



JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION
AND CERTIFICATION SYSTEMS

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**DRAFT PRINCIPLES AND GUIDELINES FOR THE ASSESSMENT AND USE OF VOLUNTARY
THIRD-PARTY ASSURANCE (vTPA) PROGRAMMES (Updated Text)¹**
(At Step 7)

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

Executive summary

Following the postponement of CCFICS25 from 2020 to 2021, the Committee Chairperson, in consultation with the Codex Secretariat, agreed to reactivate the electronic working group (EWG) so that work could be progressed until such time as CCFICS25 was able to meet again. Members of the previous EWG were automatically enrolled to the group and new members invited to join.

The EWG co-chairs, UK, Canada and Mexico, conducted a detailed analysis of the comments received in response to CL 2019/93/OCS-FICS (CX/FICS 20/25/4 Add.1) and CL 2020/26/OCS-FICS (CX/FICS 20/25/4 Add.2). Resulting from this analysis, the co-chairs launched a further consultation via the EWG Platform in November 2020 that provided:

- a summary of the key themes and proposals to emerge from the above consultations;
- a revised text incorporating members' comments and co-chairs' edits to improve the consistency and clarity of the text;
- a series of questions seeking EWG members' views on specific issues that the co-chairs felt merited further comment/discussion.

The issues on which the co-chairs sought further comments from participants were: whether Principle 8 should be retained; clarity of the text relating to conflicts of interest and confidentiality of information; and whether there is a need to maintain and/or define "significant public health risk" in section F. The consultation closed on 3 January 2021. The co-chairs analyses, the compilation of EWG participants' comments and a proposed way forward can be found in the appendices (see para 14).

The co-chairs concluded from their analysis of the comments received that there continues to be broad support for the guidelines and that there are no fundamental differences of views amongst participants.

The co-chairs' recommendations for next steps are:

- CCFICS25 to host a webinar on 25 March 2021 to update Codex Members and observers on the progress that has been made and answer any questions with a view to facilitating a smooth discussion during the formal session of CCFICS25.
- CCFICS25 to review the revised final draft Principles and guidelines contained in Appendix 1 and consider whether to recommend to CAC44 adoption of the text at Step 8.

¹ This Updated document takes into account the comments solicited through CL 2019/93/OCS-FICS and CL 2020/26/OCS-FICS.

INTRODUCTION & BACKGROUND

1. The 24th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS24) 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 (CAC) at its 42nd Session (CAC42) subsequently endorsed this recommendation and adopted the text at Step 5 along with the recommendation to establish an electronic working group (EWG) to consider the outstanding issues, primarily the text held in square brackets, and assist with Step 6 comments.
2. Subsequent to CAC42, the text at Step 5 was circulated to all Codex Members and Observers for comments at Step 6, in CL 2019/93/OCS-FICS. Comments can be found in **CX/FICS 20/25/4 Add.1**.
3. In parallel, the EWG was launched as per the recommendations of CCFICS24 to consider outstanding issues, primarily text found in square brackets. The EWG concluded its work in 2019 and the report can be found in document **CX/FICS 20/25/4**.
4. The report of the EWG, including the text as revised by the EWG, was circulated for comments early 2020, through CL 2020/26/OCS-FICS. Comments received are found in **CX/FICS 20/25/4 Add.2**.
5. The report of the EWG (CX/FICS 20/25/4) and the comments found in CX/FICS 20/25/4 Add.1 and CX/FICS 20/25/4 Add.2, were supposed to be considered at a physical working group meeting scheduled to be held on 25 April 2020, immediately prior to the CCFICS25 Plenary, which was originally due to meet in Hobart, Tasmania, 27 April – 1 May 2020.

