of its discussions at the 25th Session of CCFICS in Hobart Australia under agenda item 4.
- CCFICS 25 to review the revised draft guidelines and consider whether to recommend to CAC43 adoption at Step 8.

BACKGROUND AND HISTORY OF THE vTPA WORK

13. The work to develop guidelines on the use of vTPA programmes was approved in Mexico City at the 23rd session of CCFICS in May 2017 (CX/FICS 17/23/8). The United Kingdom and its co-chairs Canada and Mexico led the work between sessions through the establishment of an EWG and the hosting of two PWGs. The first PWG was held in Santiago, Chile in December 2017 and the second in Edinburgh, Scotland during May 2018. Both PWG meetings piloted online web-based tools to enhance participation.

14. The output from this process produced a Step 3 draft of the guidelines which was then subject to consultation (CL 2018/53-OCS) ahead of the 24th session of CCFICS in Brisbane Australia in October 2018. The Committee recommended adoption of an amended text at Step 5 and agreed to set up another EWG to consider the outstanding issues in the draft, primarily the text retained in square brackets.

APPENDIX I**DRAFT PRINCIPLES AND GUIDELINES FOR THE ASSESSMENT AND USE OF VOLUNTARY THIRD-PARTY ASSURANCE (Updated text)****(At Step 7)****A: PREAMBLE**

1. Food business operators (FBOs) have the primary role and responsibility for managing the food safety of their products and for complying with regulatory requirements relating to food under their control. Competent Authorities require FBOs to demonstrate that they have effective controls and procedures in place to protect the health of consumers and ensure fair practices in food trade. Many FBOs use quality assurance systems, including voluntary third-party assurance (vTPA) programmes to reduce supply chain risks and confirm food safety outcomes.
2. The Codex Principles and Guidelines for National Food Control Systems (NFCS) (CAC/GL 82-2013)² foresee competent authorities taking into account quality assurance systems in their national food control system. Competent authorities may choose to do this by establishing an arrangement with a vTPA programme owner to use the information/data generated by vTPA programme to support their regulatory controls. In any case, they should satisfy themselves that any information/data they intend to use is both reliable and fit for purpose.
3. These guidelines are intended to assist competent authorities in their consideration of vTPA programmes. They provide a framework and criteria for assessing the integrity and credibility of the governance structures and the reliability of information/data generated by such programmes to support NFCS objectives. When carrying out such an assessment, competent authorities should be guided by their intended use of the vTPA programme information and should only apply assessment criteria that are relevant to that purpose.
4. Reliable vTPA information/data may be used in general to better risk-profile sectors, and in some circumstances individual FBOs. This may lead to smarter data-driven prioritisation of official resources, while FBOs participating in robust vTPA programmes may benefit through an appropriate risk-based reduction in the frequency/intensity of regulatory controls e.g. inspection, sampling. Conversely, poorly performing FBOs, or sectors, may be subject to increased official regulatory controls based on trends identified through the information/data shared by the vTPA owner.

B: SCOPE

5. These guidelines are intended to assist competent authorities within their national boundaries in the effective assessment and transparent use of reliable vTPA programme information/data in support of their NFCS objectives.
6. The guidelines focus on the structure, governance and components of vTPA programmes that align with and support NFCS objectives relating to protecting consumer health and ensuring fair practices in food trade.
7. The guidelines do not oblige competent authorities to use vTPA programme outcomes nor do they mandate the use of vTPA information/data from FBOs i.e. emphasising that the decision to use vTPA information/data by the competent authority is voluntary.
8. The guidelines do not apply to official inspection systems or official certification systems administered by government agencies having a regulatory or enforcement jurisdiction, nor officially recognised inspection or certification bodies³ that certify to a regulatory standard for which compliance is mandatory.
9. The guidelines are not intended to apply to private standards that are the subject of commercial contractual arrangements between buyers and sellers, nor do they apply to components of vTPA programmes which are outside the scope or requirements of the competent authority.
10. These guidelines do not constitute approval, recognition or endorsement of vTPA programmes. It follows that competent authorities may choose approaches other than that described in these guidelines when considering how to take into account vTPA programmes in their risk-based targeting of regulatory controls.

²CAC GL 82-2013: Principles and Guidelines for National Food Control Systems paragraph 54: Where quality assurance systems are used by food business operators, the national food control system should take them into account where such systems relate to protecting consumer health and ensuring fair practices in the food trade.

³CAC/GL 20-1995: Officially recognized inspection systems and officially recognized certification systems are systems which have been formally approved or recognized by a government agency having jurisdiction.

C: DEFINITIONS⁴

Assessment: A process of determining the presence or absence of a certain condition or component, or the degree to which a condition is fulfilled. (Source: CAC/GL 91-2017)

Accreditation: third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific tasks. (Source: ISO/IEC 17000:2004)

Accreditation body: authoritative body that performs accreditation (Source: ISO/IEC 17000:2004)

Assurance: Positive declaration intended to give confidence. (Source: Oxford English dictionary).

Attestation: issue of a statement, based on a decision following review that fulfilment of specified requirements has been demonstrated. (Source: ISO/IEC 17000:2004)

Audit: is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives. (Source: CAC/GL 20-1995)

Certification body: A provider of certification services, accredited by a nationally recognised accreditation body. (Source: ISO/IEC 17000:2004)

Conformity assessment: demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. (Source: ISO/IEC 17000:2004)

Credibility (dictionary): The quality of being trusted and believed in. (Source: Oxford English dictionary)

Governance: the processes and arrangements through which organisations are administered, in particular how they are directed, controlled and led including the way management systems are structured and separated to avoid potential conflicts. (Source: new)

Inspection: is the examination of food or systems for control of food, raw materials, processing, and distribution including in-process and finished product testing, in order to verify that they conform to requirements. (Source: CAC/GL 20-1995)

Integrity (dictionary): The quality of being accurate and reliable. (Source: new)

Procedure: specified way to carry out an activity or a process. (Source: ISO/IEC 17000:2004)

Review: verification of the suitability, adequacy and effectiveness of selection and determination activities, and the results of these activities, with regard to fulfilment of **specified requirements**. (Source: ISO/IEC 17000:2004)

Specified requirement: need or expectation that is stated. (Source: ISO/IEC 17000:2004)

vTPA Standard: specified requirements contained in the vTPA programme. (Source: new)

Voluntary Third-Party Assurance Programme: An autonomous scheme comprising of the ownership of a standard that may utilise national/international requirements; a governance structure for certification and conformity assessment that provides for periodic onsite audits for FBO operations for conformance with the standard, and in which FBO participation is voluntary. (Source: new)

vTPA Owner: Person or organisation responsible for developing and maintaining a specific vTPA programme. (Source: Adapted from ISO IEC 17065)

D: PRINCIPLES

11. When considering the potential role of vTPA programmes and the potential contribution they may make to FBO compliance with regulatory requirements and broader NFCS objectives, competent authorities should be guided by the following principles:

Principle 1 Planning and decision making

- Competent authorities retain discretion whether and how to consider information/data from vTPA programmes in their regulatory oversight, inspection and control framework, planning and decision-making process.

Principle 2 Role and responsibilities

- Competent authorities remain responsible for maintaining appropriate oversight of the implementation of regulatory requirements and controls including enforcement actions regardless of the participation of FBOs in vTPA programmes.

⁴ Based (in part) on EN ISO/IEC 17000 'Conformity assessment – Vocabulary and general principles'

Principle 3 Transparency of policies and processes

- Any arrangement to use vTPA information/data to support NFCS objectives, including the assessment criteria, should be based on transparent policies and processes in line with Principle 3 of CAC/GL 82-2013⁵.

Principle 4 Regulatory framework

- The vTPA standard, its audit and inspection does not replace regulatory requirements or controls carried out by the competent authority and could be complementary to the regulatory controls.

Principle 5 Proportionality

- The depth and extent of any assessment of the vTPA programme should be commensurate with the intended use of the vTPA information/data.

Principle 6 Confidentiality

- Competent authorities should ensure the confidentiality of information/data shared by vTPA owners in line with the relevant legal requirements in their countries.

Principle 7 Avoiding burdens on business

- The processes and policies of the competent authority to make use of vTPA information/data should not directly or indirectly mandate additional requirements, costs or restrictions on FBOs over and above regulatory requirements

Principle 8 Rights and obligations

- In developing an appropriate approach to leverage the vTPA compliance information/data, competent authorities should ensure that their approach is consistent with international rights and obligations.

E: ROLES, RESPONSIBILITIES AND RELEVANT ACTIVITIES

12. The roles and responsibilities of all participants along the food chain should not change as a result of any decision by a competent authority to take account of vTPA information/data in their NFCS relating to protecting the health of consumers and ensuring fair practices in the food trade.

COMPETENT AUTHORITIES

- a. Have statutory responsibilities for regulatory requirements set down in the NFCS, as recommended in CAC/GL 82-2013 and authorised by relevant national legislation.
- b. May consider using information/data generated by vTPA programmes to support the objectives of their NFCS.
- c. Have responsibility for the delivery and frequency/intensity of regulatory controls and enforcement action for all FBOs regardless of whether a FBO participates in a vTPA programme.
- d. Need to clearly describe the use of a vTPA programme information / data within their NFCS and restrict its use when information provided is false or otherwise lacks credibility.
- e. Should ensure any arrangements to use vTPA information/data is fully transparent.
- f. Have to protect against potential conflicts of interest.
- g. Have to ensure and maintain the confidentiality of data shared by the vTPA owner.

FOOD BUSINESS OPERATORS (FBOs)

- a. Have the primary role and responsibility for managing the food safety of their products and for complying with regulatory requirements relating to food under their control.
- b. Need to demonstrate that they have effective controls and procedures in place to protect the health of consumers and ensure fair practices in food trade.
- c. May elect to participate in vTPA programmes to meet business needs, demonstrate conformance with relevant food safety standards, and provide independent assurance of the integrity of their products or production systems to buyers.
- d. Owns the information/data generated by the vTPA programme.

⁵ All aspects of a national food control system should be transparent and open to scrutiny by all stakeholders, while respecting legal requirements to protect confidential information as appropriate. Transparency considerations apply to all participants in the food chain and this can be achieved through clear documentation and communication.

- e. Has no conflicts of interest with the operation of the vTPA.

VOLUNTARY THIRD-PARTY ASSURANCE OWNERS

- a. Are responsible for implementing the governance arrangements of a vTPA programme, which may include utilising national/international standards and independent accredited audit and certification.
- b. Are accountable to participating FBOs to disclose the potential sharing of information/data generated by the vTPA programme with competent authorities.
- c. Sharing information/data generated by the vTPA programme owners for use by the competent authority, according to the process established by the vTPA programme owners and the competent authority.
- d. Have policies and processes when sharing vTPA information such as notification to the FBO and protections for proprietary information.
- e. Have policies to ensure a vTPA owner alerts the competent authority of any significant public health risks or consumer deception associated with non-conformities by the FBO(s).
- f. Have appropriate systems in place to protect against potential conflicts of interest between TPA owners, auditors and FBOs, and be able to demonstrate adherence to data protection obligations.

F: CRITERIA TO ASSESS THE CREDIBILITY AND INTEGRITY OF vTPA PROGRAMMES

13. Competent authorities that choose to use vTPA programmes in their NFCS should satisfy themselves that the vTPA information/data can be trusted and is fit for purpose. In order to do this, they may carry out a full or partial assessment of the credibility and integrity of the vTPA programme, commensurate with their intended use of the vTPA information/data. When carrying out such an assessment, competent authorities should select the criteria below that are appropriate to the extent of their intended use of the vTPA programme as a start point for this assessment.

Governance Arrangements

- 1) Are the governance arrangements and responsibilities within the vTPA programme clearly defined and documented?
- 2) Are the oversight arrangements structured to avoid potential conflicts of interest?
- 3) Does the vTPA programme have management controls to ensure consistent and effective implementation and maintenance?
- 4) Does the vTPA programme have an accreditation arrangement with an accreditation body with international standing⁶, recognition and credibility? If not, how does the vTPA programme owner ensure that accreditation bodies have the capacity and competency to perform effectively?"

Accreditation of Certification Bodies

- 1) Does the vTPA programme have an independent process to ensure the use of appropriately accredited certification bodies?
- 2) Is the accreditation of certification bodies subject to a periodic review and renewal?
- 3) Does the accreditation body assess the certifying body using relevant and internationally recognized standards⁷?
- 4) Is the certifying body accredited for the vTPA programme according to the relevant accreditation standard?

Standard Setting Process

- 1) Do the vTPA programme owners set their own standards or utilise national or international standards for assurance?
- 2) Do the vTPA standards contain specified requirements to protect consumers in relation to food safety and fair practices in food trade?

⁶ For example, the International Accreditation Forum (IAF) and the International Laboratory Accreditation Co-operation (ILAC).

⁷ Examples include: ISO/IEC 17020, ISO/IEC 17065 or ISO/IEC 17021-1 supplemented with ISO/TS 22003, ISO/IEC 17011

- 3) Have the vTPA standards been developed through a transparent consultative process with relevant experts reflecting the range of business processes within the target sector?
- 4) Are the vTPA standards open, transparent in governance and subject to continuous improvement by regular review to keep them up to date?
- 5) To what extent are the vTPA standards consistent with Codex or other relevant international standards and/or applicable national regulatory requirements?
- 6) Are the vTPA standards written in a way that they can be assessed for conformance?

Conformity Assessment

- 1) Does the vTPA programme have written policies on frequency, methodology, announced and unannounced audits and competency requirements for certification bodies?
- 2) Does the vTPA programme require a conformity assessment against the standard on a defined regular basis, e.g. annual audit of participating FBOs following an appropriate quality assurance framework?
- 3) Does the vTPA programme have procedures in place to ensure that auditors have and maintain the required auditor competence?
- 4) Does the vTPA programme have a transparent system to identify FBOs that conform to the standard (e.g. certification)?

Responses to Non-Conformance

- 1) Do the vTPA programme arrangements include clearly defined procedures for dealing with non-conformities against the standards, failures to rectify non-conformities, and other situations where sanctions might be required?
- 2) Do the arrangements include a system for review of audit reports, decisions on interpretation and sanctions, and a procedure for appeal?

Data Sharing and Information Exchange

- 1) Is there an up-to-date list of participating FBOs (including their status) that are certified or verified as conforming to the vTPA standard, and is this information available to the competent authority? Is the information available in the public domain?
- 2) Subject to national privacy legislation, will the vTPA programme owner inform the competent authority immediately when they become aware of a significant risk to public health or consumer deception?
- 3) Will the vTPA programme owner notify the competent authority of any FBO that ceases to participate?
- 4) Will the vTPA programme owner agree to notify the competent authority of any changes made to the vTPA programme, including but not limited to: the standard, governance, certification and accreditation arrangements?
- 5) Will the vTPA programme owner share information/data relating to conformance with the standard where the standard aligns with regulatory requirements to inform the NFCS?
- 6) If the data available is electronic form are there adequate arrangements for maintaining the security of the data?
- 7) Does the vTPA owner have permission to share FBO data with competent authorities and is this in accordance with national data protection obligations?
- 8) Does the vTPA owner have a protocol for data retention?

G: REGULATORY APPROACHES FOR THE USE OF vTPA INFORMATION/DATA

14. This section provides examples of process considerations and policy options available for competent authorities when they establish arrangements with vTPA owners to use vTPA information/data. It also contains examples of the practical uses that can be made by competent authorities of vTPA information/data to support their NFCS objectives.

Process considerations

- a. A vTPA programme may be considered for use by a competent authority after an appropriate assessment of its credibility and integrity informed by the criteria in this guidance.
- b. Competent authorities need only apply relevant assessment criteria commensurate with their intended use of vTPA information/data.

- c. Where there is a positive assessment outcome the competent authority may choose to enter into an arrangement with the vTPA owner by mutual consent.
- d. Competent authorities that have arrangements with vTPA owners should establish a process for the sharing of relevant information/data and processes for handling findings of non-conformities, including alerting the competent authority of any significant public health risk or consumer deception.
- e. Competent authorities may need to establish transparent procedures to verify the reliability of the vTPA information/data that it intends using.
- f. Competent authorities may choose to set up regular meetings, or other communication channels, with the vTPA owner in order to analyse the information/data shared to look for trends and the competent authority may consider the need for any intervention needed.
- g. Competent authorities may compare comparable regulatory audit data with that generated by the vTPA audits to verify consistency and reliability.
- h. In addition to specific and critical information detailed in an agreement between the competent authority and the vTPA owner, there should be routine information exchanged to demonstrate that the vTPA programme continues to operate in line with its agreed governance.
- i. Where competent authorities choose not to enter into an agreement with the vTPA owner they may access the information/data directly from the FBO.
- j. The competent authority should identify the information/data from the vTPA audits that is of most value to its NFCS objectives and agree the access arrangements for those elements. Key elements are identified in para 38 ("Data Sharing and Information Exchange" above).

Policy options

- a. Competent authorities may choose to verify the reliability of vTPA information/data through for example a comparison of the conformance data from the vTPA with their official compliance information/data.
- b. In order to validate the suitability of an assurance system, including a review of the vTPA requirements and its operation the competent authority may consider the value of comparing the vTPA requirements with relevant international standards and/or relevant national regulatory requirements.
- c. As many vTPA standards include requirements that go beyond food safety and consumer protection into supplier preferences, the competent authority should focus on the regulatory requirements that protect the health of consumers in relation to food safety and ensuring fair practices in food trade.
- d. Audit information/data generated by the vTPA programme, and FBO certification status may be used to inform NFCS planning leading to reduced intensity or frequency of regulatory inspection for participating FBOs.
- e. Competent authorities may reduce levels of official inspection where there is verification through their official data that participation in a vTPA programme is achieving higher levels of compliance with relevant regulatory requirements.
- f. The suitability and extent to which competent authorities use vTPA information/data will be determined by the depth of any assessment of the integrity and credibility of the vTPA programme.
- g. vTPA information/data indicating a trend could be used to target specific interventions such as focused inspections or national training/information programs where the vTPA information/data helps identify a systemic issue.
- h. The competent authority may determine that FBOs participating in a vTPA programme that meet the relevant assessment criteria in these guidelines pose a lower food safety risk and so subject them to less frequent regulatory oversight.
- i. Competent authorities may use the additional information/data from vTPA audits to help prioritise regulatory resources to higher risk areas to better protect consumers in relation to food safety and fair practices in food trade.

APPENDIX II**EWG CO-CHAIRS ANALYSIS OF CONSULATION COMMENTS AND PROPOSALS TO RESOLVE OUTSTANDING ISSUES**

Key	
Green text	Co-chair comments and analysis
<i>Italics and Yellow highlight</i>	Square bracketed text for comment
Red text	Proposed new text and/or heading

Below are the extracts from REP18/FICS Appendix III of the sections of the *text retained in square brackets*.

General Comments**Canada**

- Canada suggests consideration of a numbering/heading system to clarify and simplify readability of the document. *This will be looked at in due course to ensure consistency with other texts.*
- Canada suggests a review of the document to ensure consistency related to the objective of protecting the health of consumers and ensuring fair practices in the food trade (as in E. 12), noting that in some cases this is narrowed to food safety (e.g. A. 1). *A review to ensure accuracy and consistency will be carried out in due course.*
- Canada also suggests a review of the document to clarify that for the purpose of this document, the term “certification” is in reference to the vTPA programme and not the Competent Authority. *This change is not necessary as paragraph 8 of the scope makes it clear that the guidelines do not apply to official certification.*

Japan

- para1

1. Food business operators (FBOs) have the primary role and responsibility for managing the food safety of their products and for complying with regulatory requirements relating to ~~these aspects~~ of food under their control.

Rationale: Editorial. For simplicity. *This change will be made.*

- para4

4. Reliable vTPA information/data may be used in general to better risk-profiled sectors, and in some circumstances individual FBOs.

Rationale: Editorial. *This change has not been made as the current drafting is the correct use of English.*

- para12

FOOD BUSINESS OPERATORS(FBOs)

a. Have the primary role and responsibility for managing the food safety of their products and for complying with regulatory requirements relating to ~~these aspects~~ of food under their control.