POSTPONEMENT OF CCFICS25 AND REACTIVATION OF THE EWG

6. The onset of the COVID-19 pandemic led to the postponement of all of the subsidiary body meetings of Codex scheduled for 2020, including CCFICS25. The importance of continuing to progress Codex work in the absence of physical meetings was acknowledged by the wider membership.
7. In consultation with the Codex Secretariat and the Chairperson of CCFICS, it was agreed to re-activate the EWG to consider comments in CX/FICS 20/25/4 Add.1 and CX/FICS 20/25/4 Add.2, in advance of the re-scheduled plenary session of CCFICS25. Previous members of the EWG were automatically enrolled and a call for new members went out in August 2020. As before, the EWG conducted its business on the electronic platform and the group comprised 33 member countries and 9 observer organisations giving a total of 63 participants.
8. The co-chairs conducted a detailed review and analysis of comments in CX/FICS 20/25/4 Add.1 and CX/FICS 20/25/4 Add.2 and submitted a revised text to EWG participants on November 3, 2020, with a deadline for comments of January 3, 2021. In areas where views were divided with no clear consensus, the co-chairs posed a series of questions and options to EWG participants. In their analysis of comments and proposals for a way forward, the co-chairs sought to address a number of elements/themes, in particular:
 - a. Ensuring consistency of terminology throughout the text, in the Definitions section, and with other Codex texts;
 - b. Simplifying the Definitions section to maintain essential definitions, and updating references to external texts (i.e., ISO references);
 - c. Renumbering the text to ensure all sections and sub-sections were numbered, for ease of reference;
 - d. Clarifying several areas in the text based on comments received; and, omitting duplicative text in Section G.14. 2) *Policy Options*.
 - e. Where views were divided, the Co-Chairs asked targeted questions to the EWG participants and proposed text options, in order to facilitate consensus. These areas include: whether principle 8 should be retained; clarity of the text relating to conflict of interest and confidentiality of information; and whether there is a need to maintain and/or define “significant public health risk”.
9. The co-chairs also noted some areas where consistency of English to Spanish translation should be addressed.

10. A total of 14 participants responded, comprising ten Member countries, one Member organization and three observer organizations. The feedback of the re-activated EWG participants and responses to the specific questions were analyzed and the outcome of the co-chairs' analysis and proposed way forward was posted to the EWG Platform on 11 March 2021 for information, with a request that any high level comments be sent to the co-chairs by 12 April to further aid preparations for CCFICS25.
11. The output from the co-chairs' analysis was a track changes version of the text with embedded co-chair rationale for the revisions. This version was used to produce a clean copy for discussion at CCFICS25.

CONCLUSIONS

12. The co-chairs are of the view that there continues to be broad support for the guidelines and that there are no fundamental differences of views amongst the members of the EWG. The co-chairs have therefore proposed that discussion at CCFICS25 be based around the revised text that can be found in **Appendix 1**.
13. Further, recognizing that it will have been almost 2.5 years between CCFICS24 and CCFICS25, the co-chairs aim to hold a virtual webinar prior to CCFICS25 (on 25 March 2021) in order to provide an update on the progress of this work and to recap the key issues and discussions raised over the prolonged period that has passed since CCFICS last met. The purpose of such a session would be to facilitate the efficient use of time at CCFICS25 given the novel and new modality of virtual working in the subsidiary bodies.
14. To aid with full transparency of the work, the co-chairs are pleased to provide the following additional supporting information. For ease of navigation, a brief summary of the content of each appendix is provided below.

Appendix 1	The final output from the work of the reactivated EWG (clean version of Appendix 5 text) for discussion at CCFICS25.
Appendix 2	The co-chairs' analysis and summary of the comments submitted by members and observers in CX/FICS 20/25/4 Add.1 and CX/FICS 20/25/4 Add.2.
Appendix 3	The revised text and questions to the reactivated EWG's participants that formed the basis of the consultation between 3 November 2020 and 3 January 2021.
Appendix 4	The co-chairs analysis and proposals to the responses received from the reactivated EWG's participants to the 2 Nov 2020 consultation contained in Appendix 3.
Appendix 5	The output from the work of the reactivated EWG (track change version) including embedded co-chair rationale for the revisions.
Appendix 6	Chronology/timeline of the work.

Appendix 1

The final output from the work of the reactivated EWG (clean version of the EWG's Appendix 5 text) for discussion at CCFICS25.

**FINAL DRAFT PRINCIPLES AND GUIDELINES FOR THE ASSESSMENT
AND USE OF VOLUNTARY THIRD-PARTY ASSURANCE PROGRAMMES (Updated text – Clean version)
(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 Systems² foresee competent authorities taking into account quality assurance systems in their national food control system (NFCS). Competent authorities may choose to do this by establishing an arrangement with a vTPA 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 of vTPA programmes 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/data and should only apply assessment criteria that are relevant to that purpose.
4. Reliable vTPA programme 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 programme information/data from FBOs i.e. emphasising that the decision to use vTPA programme 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.