Rationale: Editorial. For simplicity. *This change will ensure consistency with the earlier change.*

- para14

Policy options

a. In developing an appropriate approach to leverage the vTPA compliance information/data, competent authorities should ensure that the approach is consistent with international ~~rights and obligations~~.

Rationale: This content is not “policy option”. This is rather a principle and could be contained in para 11 D: Principles. *This comment is correct as international rights and obligations are not a choice. A suggested new principle entitled “Rights and obligations” has been inserted in Section D.*

Comments by Section• **Section B: Scope****The text in square brackets:**

1. 9. The guidelines are not intended to apply to private standards *[that are the subject of commercial contractual arrangements between buyers and sellers, and does not apply to components of vTPA programmes]* that are outside the scope or requirements of the competent authority.

Co-chair comments:

There is a question over the amount of detail/qualification required in this paragraph. The drafter's intention was to provide a clear distinction between the standard contained and audited against in a vTPA programme versus a private buying specification.

EWG member comments (general)	Proposed alternative text (or support retention/deletion)	Rationale for proposed alternative text (or retention/deletion)	Co-Chair Comments / Response
Canada			
Canada agrees with the principle that scope of guidance is specific to the parts of the vTPA that align with the regulatory requirements of the National Food Control System.	Canada supports deleting the text in brackets and proposes a small revision as follows: "The guidelines are not intended to apply to private standards, which are outside the scope or requirements of the competent authority."	The use of "that" in the sentence implies that some private standards may be within the scope of competent authorities, which is inaccurate in Canada's view. Canada does not feel it is necessary to define private standards in this section.	This comment supports deletion of the square bracketed text in order to simplify the sentence rather than add complexity.
EU			
[No comment provided]	The EU supports retaining the square bracketed text as currently drafted	The square-bracketed text provides a useful clarification of which type of private standards fall outside the scope of the guidelines.	This comment supports retention on the basis that the qualification aids understanding and provides the necessary certainty that private standards are out of scope.
France			
Delete	[No comment provided]	If the Competent authorities have concluded during their assessment of the vTPA that there were no conflict of interests and that guarantees are in place to ensure and maintain impartiality between both parties (accreditation, then the contractual arrangements in place have no importance.	This comment supports deletion of the square bracketed text on the basis that contractual arrangements are irrelevant if there are no conflicts of interest.
Indonesia			
Indonesia would prefer to keep the square-bracketed text.	[No comment provided]	To make it clear and provide useful information.	This comment supports retention of the square bracketed text.

Japan			
We agree with the text in square brackets. (delete the square brackets)	[No comment provided]	[No comment provided]	This comment supports retention of the square bracketed text.
Morocco			
The square bracketed text should be maintained as it's drafted	[No comment provided]	The square-bracketed text further clarifies the scope and distinguishes between the standard contained in a vTPA programme and a private buying specification.	This comment supports retention of the square bracketed text and provides a helpful illustration of how the additional text should be interpreted.
New Zealand			
[No comments provided]	Delete	New Zealand comment: the bracketed text does not really add any additional clarity and could be deleted	This comment supports deletion of the square bracketed text on the basis that it does not add any further clarity.
Norway			
We support retaining the text in square brackets.	[No comment provided]	The text provides clarity and gives necessary and useful information.	This comment supports retention of the square bracketed text on the basis it adds clarity.
Singapore			
[No comment provided]	Support for retention	Agree that the content in square brackets would help to clearly distinguish between private buying specifications and vTPA programmes.	This comment supports retention of the square bracketed text in order to clearly distinguish what is in scope.
USA			
We are fine with the shortened version.	[No comment provided]	[No comment provided]	This comment supports deletion of the square bracketed text for brevity.
Chile			
Too much detail. It could be confusing. It is suggested that text in square brackets be in a foot note.	[No comment provided]	[No comment provided]	This comment supports deletion of the square bracketed text on the basis that the sentence is overly long and confusing. It suggests moving the square bracketed text to a footnote to simplify the sentence.
Mexico			
[No comment provided]	Accept text in square brackets	The proposed text in square brackets is accepted as it explains the aspects that are not included in the Guideline and is complemented by what is mentioned in Para. 6 and 8.	This comment supports retention of the square bracketed text and helpfully illustrates consistency with other parts of the text.

Uruguay			
Uruguay agrees to include the proposed text in square brackets.	[No comment provided]	[No comment provided]	This comment supports retention of the square bracketed text.
GFSI			
To remove the text in square bracket	[No comment provided]	[No comment provided]	This comment supports deletion of the square bracketed text.
Co-Chair views and overarching proposal / suggested text			
<p>Most of the comments received support retention of the square bracketed text on the basis that it adds needed clarity and certainty. Those that support deletion did so on the basis that the sentence was overly long and did not need the qualifying text in square brackets in order to be properly understood. However, the Co-Chairs felt they could not ignore the concerns raised at CAC42 about private standards. The Co-Chairs therefore favour retaining the text contained in the square brackets. The suggestion to move the text to a footnote, whilst attractive, may risk losing some clarity from the main body of the text.</p> <p>The Co-Chairs have removed the square brackets and added a comma plus the contraction “nor” to help break the length of the sentence.</p> <p><u>[Proposed revised text]</u></p> <p>1. 9 The guidelines are not intended to apply to private standards that are the subject of commercial contractual arrangements between buyers and sellers, <u>nor do they apply to components of vTPA programmes which are outside the scope or requirements of the competent authority.</u></p>			

- Section D: Principles

The text in square brackets:			
Principle 3 [Process and policies]			
<i>[Where the competent authority has assessed vTPA arrangements and identified information/data that aligns and indicates compliance with relevant regulatory requirements and NFCS objectives, the competent authority may establish a mechanism / process with the vTPA owner for information/data sharing and handling of non-compliance where failure to alert the competent authority of any significant public health risk or consumer deception is identified.]</i>			
Co-chair comments:			
This principle links to section G and the committee questioned whether the text fitted better in that section. If the text is moved to G should the principle be retained or deleted? If it is retained, please suggest alternative/ shortened text to capture the intent – that competent authorities need policies and process to support implementation of the approach?			
EWG member comments (general)	Proposed alternative text (or support retention/deletion)	Rationale for proposed alternative text (or retention/deletion)	Co-Chair Comments / Response
Canada			
Canada would like to see this Principle retained in this section, with amended text, as it supports roles and responsibilities of the various participants and provides direction for content that is set out under Section G. These are two different steps in the process.	Canada supports retaining the principle regarding process and policies but proposes alternative text: "The competent authority should establish appropriate mechanisms with the vTPA owner to enable continued information sharing by the vTPA owner (including changes to the vTPA programme, the vTPA certification status	The principle regarding processes and policies remains but written at a high level. A vTPA owner may not have detailed information on an FBO's conformance to the competent authority's food inspection or certification system, and hence, would not be in a position to share information on that regard with the competent authority. Rather, the vTPA owner will have information and would be in a position to share the vTPA	This comment supports retention of this principle in a revised and shortened format. The Co-Chairs note the helpful comment about vTPA audits reporting on “non-conformities” rather than “non-compliances” and would suggest effecting changes throughout the text to ensure consistency. The Co-Chairs note that the text (highlighted) suggests the certification body should notify the competent authority when their audit

	of the FBO and any risk to public health or consumer deception)."	certification status of the FBO with the competent authority With respect to the use of terminology: " <u>non-compliance</u> ": A certification body will audit an FBO for conformity or non-conformity, not to assess "compliance" or "non-compliance". Should a certification body, during its audit, identify significant public health risk or consumer deception, then it should notify the competent authority.	identifies a potential significant public health risk. The text in Section E suggests this responsibility falls to the vTPA owner rather than the certification body.
EU			
The EU supports moving the text to section G and introducing a more holistic text on policies and processes in principle 3.	Where the competent authority has established an arrangement with a vTPA programme owner to use vTPA data/information to support their NFCS objectives, the arrangement should be based on transparent policies and processes.	[No comment provided]	This comment supports retention of the principle in a revised and shortened format and suggests moving the first sentence to Section G. The Co-Chairs note the suggested inclusion of "transparency" in the revised text which raises a question over whether Principle 6 could be merged with Principle 3.
France			
This principle should be deleted, as it is not a principle. It fits better in G, as suggested here as it is an approach on how to work with vTPA.	[No comment provided]	[No comment provided]	This comment supports deletion of this principle and for the text to be moved to Section G.
Indonesia			
We support moving this principle to Section G and support a proposed text for principle as EU drafted.	We agree with EU's proposal, as follow: Principle 3 [Process and policies] Where the competent authority has established an arrangement with a vTPA programme owner to use vTPA data/information to support their NFCS objectives, the arrangement should be based on transparent policies and processes.	The content of this principle explains the competent authorities' activity and the process of vTPA assessment. Therefore, this principle should be better moved to Section G.	This comment supports retention of this principle in a revised and shortened format and suggests moving the first sentence to Section G.
Japan			
We agree to move the text to section G and this principle should be deleted here.	[No comment provided]	[No comment provided]	This comment supports deletion of this principle and for the text to be moved to Section G.