²CXG 82-2013: Principles and Guidelines for National Food Control Systems.

³CXG 20-1995: Principles for Food Import and Export Certification.

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. Competent authorities may choose approaches other than those described in these guidelines when considering how to take into account vTPA programmes information/data in their risk-based targeting of regulatory controls.

C: DEFINITIONS⁴

For the purposes of this document, the following definitions apply:

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

Accreditation: third party attestation related to a certification/conformity assessment body conveying formal demonstration of its competence to carry out specific tasks. (Adapted from ISO.IEC 17000:2020)

Accreditation body: authoritative body that performs accreditation (Adapted from ISO.IEC 17000:2020)

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

Certification body: Third party conformity assessment body operating certification services. (Adapted from: ISO/IEC 17065:2102).

Note: For the purposes of this document, the term “certification body” has the same meaning as “conformity assessment body”.

Conformity assessment: demonstration that specified requirements are fulfilled. (Adapted from ISO.IEC 17000:2020)

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.

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. (CXG 20-1995)

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. (Adapted from ISO.IEC 17000:2020)

Specified requirement: need or expectation that is stated. (Adapted from ISO.IEC 17000:2020)

vTPA Standard: specified requirements contained in the vTPA programme.

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 of FBO operations for conformity with the standard, and in which FBO participation is voluntary.

vTPA Owner: Person or organisation responsible for developing and maintaining a specific vTPA programme. (Source: Adapted from ISO IEC 17065:2012)

D: PRINCIPLES

11. When considering the potential role of vTPA programmes and the potential contribution their information/data 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.

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

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.

Principle 3 Transparency of policies and processes

- Any arrangement to use vTPA programme information/data to support NFCS objectives, including the assessment criteria, should be based on transparent policies and processes in line with Principle 3 of CXG 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 programme 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 programme 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 make use of vTPA programme conformity information/data, competent authorities should ensure that their approach is consistent with applicable [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 reliable vTPA programme information/data in their NFCS relating to protecting the health of consumers and ensuring fair practices in the food trade.

1) 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 [meeting](#) 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. [Should](#) clearly describe the use of a vTPA programme information/data within their NFCS.
- d. (bis). Should have mechanisms in place to verify the continued credibility and reliability of vTPA programme information/data.
- e. Should ensure any arrangements to use vTPA [programme](#) information/data is fully transparent.
- f. Should recognize potential conflicts of interest and their impact on the reliability of the information/data of 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.

- g. Should maintain the confidentiality of information/data shared by the vTPA owner, according to the legislative framework of the country.

2) 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 address regulatory requirements.
- c. May elect to participate in vTPA programmes to meet business needs, demonstrate conformity with relevant food safety standards, and provide independent assurance of the integrity of their products or production systems to relevant stakeholders.
- d. Owns the information/data generated by the vTPA programme.
- e. Has no conflicts of interest with the operation of the vTPA programme.

3) 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. Have mechanisms to share information/data with the competent authority, according to the process established by the vTPA owners and the competent authority.
- d. Have policies and processes when sharing vTPA programme information/data with competent authorities such as notification to the FBO.
- h. Have policies and processes to alert the competent authority of any significant public health risks or consumer deception associated with non-conformities by the FBO(s).
- e. Have policies and processes in place to protect against potential conflicts of interest between vTPA 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 information/data from vTPA programmes to help inform their NFCS should satisfy themselves that the vTPA programme 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 programme 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 and ensure that the vTPA programme has implemented them in a comprehensive way to assure successful outcomes.

1) Governance Arrangements

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

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

2) Accreditation of Certification Bodies

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

3) Standard Setting Process

- a. Do the vTPA owners set their own standards or utilise national or international standards for assurance?
- b. To what extent are the vTPA standards consistent with Codex or other relevant international standards and/or applicable national regulatory requirements?
- c. Do the vTPA standards contain specified requirements to protect consumers in relation to food safety and fair practices in food trade?
- d. Have the vTPA standards been developed through a transparent consultative process with relevant experts and stakeholders reflecting the range of business processes within the target sector?
- e. Are the vTPA standards open, transparent in governance and subject to continuous improvement by regular review to keep them up to date?
- f. Are the vTPA standards written in a way that they can be assessed for conformity?