Morocco			
The wording of this principle is so long. Morocco proposed to keep the terms of this principle but moving it to section G	Principle 3 [Process and policies] can be maintained, Morocco proposed alternative text: 'If necessary, the competent authority may establish a mechanism / process with the VTPA owner for information/data sharing".	Section G provide practical uses that can be made by competent authorities of VTPA information/data.	This comment supports retention of this principle in a revised and shortened format and suggests moving the first sentence to Section G.
New Zealand			
[No comments provided]	New Zealand support deleting this as a standalone principle.	New Zealand comment: We suggest that the intent to clarify that competent authorities need policies and processes to support implementation can be better captured by amending Principle 5 (see below comment)	This comment supports deletion of this principle and its content to be added to Principle 5. The Co-Chairs are not minded to re-open Principle 5 in light of the comments from other members which favour merging principles 3 & 6.
Norway			
We support moving this text to section G. If a principle on the process is needed, alternative text could be explored.	Proposal for alternative text if needed: <u>A mechanism/ process should be in place for information/ data sharing between the vTPA owner and the competent authority.</u>	The way it is worded, it is an activity, and we support moving this to section G. If there is a need for a principle when moving this to section G, we can support alternative text for a principle (as suggested).	This comment supports retention of this principle in a revised and shortened format and suggests moving the first sentence to Section G.
Singapore			
[No comment provided]	The principle can be retained.	Content of this principle is also covered under roles and responsibilities of the CAs and vTPA owners.	This comment supports retention of this principle and makes a clear link between it and the text in Section G.
USA			
Revised language could be kept as a principle that follows the current Principle 7 Assessment. Section G, bullet c lends itself to additional language to capture the intent of this item.	Additional text for inclusion in Section G bullet c as a second sentence. 'That arrangement should establish a process with the vTPA owner for sharing of information/data and processes for handling findings of non-compliance.'	This shortened sentence would cover this issue with less confusing language. Information sharing processes should cover non-compliances generally. The final clause of the sentence is unnecessarily restrictive and has the potential to add confusion.	This comment supports retention of a revised (shortened) Principle 3 and provides a helpful addition for Section G to enhance consistency with this principle. The Co-Chairs note the comment to delete the final clause.
Chile			
It is a more descriptive wording that seems more appropriate in section G.	[No comment provided]	[No comment provided]	This comment supports deletion of this principle and moving the text to Section G.

Mexico			
[No comment provided]	Delete Principle 3.	The text does not properly refer to a principle instead is a consideration of an operational nature. It is considered that the provisions of section G are sufficient.	This comment supports deletion of this principle on the basis that the content of Section G is sufficient.
Uruguay			
Uruguay agrees to delete Principle 3 of section D and move the text in square brackets to section G.	[No comment provided]	[No comment provided]	This comment supports deletion of this principle and moving the text to Section G.
GFSI			
To remove the paragraph.	[No comment provided]	[No comment provided]	This comment supports deletion of this principle.
Co-Chair views and overarching proposal / suggested text			
<p>There is general agreement that as drafted the text is not a principle. However, most of the comments support retaining the concept captured in the second part of the principle, and the drafting suggestions from Canada, EU, Indonesia, Norway and USA are helpful in terms of reframing the language. The thrust of the changes, in particular the addition of “transparency” to the text lends itself to a merging of Principle 3 with Principle 6 along with the addition of a new footnote to help maintain brevity. The Co-Chairs can support the deletion of the final clause (“significant public health.....”) on the basis that it is already covered in Section E “Roles, Responsibilities and Relevant Activities”, vTPA owner paragraph (e) so does not need to be included in this Principle.</p> <p>Section G has been amended as suggested by some members to provide a better flow and coherence (see Section G below).</p> <p>[Proposed revised text]</p> <p>Principle 3 <u>Transparency of processes and policies</u></p> <ul style="list-style-type: none"> Any arrangement to use vTPA information/data to support NFCS objectives, <u>including the assessment criteria</u>, should be based on transparent policies and processes in line with Principle 3 of CAC/GL 82-2013⁴. <p>[Proposed new footnote]</p> <p>⁴ All aspects of a national food control system should be transparent and open to scrutiny by all stakeholders, while respecting legal requirements to protect confidential information as appropriate. Transparency considerations apply to all participants in the food chain and this can be achieved through clear documentation and communication.</p>			

<p>The text in square brackets:</p> <p>Principle 5 [Proportionality]</p> <ul style="list-style-type: none"> The actions of the competent authority to make use of vTPA information/data should not directly or indirectly mandate additional requirements, costs or restrictions on FBOs over and above regulatory requirements. <p>Principle 7 Assessment</p> <p>The depth and extent of any assessment of the vTPA programme should be commensurate with the intended use of the vTPA information/data.</p>			
<p>Co-chair comments:</p> <p>This should be looked at alongside Principle 7. Is “proportionality” the right heading and could 5 & 7 be combined?</p>			
EWG member comments (general)	Proposed alternative text (or support retention/deletion)	Rationale for proposed alternative text (or retention/deletion)	Co-Chair Comments / Response
<p>Canada</p>			
<p>Canada supports retaining both concepts of Principles 5 and 7 and can support combining them. Should eWG members support retaining these concepts separately, Canada would suggest that the text in Principle 7 be placed ahead of Principle 5 as it leads to a logical flow of information.</p>	<p>Canada supports retention and combination of principles 5 and 7 under the title ‘Assessment and Costs’ and placing principle 7 prior to principle 5.</p> <p>Principle 5 Assessment and Costs</p> <p>“The depth and extent of any assessment of the vTPA programme should be commensurate with the intended use of the vTPA information or/and data. The actions of the competent authority to make use of vTPA information or/and data should not directly or indirectly mandate additional requirements, costs or restrictions on FBOs over and above regulatory requirements.”</p>	<p>Both concepts are retained under an appropriate heading, and the text for Principle 7 is placed ahead of Principle 5 as it leads to a logical flow of information.</p> <p>For the purpose of greater clarity, the dash symbol is replaced by either the words “and” or “or” depending on the circumstances.</p>	<p>This comment supports the merging of the concepts contained in principles 5 & 7 into a single principle.</p> <p>The Co-Chairs note that the balance of comments support retention of two separate principles on the basis that the content of each is distinctly different. Furthermore, that Principle 5 is broader than just costs.</p> <p>The Co-Chairs further note the suggestion to reorder the principles and place Principle 7 before Principle 5.</p>
<p>EU</p>			
<p>[No comment provided]</p>	<p>Principle 5 could be combined with principle 4.</p>	<p>[No comment provided]</p>	<p>This comment supports merging Principle 5 and Principle 4.</p> <p>The Co-Chairs prefer not to reopen Principle 4 as this is an important standalone Principle that serves a different purpose to Principle 5, e.g. reassuring consumers that regulatory powers are not being handed over to a vTPA owner and/or certification body.</p>
<p>France</p>			
<p>Principle 5 and 7 should be retained as principles.</p>	<p>[No comment provided]</p>	<p>While there should be proportionality during the assessment (it should not imply any</p>	<p>This comment supports retention of both principles and the word “proportionality”</p>

		<p>additional cost), the general framework of the vTPA use by competent authorities should also be proportional.</p> <p>Proportionality applies at all stages and therefore should be retained.</p>	<p>because it recognises it is used in a broader sense beyond just costs.</p>
Indonesia			
<p>We propose principle 5 as a standalone principle and separated from principle 7.</p>	<p>[No comment provided]</p>	<p>Both of these principles are two distinctly clear principles.</p>	<p>This comment supports retention as two separate principles on the basis that the purpose of each is distinct.</p>
Japan			
<p>[No comment provided]</p>	<p>Principle 5 [Proportionality]- The actions of the competent authority to make use of vTPA information/data should not directly or indirectly mandate additional requirements, costs or restrictions on FBOs over and above regulatory requirements</p> <p>Principle 7 Proportionality</p> <p>The depth and extent of any assessment of the vTPA programme should be commensurate with the intended use of the vTPA information/data.</p>	<p>Principle5 “proportionality” should be deleted since it is already common action of the competent authority and this does not change by making use of vTPA information/data.</p> <p>“Proportionality” fits better to Principle 7.</p>	<p>This comment supports deletion of Principle 5 and re-use of the heading “Proportionality for Principle 7.</p> <p>The Co-Chairs note that re-use of “Proportionality” for Principle 7 becomes possible if the alternative heading “Economic Impacts” or similar language is adopted for Principle 5, as suggested by the USA.</p>
Morocco			
<p>Morocco supports keeping the principle 5 independent from principle 7, because it promotes a good understanding</p> <p>Morocco proposes to move Principle 7 to Paragraph 15 of G</p>	<p>[No comment provided]</p>	<p>The two principles are complementary but cover different objectives.</p>	<p>This comment supports retention as two separate principles on the basis that the purpose of each is distinct.</p> <p>The Co-Chairs note the suggestion to directly lift Principle 7 to para 15 of Section G. This will be considered alongside other comments and suggestions on Section G.</p>
New Zealand			
<p>New Zealand comment:</p> <p>We do not have a strong view on using the word ‘Proportionality’ and do not have an alternative to offer at this time.</p> <p>Combining with 7 is not supported as regardless of the title these are two separate principles.</p>	<p>New Zealand also suggest replacing ‘actions’ with ‘processes and policies’</p>	<p>This change will pick up what is currently Principle 3 which as written is not a standalone principle</p>	<p>This comment supports retention as two separate principles on the basis that the purpose of each is different/distinct.</p> <p>The Co-Chairs note the suggestion to replace “actions” with “processes and policies” to enhance consistency of language used throughout the document.</p>

Norway			
We support the draft principle 5 as a principle.	[No comment provided]	Principle 5 is about not adding additional requirements on FBOs. The principle is clear, however assessment in principle 7 might be taken care of in 5 and could be deleted. It might be that the heading of 7 (Assessment) could be used for 5. The content in principle 5 could be captured under para 15 or 15 bis in G	This comment supports the merging of the concepts contained in principles 5 & 7 into a single principle and changes to the heading to address the issues identified. The Co-Chairs note the suggestion to move the content of Principle 5 to Section G and will consider this alongside other comments on that Section G.
Singapore			
Propose to keep the two principles separate as the two principles are different.	We feel that it is important to retain Principle 5. The heading of Principle 5 could be "Co-relation" or "Inter-dependence"	[No comment provided]	This comment supports retention of two separate principles on the basis that the purpose of each is distinct.
USA			
<i>Proportionality</i> is an appropriate title. That said, we have also provided an alternative for consideration. We do not recommend combining 5 & 7 as we feel they are two distinct principles – one about costs for FBOs and the other about assessments by competent authorities.	An alternative to <i>Proportionality</i> could be <i>Economic Impacts</i>	The section addresses economic impacts to FBOs.	This comment supports retention of 2 separate principles. The Co-Chairs note the suggestion to replace "Proportionality" with "Economic Impacts" in Principle 5. If this or similar language is adopted this would allow the use of "Proportionality" for Principle 7 which fits well with the phrase "commensurate" in that principle. The Co-Chairs further note that the term "economic impacts" is used in a broad sense, e.g. to include additional requirements that could indirectly lead to such impacts so have considered alternative language e.g. "Avoiding burdens on business".
Chile			
[No comment provided]	[No comment provided]	[No comment provided]	
Mexico			
[No comment provided]	Maintain Principle 5. Delete at the end of the paragraph the term "... above"	The term does not apply to refer to the Regulations, since they have not been cited above.	This comment supports retention of Principle 5. The Co-Chairs view is that the qualification at the end of Principle 5 is important as it is requirements <u>above</u> regulatory requirements that are burdensome to FBOs.

Uruguay			
<p>Uruguay considers that both principles pursue different objectives, so they must be kept separate.</p> <p>In the case of Principle 5 the proposed title we understand does not reflect the content of the principle.</p> <p>We understand that the title proportionality fits better as the title of principle 7.</p>	[No comment provided]	[No comment provided]	<p>This comment supports retention as two separate principles on the basis that the purpose of each is different/distinct.</p> <p>The Co-Chairs note the views on retitling the Principles to better describe their purpose.</p>
GFSI			
Principles 5: Keep the title "Proportionality"	[No comment provided]	[No comment provided]	
Co-Chair views and overarching proposal / suggested text			
<p>The balance of comments support retention of two separate principles. Those that support the merging or deletion of Principle 5 & 7 do so on the basis that the concepts in each could be moved to Section G. There are additional suggestions on the headings and the ordering of the two principles, including suggestions that "Proportionality" is a better suited heading for Principle 7 than for Principle 5.</p> <p>The Co-Chairs take note of the arguments supporting the retention of two separate principles on the basis that they are distinct concepts so work better individually. Also the suggestions in respect of ensuring that the concepts are adequately captured in Section G, and the suggested changes to the headings to better reflect the content of each. The Co-Chairs have suggested the promotion of what was Principle 7 to Principle 5 and amended the heading to "Proportionality". As a result of this the old Principle 5 becomes Principle 7 with a new suggested heading "Avoiding burdens on business" in order to capture "economic impacts" in its broadest sense.</p> <p>The Co-Chairs note the "general comment" from Japan that the text relating to international rights and obligations should be a principle rather than a choice. Whilst not strictly in the scope of this consultation the Co-Chairs have suggested a new Principle 8 entitled "Rights and obligations" to address this issue now rather than later.</p> <p><u>[Proposed revised Principle 7 becomes Principle 5]</u></p> <p>Principle 5 Proportionality</p> <ul style="list-style-type: none"> The depth and extent of any assessment of the vTPA programme should be commensurate with the intended use of the vTPA information/data. <p><u>[Proposed revised Principle 5 becomes Principle 6]</u></p> <p>Principle 6 Avoiding burdens on business</p> <ul style="list-style-type: none"> The processes and policies of the competent authority to make use of vTPA information/data should not directly or indirectly mandate additional requirements, costs or restrictions on FBOs over and above regulatory requirements. <p><u>[Proposed new Principle]</u> (Japan):</p> <p>Principle 7 Rights and obligations</p> <ul style="list-style-type: none"> In developing an appropriate approach to leverage the vTPA compliance information/data, competent authorities should ensure that their approach is consistent with international rights and obligations. 			

- Section E: Roles, responsibilities and relevant activities

The text in square brackets:			
COMPETENT AUTHORITIES			
(g) Have to maintain appropriate confidentiality of data <i>[In accordance with the corresponding legal framework in each country.]</i>			
Co-chair comments:			
Is it sufficient to say “appropriate” to direct the competent authority to adherence with pertaining legal safeguards, or should the text be more explicit?			
EWG member comments (general)	Proposed alternative text (or support retention/deletion)	Rationale for proposed alternative text (or retention/deletion)	Co-Chair Comments / Response
Canada			
Canada believes in the importance of safeguarding confidentiality of data.	Canada supports deleting the highlighted text and proposes alternative text: g. “Have to safeguard confidentiality of data”.	Specification is required, as ‘appropriate’ is not specific and may have different meaning for individuals, organisations and competent authorities. The text in brackets does not add value to the text.	This comment supports deletion of the square bracketed text and the qualifier “appropriate” to shorten the text.
EU			
[No comment provided]	There is no need for the qualifier “appropriate”.	The confidentiality should be applied in accordance with the relevant national legislation and this legislation lays down what is appropriate confidentiality.	This comment supports deletion of the qualifier “appropriate” and suggests “relevant” may be a better qualifier than “corresponding”.
France			
Appropriate seems sufficient, square-bracketed part can be deleted.	[No comment provided]	There is enough guidance in the document.	This comment supports deletion of the square bracketed text and retention of the qualifier “appropriate”.
Indonesia			
We propose to delete the square-bracketed text.	[No comment provided]	[No comment provided]	This comment supports deletion of square bracketed text.
Japan			
[No comment provided]	<u>COMPETENT AUTHORITIES</u> g. Have to maintain appropriate confidentiality of data. [In accordance with the corresponding legal framework in each country.]	Yes, the text without the brackets is sufficient.	This comment supports deletion of square bracketed text and retention of the qualifier “appropriate”.
Morocco			
There is no need to keep ‘appropriate’ in the text.	[No comment provided]	The legal framework in each country defines the confidentiality requirements of data.	This comment supports deletion of the qualifier “appropriate and retention of the square brackets”.

New Zealand			
[No comment provided]	New Zealand comment: we support retaining the text	This explicit text is used in other CCFICS text and its use has had strong support from many delegations.	This comment supports retention of the whole sentence and argues that similar language is used in other Codex texts.
Norway			
We would like to keep the text as currently drafted.	[No comment provided]	This text gives the necessary information and guidance.	This comment supports retention of the square bracketed text and qualifier "appropriate".
Singapore			
[No comment provided]	Ok to say 'appropriate', since this is meant to be a guide	The 'appropriateness' can be defined by CA in their internal protocol.	This comment supports retention of the square bracketed text and qualifier "appropriate" recognizing that this is a helpful guide.
USA			
We believe appropriate is sufficient and the text in brackets could be deleted.	[No comment provided]	[No comment provided]	This comment supports deletion of square bracketed text and retention of the qualifier appropriate.
Chile			
It should be more explicit. What is appropriate in one country is not necessarily the same for another. The base line must be the legal framework. Proposal made by Chile. It is a subject of high sensitivity and complexity such as confidentiality, so it should be as clear as possible.	[No comment provided]	[No comment provided]	This comment emphasises the importance of confidentiality of data and urges clarity. The Co-Chairs note that the qualifier "appropriate" was intended to recognise that legal requirements might differ from one country to another.
Mexico			
[No comment provided]	Accept the text in square brackets.	The text in square brackets is accepted, as it is important to narrow the confidentiality provisions to the legal framework.	This comment supports retention of the square bracketed text.
Uruguay			
Uruguay considers that the text "maintain appropriate" should be replaced with ensure confidentiality.	They must ensure the confidentiality of the data according to the corresponding legislative framework of the country	It is understood that increasing the level of confidence for information exchange between the parties collaborates in the possible implementation of the guideline's objective.	This comment supports retention and suggests a drafting change to add clarity and certainty to the intention.
GFSI			
Propose to delete the paragraph to bring more clarity in the text	[No comment provided]	[No comment provided]	This comment supports deletion of the text in square brackets.

Co-Chair views and overarching proposal / suggested text
<p>There is general support for deletion of the text in square brackets along with some suggestions that add clarity and certainty to the intent. The Co-Chairs suggestion is to simplify the text in this section of the guidelines and add the qualification that it applies to the information/data shared with the competent authority by the vTPA owner in line with the comments submitted on Section D: Roles, Responsibilities and Relevant Activities.</p> <p><u>[Proposed revised text]</u></p> <p><u>COMPETENT AUTHORITY</u></p> <p>(g) Have to ensure and maintain the confidentiality of data shared by the vTPA owner.</p>

<u>The text in square brackets:</u>			
FBOs			
e. <i>[Is able to demonstrate that it has no conflicts of interest with the operation of the vTPA.]</i>			
<u>Co-chair comments:</u>			
The responsibility to avoid conflicts with FBO participants is included in sub para (f) of the vTPA Owner section. Does it need to be repeated here?			
EWG member comments (general)	Proposed alternative text (or support retention/deletion)	Rationale for proposed alternative text (or retention/deletion)	Co-Chair Comments / Response
Canada			
[No comment provided]	Canada supports retaining the highlighted text and text included in sub para (f) of the vTPA Owner section.	This provides assurance to the competent authority that the FBO is accountable for the absence of conflict of interest while on the vTPA programme.	This comment supports retention of the text in square brackets.
EU			
It is useful to have this responsibility also for the FBO.	The text could be shortened to read: "Has no conflicts of interest with the operation of the vTPA."	It is not clear how the FBO should demonstrate that there is no conflict of interest with the operation of the vTPA.	This comment supports retention of the text in square brackets and proposes a shortened version.
France			
Has to be maintained.	[No comment provided]	Conflict of interest is what entails the most discussion and controversy. FBO being capable to demonstrate that there is no conflict of interest.	This comment supports retention of the text in square brackets.
Indonesia			
We support this bullet as a responsibility of FBO	The text should be read: <u>"e. Has no conflicts of interest with the operation of the vTPA"</u>	[No comment provided]	This comment supports retention of the text in square brackets and suggests revisions similar to the EU.