4) Conformity Assessment

- a. Does the vTPA programme have written procedures on frequency, methodology, announced and unannounced audits and competency requirements for certification bodies?
- b. 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?
- c. Does the vTPA programme have procedures in place to ensure that auditors have and maintain the required auditor competence?
- d. Does the vTPA programme have a transparent system to identify FBOs that conform to the standard (e.g. certification)?

5) Responses to Non-Conformity

- a. Do the vTPA programme governance arrangements include clearly defined procedures for dealing with non-conformities against the vTPA programme standards, failures to implement corrective actions to rectify non-conformities, and other situations where sanctions (e.g., withdrawal of certification of the FBO) might be required?
- b. Do the governance arrangements include a system for review of audit reports, review of decisions relating to non-conformities, potential use of sanctions, and a procedure for appeal?

6) Data Sharing and Information Exchange

- a. 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, for example through a publicly accessible database?
- b. Subject to national privacy legislation, does the vTPA owner inform the competent authority immediately when they become aware of a significant risk to public health or consumer deception?

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

- c. Does the vTPA owner have permission to share FBO information/data with competent authorities and is this in accordance with national data protection obligations?
- d. Does the vTPA owner inform competent authority of any FBO that ceases to participate either directly or via a web-accessible platform?
- e. Does the vTPA owner agree to notify the competent authority of any changes made to the vTPA programme, including but not limited to: the standard, governance, certification, information sharing and accreditation arrangements?
- f. Does the vTPA owner share information/data relating to conformity with the standard where the standard aligns with regulatory requirements to inform the NFCS?
- g. If the data available is in electronic form are there adequate arrangements for maintaining the security of the data?
- h. Does the vTPA owner have a protocol in place for information/data retention?

G: REGULATORY APPROACHES FOR THE USE OF vTPA PROGRAMME 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 information/data from vTPA programmes. It also contains examples of the practical uses that can be made by competent authorities of vTPA programme information/data to support their NFCS objectives.

1) Process considerations

- a. Information/data from a vTPA programme may be considered for use by a competent authority after an appropriate assessment of the vTPA programme's credibility and integrity as informed by the criteria in this guidance.
- b. Competent authorities need only apply relevant assessment criteria commensurate with their intended use of vTPA programme 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. Where an arrangement is in place between a competent authority and a vTPA owner, the vTPA owners should establish processes for the sharing of relevant information/data with the competent authority 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 should have transparent procedures to verify the reliability of the vTPA programme information/data that they intend to use.
- 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. The competent authority may consider the need for any intervention.
- g. Competent authorities may compare relevant 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 arrangement 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 arrangement 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 programme audits that are of most value to support its NFCS objectives and agree upon the access arrangements for those elements.

2) Policy options

- a. In order to validate the suitability of an assurance system, including a review of the vTPA programme governance arrangements and their operation, the competent authority may consider the value of

- comparing the vTPA standards with relevant international standards and/or relevant national regulatory requirements.
- b. 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.
 - c. Competent authorities may choose to verify the reliability of vTPA programme information/data through for example a comparison of conformity data from the vTPA programme with their official compliance information/data.
 - d. Competent authorities may reduce the intensity and/or frequency of official inspection where there is verification through their official data that participation in a vTPA programme is achieving similar or higher levels of compliance with relevant regulatory requirements.
 - e. The suitability and extent to which competent authorities use vTPA programme information/data will be determined by the depth of any assessment of the integrity and credibility of the vTPA programme.
 - f. Audit information/data generated by the vTPA programme and FBO certification status may be used to help determine the food safety or consumer deceptions risks associated with the participating FBOs, to inform NFCS planning and adjust frequency or intensity of regulatory oversight, and hence, help prioritise resources to higher risk areas.
 - g. vTPA programme information/data indicating a trend could be used to target specific interventions such as focused inspections, targeted sampling and testing, or national training/information programs where the vTPA programme information/data helps identify a systemic issue.

Appendix 2

The co-chairs' analysis and summary of the comments submitted by members and observers in CX/FICS 20/25/4 Add.1 and CX/FICS 20/25/4 Add.2.