Japan			
[No comment provided]	e. [Is able to demonstrate that it has no conflicts of interest with the operation of the vTPA.]	It does not need to be repeated here. Sub para(f) of the vTA owner section is sufficient to capture this.	This comment supports deletion of the square bracketed text.
Morocco			
This paragraph should be deleted	[No comment provided]	It is more relevant to mandate the VTPA Owners to demonstrate that it has no conflicts with FBO,	This comment supports deletion of the square bracketed text.
New Zealand			
[No comment provided]	New Zealand comment: we support retaining the text	The owner of the scheme and the FBOs are two separate parties and it is appropriate that this obligation is clear.	This comment supports retention of the text in square brackets
Norway			
This text does not need to be repeated here.	[No comment provided]	The reader of the guidance is CA, and this is already included under sub para f.	This comment supports deletion of the square bracketed text on the basis that it is covered already in sub para f.
Singapore			
[No comment provided]	It is ok to be repeated.	It is important that FBOs are able to demonstrate that it has no conflicts of interest with the operation of the vTPA.	This comment supports retention of the text in square brackets.
USA			
Yes, we would like to see this repeated here.	Is able to demonstrate that it has no conflicts of interest with the operation of the vTPA to which the FBO chooses to participate in.	To make it clear that the conflicts of interest relate to the program to which an FBO is participating in.	This comment supports retention of the text in square brackets a revised expanded text to make the intention clearer.
Chile			
It is not necessary to repeat, it is enough that it appears in subparagraph f) under the title vTPA owners.	[No comment provided]	[No comment provided]	This comment supports deletion of the square bracketed text.
Mexico			
[No comment provided]	Repetition is not considered necessary.	Repetition is not necessary, since the responsibility for the non-conflict of interest described in subparagraph (f) is sufficient.	This comment supports deletion of the text on the basis that sub para (f) is sufficient.
Uruguay			
Uruguay considers that both points are maintained as they cover different areas of application.	[No comment provided]	[No comment provided]	This comment supports retention of the text in square brackets

GFSI			
[No comment provided]	[Is able to demonstrate that it has no conflicts of interest with the operation of the vTPA.] GFSI would like to propose to add after vTPA: eg. use of accredited certification bodies by IAF Multilateral Recognition Arrangement signatories.	[No comment provided]	This comment supports retention of the text in square brackets and suggests additional text. The Co-Chairs note that the additional text provides examples of how the FBO might demonstrate there are no conflicts with the vTPA owner. This additional information does not really fit under the Section headed: "Roles and responsibilities".
Co-Chair views and overarching proposal / suggested text			
<p>Most comments support retention of a shorted version of the square bracketed text whilst some believe it to be repetitive so favour deletion, principally as it appears to be a duplication of sub para (f) of the vTPA Owner section. The co-chairs contend that there is no duplication as the FBOs and vTPA owners are separate entities. On balance the Co-Chairs suggest retaining a shorter construction as suggested by some members.</p> <p>FBOs [Revised sub-paragraph] (e) Has no conflicts of interest with the operation of the vTPA. [Other change to this section] (Japan): FBOs a. Have the primary role and responsibility for managing the food safety of their products and for complying with regulatory requirements relating to these aspects of food under their control.</p>			

<u>The text in square brackets:</u>			
vTPA Owner			
b [Are accountable to FBOs that participate in vTPA programmes.]			
<u>Co-chair comments:</u>			
Is this important and therefore necessary? The drafter's intention was to illustrate accountability, for example decisions to share aggregated information/data generated by the vTPA programme.			
EWG member comments (general)	Proposed alternative text (or support retention/deletion)	Rationale for proposed alternative text (or retention/deletion)	Co-Chair Comments / Response
Canada			
[No comment provided]	[No comment provided]	[No comment provided]	
EU			
[No comment provided]	This provision should be deleted.	Accountability to FBOs could compromise the integrity of the vTPA programme.	This comment supports deletion of the square bracketed text.

France			
We support the deletion of this paragraph	[No comment provided]	vTPAs are not responsible for what FBOs do (just as CA are not responsible either)	This comment supports deletion of the square bracketed text.
Indonesia			
It is not necessary to include the square-bracketed text as a responsibility of vTPA owner.	[No comment provided]	Accountability to FBOs is a common thing, for example present the result of vTPA program to FBO.	This comment supports deletion of the square bracketed text.
Japan			
[No comment provided]	b Are accountable to FBOs that participate in vTPA programmes. <u>e.g. an agreement with the competent authority, decisions to share aggregated information/data generated by the vTPA programme.</u>	We think this is important to illustrate accountability. The examples can be given.	This comment supports retention with a helpful illustration of the purpose.
Morocco			
This paragraph should be kept as it's drafted	[No comment provided]	In accordance with the paragraph d [d. Owners the information/data generated by the VTPA programme]	This comment supports retention of the square bracketed text.
New Zealand			
[No comment provided]	New Zealand comment: we support deleting the text.	This obligation is covered by point d and f	This comment supports deletion of the square bracketed text.
Norway			
We support deleting this para.	[No comment provided]	The FBOs are the primary responsible party. It is not possible for the vTPA owners to be held responsible for everything that an FBO does.	This comment supports deletion of the square bracketed text.
Singapore			
It is important that the vTPA Owner keeps confidentiality of data to demonstrate its credibility. For sharing of data with CA, the next clause says there must be process established between the vTPA programme owners and the CA. <i>"Sharing information/data generated by the vTPA programme owners for use by the competent authority, according to the process established by the vTPA</i>	[No comment provided]	[No comment provided]	This comment supports retention and helpfully explains the need for more clarity on the purpose of this sub-paragraph.

<i>programme owners and the competent authority.”</i>			
USA			
As written the bullet is unclear. Also, the preceding section clearly identifies that the data is owned by the FBO. Expanding the language	Are accountable to participating FBOs to disclose the potential sharing of information/data generated by the vTPA programme with competent authorities.	Expanding the language of this bullet to better articulate the connection between the parties, from the information owner (FBO) to the party that has responsibility and approval to share the data (vTPA owner) would benefit all involved in the process (i.e. FBO, vTPA & regulator)	This comment supports retention and suggests language to qualify (and limit) the intent of this sub-paragraph to illustrate that the vTPA owner is accountable to the FBOs for the information/data it shares with the competent authority. The Co-Chairs wish to note that that this accountability should not be viewed as a potential conflict of interest.
Chile			
More clarity is needed regarding what is sought in this language.	[No comment provided]	[No comment provided]	This comment supports retention of the square bracketed text but calls for more clarity in the drafting.
Mexico			
[No comment provided]	Accept text in square brackets.	The text in square brackets is accepted since it is important that holders of vTPA programs assume responsibility for the exchange of information / data with the authority, considering that such information / data belongs in the first instance to the FBO.	This comment supports retention of the square bracketed text and picks up on the same point made by others regarding vTPA owner accountability for the exchange of FBO information/data.
Uruguay			
Uruguay considers this point to be maintained.	[No comment provided]	[No comment provided]	This comment supports retention of the square bracketed text.
GFSI			
Delete the paragraph	[No comment provided]	[No comment provided]	This comment supports deletion of the square bracketed text
Co-Chair views and overarching proposal / suggested text			
<p>Members comments/views are divided between those seeking to delete and those arguing for the retention of this text. On balance the Co-Chairs take the view that the text could be retained with the addition of the suggested clarification that the accountability relates to the sharing of FBO information/data with the competent authority.</p> <p><u>[Revised sub-paragraph]</u></p> <p>vTPA Owner</p> <p>(b) Are accountable to participating FBOs to disclose the potential sharing of information/data generated by the vTPA programme with competent authorities.</p>			

The text in square brackets:			
vTPA Owner			
e. Have policies to ensure a vTPA alerts the competent authority of any significant [public health risks associated with] non-compliances by the regulated industry.			
Co-chair comments:			
Is this qualification necessary/helpful? The drafter's intention was to differentiate between routine non-compliances that may be corrected as part of the vTPA governance arrangements versus significant non-compliance for which public health risks may trigger a sense of urgency/immediacy.			
EWG member comments (general)	Proposed alternative text (or support retention/deletion)	Rationale for proposed alternative text (or retention/deletion)	Co-Chair Comments / Response
Canada			
[No comment provided]	Canada supports retaining this qualification but proposes alternative text: e. "Have policies and processes to share information with the Competent Authority on any changes to the vTPA programme and the vTPA certification status of the FBO and alert the competent authority of any significant risk to public health or consumer deception "	The proposed alternative text aligns with section F. Data Sharing and Information Exchange #2.	This comment supports retention of the square bracketed text along with a broadening of the criteria beyond public health to include consumer deception.
EU			
[No comment provided]	The qualification is helpful but non-compliances leading to consumer deception should be added, i.e. it should read "...any significant public health risks or consumer deception associated with non-compliances..."	[No comment provided]	This comment supports retention of the square bracketed text along with a broadening of the criteria beyond public health to include consumer deception.
France			
We support the deletion of the square-bracketed part.	[No comment provided]	Significant non compliances can be broader than public health (ie : fair practices in food trade)	This comment suggests deletion on the basis that significant non-compliances may have implications beyond just public health. This comment would be addressed by the addition of e.g. consumer deception/fair practices in food trade as suggested by those members supporting retention.
Indonesia			
We support deleting the square-bracketed text.	[No comment provided]	The term "significant" has a broad meaning which can be adjusted to the policy in each country.	This comment supports deletion of the square bracketed text on the basis that "significant" has a broad meaning.

Japan			
Yes, it is helpful. We agree with the co-chairs.	[No comment provided]	[No comment provided]	This comment supports retention of the square bracketed text.
Morocco			
The square bracketed text should be deleted	[No comment provided]	The qualification 'significant non-compliances' covers public health risks,	This comment supports deletion of the square bracketed text preferring the qualifier "significant to be applied to non-compliances.
New Zealand			
[No comment provided]	New Zealand comment: we support retaining the text	This must be clearly stated as a responsibility – without such a commitment any vTPA will be suspect.	This comment supports retention of the square bracketed text on the basis it is integral to trust in the vTPA programme.
Norway			
We support deleting the text in square brackets, as it will narrow the understanding of "significant non-compliance".	[No comment provided]	Can be broader than just public health.	This comment supports deletion of the square bracketed text preferring the qualifier "significant to be applied to non-compliances. This comment would be addressed by a broadening to include consumer deception/fair practices in food trade as suggested by those members supporting retention.
Singapore			
May not be necessary to have the qualification 'public health risk associated with', since it is already mentioned to alert CA of any significant NCs by the regulated industry. Will be good that vTPA alerts CA on any other significant CA that is not directly associated with public health risks.	[No comment provided]	[No comment provided]	This comment supports deletion of the square bracketed text preferring the qualifier "significant to be applied to non-compliances. This comment would be addressed by a broadening to include consumer deception/fair practices in food trade as suggested by those members supporting retention.
USA			
We agree with the drafters' intention and support retention of the language in brackets. We note that consumer deception is listed in Data Sharing, bullet two, and it could be added here.	Have policies to ensure a vTPA alerts the competent authority of any significant public health risks or consumer deception associated with non-compliances by the regulated industry	Page 9 Data Sharing and Information Exchange bullet 2 speaks to significant public health risk or consumer deception. We recommend utilizing consistent language on scope throughout	This comment supports retention and suggests a broadening of the criteria beyond public health to include consumer deception which would also address the concerns of those members that have commented that significant goes beyond public health.

Chile			
[No comment provided]	[No comment provided]	[No comment provided]	
Mexico			
[No comment provided]	Accept text in square brackets.	The text is accepted in square brackets since it is important to guarantee the timely transmission of information to the Authority, in case of serious risks to the public health, in order to allow the pertinent actions to be carried out.	This comment supports retention of the square bracketed text and acknowledges its use for serious situations when swift action is needed.
Uruguay			
Uruguay proposes to delete the text "any significant " and keep the text in square brackets.	They must have regulations to ensure that the vTPA program notifies the competent authority in case of public health risks related to non-compliance by the regulated industry.	[No comment provided]	This comment supports retention of square bracketed text and suggests deletion of qualification "any significant". The Co-Chairs suggest that the qualification is necessary in order to differentiate between non-conformities that are minor and those that may for example create an imminent risk to public health, or as mentioned by other members lead to consumers being deceived.
GFSI			
[No comment provided]	Proposition to replace what is in square bracket by: Have policies to ensure a vTPA alerts the competent authority of any significant to alert the competent authority if a certificate is withdrawn or suspended for cause non-compliances by the regulated industry.	[No comment provided]	This comment suggests alternative text to that contained in the square brackets. The alternative text would limit alerting the competent authority to when a certificate is withdrawn or suspended for non-compliances. The Co-Chairs suggest "significant non-conformities" or "significant public health or consumer deception address the issue of e.g. certification status. Supporting text is provided in Section F, "Data sharing and information exchange" sub para (2) and (4).
Co-Chair views and overarching proposal / suggested text			
<p>A number of comments suggest deletion on the basis that the qualifier "significant" is broader than public health. Some comments that support retention make the same point (about it being broader) and suggest the addition of "consumer deception" as a fix. The Co-Chairs note that an earlier suggested change led to the deletion of the text in Principle 3 about "significant public health risk and consumer deception" on the basis that it was adequately covered in this Section. The Co-Chair suggest that broadening the text to include consumer deception and retaining the text here is consistent with the changes suggested for Principle 3.</p> <p>[Revised sub-paragraph]</p> <p>vTPA Owner</p>			

e. Have policies to ensure a vTPA owner alerts the competent authority of any significant public health risks or consumer deception associated with non-conformities by the FBO(s).

• **Section F: Criteria to Assess the Credibility and Integrity of vTPA Programmes**

The text in square brackets:

Governance arrangements

5) If the accreditation arrangement does not adhere to IAF or ILAC, does the vTPA programme owner ensure that [certification/accreditation] bodies have the capacity and competency to perform effectively?

Co-chair comments:

The key question is whether the vTPA owner is able to influence the accreditation body?

EWG member comments (general)	Proposed alternative text (or support retention/deletion)	Rationale for proposed alternative text (or retention/deletion)	Co-Chair Comments / Response
Canada			
Canada supports the intent of the text but prefers to not reference other organizations such as IAF and ILAC. Canada suggests combining 4) and 5) and removing references to IAF and ILAC.	Canada suggests the following alternative text: 4.) Does the vTPA programme have an accreditation arrangement with an accreditation body with international standing, recognition and credibility? If not, does the vTPA programme owner ensure that [accreditation] bodies have the capacity and competency to perform effectively?	As appropriate, it is preferable to limit specific references to other international organizations outside the purview of Codex. Removing references will also help ensure longevity of the Codex text.	This comment supports retention with some revisions. The Co-Chairs notes that this comment helpfully explains the purpose of the simplified drafting that combines the concepts in paras 4 and 5 into a single paragraph. The suggestion to delete reference to IAF and ILAC is also noted.
EU			
[No comment provided]	This provision should be deleted.	This provision is covered by point 4 which refers to accreditation bodies not adhering to IAF or ILAC. Requirements for certification bodies are provided under the following section "Accreditation of Certification Bodies".	This comment supports deletion of para (5) on the basis that para (4) is sufficient. The Co-Chair note that this point is addressed by Canada's suggested revisions and the section that follows in the guidelines entitled: "Accreditation of Certification Bodies".
France			
We would agree with certification but would delete accreditation.	[No comment provided]	vTPA have to ensure the CB certifying against the vTPA's standards is accredited or can provide the same guarantees than accreditation.- In other words, the vTPA owner needs to ensure the 'certification' bodies are capable	This comment supports retention of certification and deletion of accreditation. The Co-Chairs note that this point is addressed by Canada's suggested revisions and the section that follows in the guidelines entitled: "Accreditation of Certification Bodies".

		and competent if these are not accredited through IAF or ILAC	
Indonesia			
[No comment provided]	[No comment provided]	[No comment provided]	
Japan			
vTPA owner sets rules on the implementation of their programme and certification/accreditation bodies follow the rules.	[No comment provided]	[No comment provided]	This comment supports retention of both terms.
Morocco			
This paragraph should be deleted	[No comment provided]	There is an overlap between the current and the previous paragraph, The point 4 covers the case when the accreditation arrangement does not adhere to IAF or ILAC.	This comment picks up the same point addressed by Canada and their suggested revisions.
New Zealand			
[No comments provided]	New Zealand comment: we support retaining 'certification' and deleting 'accreditation'	The vTPA owner needs to ensure the 'certification' bodies are capable and competent if these are not accredited through IAF or ILAC	This comment supports retention of certification and deletion of accreditation. This point is addressed by Canada's suggested revisions and the section that follows in the guidelines entitled: "Accreditation of Certification Bodies".
Norway			
We would prefer to keep the text.	[No comment provided]	[No comment provided]	This comment supports retention of both terms.
Singapore			
vTPA programme owner should be independent of the certification/accreditation body.	[No comment provided]	[No comment provided]	This comment addresses the question in a slightly different way, in relation to potential conflicts, but supports the revised/simplified drafting proposed by Canada.
USA			
Would recommend keeping the highlighted portion of the sentence.	'If the accreditation arrangement does not adhere to IAF or ILAC, how does the vTPA programme owner ensure accreditation and certification bodies have the capacity and competency to perform effectively?	Minor revisions as proposed may address the objectives of the co-chairs	This comment accords with the revisions suggested by Canada with the addition of "how".
Chile			
[No comment provided]	[No comment provided]	[No comment provided]	

Mexico			
[No comment provided]	5) If the accreditation arrangement does not adhere to <u>an accreditation body that complies with the characteristics indicated in paragraph 4</u> IAF or ILAC, does the vTPA programme owner ensure that [certification/accreditation] bodies have the capacity and competency to perform effectively?	It is suggested to avoid citing non-governmental organizations, in order to maintain the impartiality of the document.	This comment accords with the revisions suggested by Canada. The Co-Chair note the suggestion to delete reference to IAF and ILAC.
Uruguay			
Uruguay considers that point 5 should be eliminated. It is understood that the vTPA program must necessarily have an accreditation agreement that adheres to an accreditation body with sufficient recognition, international reputation and credibility.	[No comment provided]	[No comment provided]	This comment supports simplifying the text and avoiding unnecessary repetition based on common understanding of the intention and terminology.
GFSI			
Delete paragraph 5	[No comment provided]	[No comment provided]	The comment supports the revised simplified drafting suggested by Canada.
Co-Chair views and overarching proposal / suggested text			
<p>There is clear support for retention of the concepts contained in sub-paragraphs 4 and 5 but also to merge the two sub-paragraphs to simplify and add clarity to the drafting. A few members suggest deletion of the references to the international organisations and comment that this will avoid the text becoming dated. The Co-Chairs noting this comment suggest a compromise that moves the reference to IAF and ILAC to a footnote so that examples are retained as this may be of value to some members and also address the issue of the main body of the text becoming dated.</p> <p>[Proposed revised/merged sub-paragraph]</p> <p>4) Does the vTPA programme have an accreditation arrangement with an accreditation body with international standing, recognition and credibility? If not, how does the vTPA programme owner ensure that accreditation bodies have the capacity and competency to perform effectively?"</p> <p>[Proposed new footnote]</p> <p>⁵Examples include: The International Accreditation Forum (IAF) and the International Laboratory Co-operation (ILAC).</p>			

The text in square brackets:			
Accreditation and certification arrangements			
3) Does the Accreditation Body assess the certifying body using the relevant standards including for example [ISO/IEC 17020], ISO/IEC 17065 or ISO/IEC 17021-1 supplemented with ISO/TS 22003?			
Co-chair comments: Is this reference correct/needed?			
EWG member comments (general)	Proposed alternative text (or support retention/deletion)	Rationale for proposed alternative text (or retention/deletion)	Co-Chair Comments / Response
Canada			
Canada prefers to limit references to other organizations and notes that these are examples that don't provide any additional guidance on the subject. Canada supports deleting all references to ISO and is considering whether 3) is covered already by 4) and therefore necessary to the text.	Canada supports deleting the text retained in square brackets and suggests amending the text as follows: 3.) Does the Accreditation Body assess the certifying body using relevant and internationally recognized standards? Alternatively, Canada suggests removing #3 in its entirety.	For deletion of all references to ISO: as appropriate, it is preferable to limit references to other international organizations outside the purview of Codex. Removing references will also help ensure longevity of the Codex text.	This comment supports deletion of the text in square brackets. The Co-Chairs note the suggestion to delete the references to ISO.
EU			
No comment.	[No comment provided]	[No comment provided]	
France			
Yes	[No comment provided]	vTPAs can be inspection schemes (IFS Food store for example), therefore ISO/IEC 17020 must be kept	This comment supports retention of the text in square brackets.
Indonesia			
Indonesia agrees to include ISO/IEC 17020 as a reference.	[No comment provided]	To make it clear what the example of standard refers to.	This comment supports retention of the text in square brackets.
Japan			
[No comment provided]	Does the Accreditation Body assess the certifying body for example whether the certifying body complies with ISO/IEC 17020, ISO/IEC17065 or ISO/IEC17021-1 based on ISO/IEC 17011?	[No comment provided]	This comment supports retention of the text in square brackets and adds a reference to ISO/IEC 17011.
Morocco			
We would prefer to retain this reference	[No comment provided]	It provides more guidance about relevant standards.	This comment supports retention of the text in square brackets.

New Zealand			
New Zealand comment: we support retaining the reference	Suggest amending the entire point as follows: 3) Does the accreditation Body assessment of the certifying body apply using the relevant standards including	To be clear that it is the accreditation process that needs to follow the relevant standard and not confuse the reader about who undertakes this.	This comment supports retention of amended text that does not refer to the international organisations.
Norway			
[No comment provided]	[No comment provided]	[No comment provided]	
Singapore			
[No comment provided]	We are ok to retain reference to the respective ISO standards.	This would provide some context as to what are "relevant standards".	This comment supports retention of the text in square brackets.
USA			
We support keeping the reference. ISO 17020 speaks to how certification bodies perform their audits/inspections	[No comment provided]	[No comment provided]	This comment supports retention of the text in square brackets.
Chile			
[No comment provided]	[No comment provided]	[No comment provided]	
Mexico			
[No comment provided]	3) Does the Accreditation Body assess the certifying body using the relevant standards including for example [ISO/IEC 17020], ISO/IEC 17065 or ISO/IEC 17021-1 supplemented with ISO/TS 22003?	It is suggested to avoid citing non-governmental organizations, in order to maintain the impartiality of the document.	This comment supports deletion of the text in square brackets and the earlier comment made by Canada to avoid references to ISO in the text.
Uruguay			
Uruguay considers that it is not necessary to include the text in square brackets, it is not necessary to include the references.	3) Does the accreditation body evaluate the certification body using the relevant standards?	[No comment provided]	This comment supports deletion of the text in square brackets and the earlier comment made by Canada to avoid references to ISO in the text.
GFSI			
[No comment provided]	[No comment provided]	[No comment provided]	

Co-Chair views and overarching proposal / suggested text
<p>The balance of comments favour retention of the text in square brackets, however the Co-Chairs note the arguments put forward by those seeking to delete references to international organisations and specific ISO standards, including the potential for the guidelines to become dated. As a compromise the Co-Chairs suggest using the text in square brackets as examples in a footnote as comments from some members suggest it is useful to have these examples to hand and as for the other section helps avoid the main body of the text becoming outdated in the future.</p> <p>[Proposed revised sub-paragraph]</p> <p>3) Does the accreditation body assess the certifying body using relevant and internationally recognized⁶ standards?</p> <p>[Proposed new footnote]</p> <p>⁶Examples include: ISO/IEC 17020, ISO/IEC 17065 or ISO/IEC 17021-1 supplemented with ISO/TS 22003, ISO/IEC 17011</p>

- **Section G: Regulatory approaches for the use of vTPA data/information**

The text in square brackets:
<p>14. This section provides examples of necessary considerations and the practical uses that can be made by competent authorities of vTPA information/data to support their NFCS objectives.</p> <p>15. <i>[Where the competent authority has assessed vTPA arrangements and identified information/data that aligns and indicates compliance with relevant regulatory requirements and NFCS objectives, the competent authority may establish a mechanism / process with the vTPA owner for information/data sharing and handling of non-compliance where failure to alert the competent authority of any significant public health risk or consumer deception is identified.]</i></p>

Co-chair comments: This has been lifted from Principle 3 and becomes part of the chapeaux/introduction to Section G with para 14 (also shown). The two subheadings in Section G are titled "Process considerations" and "Policy options" so the text in 14 and 15 needs to be refined to better reflect the content of the two sub headings.

EWG member comments (general)	Proposed alternative text (or support retention/deletion)	Rationale for proposed alternative text (or retention/deletion)	Co-Chair Comments / Response
Canada			
[No comment provided]	<p>Canada suggests combining text 14 and 15 and to keep the rewording of principle 3 (see comments in Section D: Principles).</p> <p>14.) This section provides examples of necessary considerations and the practical uses that can be made by competent authorities of vTPA information or data to support their NFCS objectives. "The competent authority should establish appropriate mechanisms with the vTPA owner to enable continued information exchange on any changes to the vTPA programme and the vTPA certification status of the FBO and alert the competent authority of any significant risk to public health or consumer deception "</p>	<p>This section provides examples of process considerations and policy options to support regulatory requirements and NFCS should the competent authority decide to make use of the vTPA information/data.</p>	<p>This comment supports combining the text lifted from Principle 3 with the existing para 14 of Section G.</p>

EU			
[No comment provided]	This section provides examples of process considerations and policy options available for competent authorities when they establish arrangements with vTPA owners to use vTPA information/data to support their NFCS objectives.	[No comment provided]	This comment provides revised text for a chapeau that is concise and provides a better link to the text that follows in the process and policies sub-paragraphs.
France			
We agree with this move	[No comment provided]	[No comment provided]	This comment supports the lifting of text from Principle 3 to better introduce the purpose of Section G.
Indonesia			
We support this para included under Section G.	[No comment provided]	[No comment provided]	This comment supports the lifting of text from Principle 3 to better introduce the purpose of Section G.
Japan			
[No comment provided]	<p>14. Where the competent authority has assessed vTPA arrangements and identified information/data that aligns and indicates compliance with relevant regulatory requirements and NFCS objectives, the competent authority may establish a mechanism / process with the vTPA owner for information/data sharing and handling of non-compliance where failure to alert the competent authority of any significant public health risk or consumer deception is identified. This section provides examples of necessary considerations and the practical uses that can be made by competent authorities of vTPA information/data to support their NFCS objectives.</p> <p>15. This section provides examples of necessary considerations and the practical uses that can be made by competent authorities of vTPA information/data to support their NFCS objectives.</p>	We agree with the co-chairs to lift the text from Principle 3 but we propose to put it before the existing introduction (para14).	This comment supports the lifting of text from Principle 3 and proposes that it should be positioned at the start of para 14 to better order the introduction to Section G.
Morocco			
Morocco support moving the point 15 under the sub headings titled "Process considerations"	[No comments provided]	[No comments provided]	This comment suggests that the text lifted from Principle 3 fits better under a "Process" sub-paragraph.

New Zealand			
New Zealand comment: the square bracket text of Para 15 is not really necessary as the need for agreed processes for information exchange and handling non-compliances is already captured in the various points. What is needed is a clearer introduction to Section G	14. The section sets out examples of the necessary process considerations and policy options competent authorities should take into account . 15 This section also provides examples of the practical uses that can be made by competent authorities of vTPA information/data to support their NFCS objectives.	To clearly state what is in section G.	This comment does not support the lifting of Principle 3 to para 15. It provides changes to para 14 similar to those suggested by the EU and introduces a new construct for para 15 that focuses on the practical nature of the text in Section G.
Norway			
We support including para 15 under section G, however we do not have proposals for refinement.	[No comment provided]	[No comment provided]	This comment supports lifting text from Principle 3 into Section G.
Singapore			
[No comment provided]	There may not be a need to repeat para 15 in Sections G.	We feel that para 15 is elaborated in subsequent sections and therefore there is no need to have para 15 as a preamble.	This comment supports lift the text from Principle 3 to this text but suggests it might fit better under a "Process" sub-paragraph.
USA			
As suggested in an earlier response, Section G, bullet c lends itself to additional language to capture the intent of this item.	Add a second sentence to in Section G bullet c: 'That arrangement should establish a process with the vTPA owner for sharing of information/data and processes for handling findings of non-compliance.	This shortened sentence would cover this issue with less confusing language. Information sharing processes should cover non-compliances generally. The final clause of the sentence is unnecessarily restrictive and has the potential to add confusion.	This comment suggests that the text lifted from Principle 3 fits better under a "Process" sub-paragraph.
Chile			
[No comment provided]	[No comment provided]	[No comment provided]	
Mexico			
[No comment provided]	No se tienen comentarios	No comment provided]	
Uruguay			
Uruguay agrees to include the text in square brackets in section G.	[No comment provided]	[No comment provided]	This comment supports retention of the text in square brackets.
GFSI			
[No comment provided]	15. Proposition to replace the last part of the paragraph with: [Where the competent authority has assessed vTPA arrangements and identified information/data that aligns	[No comment provided]	This comment supports the lifting of the text from Principle 3 and suggests an additional qualifier relating to certification status.

	and indicates compliance with relevant regulatory requirements and NFCS objectives, the competent authority may establish a mechanism / process with the vTPA owner for being alerted when a certificate is withdrawn or suspended for cause.		The Co-Chairs note that the issue of certification status is covered in Section F under " Data Sharing and Information Exchange " sub-para 4.
Co-Chair views and overarching proposal / suggested text			
<p>Members have made a number of drafting suggestions aimed at improving the clarity of the introductory paragraph. The Co-Chairs are attracted by member's suggestions that seek to combine the concepts contained in paragraphs 14 and 15 to help clarify the purpose of this section of the guidelines.</p> <p>Members will recall earlier comments to move text from Principle 3 to Section F. The Co-Chairs agree with those members that suggest this text fits better as a sub-paragraph under "process considerations" and consider it should be placed below the current sub-para (c).</p> <p>[Proposed revised introduction to this section]</p> <p>14. This section provides examples of process considerations and policy options available for competent authorities when they establish arrangements with vTPA owners to use vTPA information/data. It also contains examples of the practical uses that can be made by competent authorities of vTPA information/data to support their NFCS objectives.</p> <p>[Proposed revised sub-paragraphs]</p> <p>(c) Where there is a positive assessment outcome the competent authority may choose to enter into an arrangement with the vTPA owner by mutual consent.</p> <p>New</p> <p>(c - bis) Competent authorities that have arrangements with vTPA owners should establish a process for the sharing of relevant information/data and processes for handling findings of non-conformities, including alerting the competent authority of any significant public health risk or consumer deception.</p>			