Update on Status of the work

The co-chairs thank the members of the electronic working group (EWG) for their continued engagement in this work and would like to offer the following update on the current status of the work:

- The text was adopted at step 5 by CAC42, with minimal discussion, hence reflecting the significant degree of consensus achieved on the document that emerged from CCFICS24.
- The text has since undergone a further two rounds of consultation:
 - CX/FICS 20/25/4 Add.1: Comments at Step 6, following adoption of the document by CAC42 at Step 5. These comments were made in response to the CL/FICS 2019/93/OCS-FICS.
 - CX/FICS 20/25/4 Add.2: Comments provided by Codex members and observers on the text at Step 5, as revised by the electronic working group established by CCFICS24. These comments were made on the text revised by the EWG in response to CL 2020/26/OCS-FICS.
- There continues to be significant overall support for the Step 5 draft based on Codex members' comments in both Add.1 and Add.2. Codex members have continued to engage positively with comments largely aimed at improving the overall clarity, readability and structure of the document. In analysing the comments and making revisions to the text, the co-chairs have been guided by past discussions and members' clear desire for flexibility over prescription so that the approach can be tailored to national circumstances.
- It should be noted that the comments found in CX/FICS 20/25/4 Add.1 were made on the text prior to its revisions by the EWG established by CCFICS24. Some of the comments in Add.1 were therefore no longer relevant since the text was modified by the EWG. The revised text was due for discussion at a PWG that had been scheduled to take place immediately prior to CCFICS25.
- Where a member country or observer proposed revisions to the same paragraph in both Add.1 and Add. 2 and the proposed revisions were different between Add.1 and Add. 2, only Add. 2 comments were considered, since, in the co-Chairs' views, they reflect the member's most up-to-date views on the text.
- A number of comments were made on the Spanish version of the text. These comments appear to be applicable to the Spanish version of the text only and so likely due to translation issues that do not affect the English version.

Key themes and issues to emerge

- Comments were received suggesting that the draft guidelines should acknowledge that competent authorities may wish to recognise vTPAs that have been recognised by an international organization that benchmarks food safety standards, for example, the Global Food Safety Initiative (GFSI). The co-chairs note that the GFSI is part of the Consumer Goods Forum which is an industry-led and funded body rather than an "international organization", e.g., OIE or IPPC, typically referenced in Codex texts. The co-chairs would also like to remind working group members of the guidance provided by the 78th session of the CCEXEC relating to the use of references in Codex texts: "*CCEXEC78 emphasized that while there may on occasion be merit in including references to standards of another standard setting organization, these should be kept to a minimum since they become an integral part of a Codex text and require life-long monitoring*". The co-chairs do not therefore support including a reference to GFSI in the document though note that the guidelines, as drafted, are flexible so would allow competent authorities to choose approaches that are most suitable to them, including relying on external parties in which they have established confidence.
- The co-chairs made a number of editorial revisions to streamline and enhance the consistency of terminology used throughout the document, specifically:
 - The term "arrangement" is used throughout the text, except in two (2) locations where the term "agreement" is used. Those occurrences were revised to "arrangement" to reflect the desire for flexibility from members throughout the development of the text. The co-chairs note that there seems

to be a difference between the English and Spanish versions, where “arrangement” is used in the English version and “acuerdo” (agreement) is used in the Spanish version. The co-chairs seek guidance from Spanish speaking countries on the correct term to use for “arrangement” in order to make the necessary amendments to the Spanish version of the text in order to introduce a similar level of flexibility.

- The terms “conformance” and “conformity” are used throughout the text, occurring an equal number of times. These terms have a similar meaning. Since “conformity” is a more commonly used term, the co-chairs propose replacing “conformance” with “conformity” throughout the text.
- In some areas, either the word “information” or the word “data” was missing. The text has been reviewed to ensure consistency in the use of “information/data” throughout the document.
- The term “programme” was missing or erroneously included in a number of areas. The text was revised for coherence.
- Where the term “have to” was used, it was replaced with “should” as commonly used in Codex texts. Other similar editorial comments were made, e.g., in the way questions are posed in Section F. 13. 6), for consistency with the manner in which other questions were posed in that Section.
- Footnotes 1 & 2 contained additional quotes from other Codex texts. These were included in the draft guidelines during the initial drafting stages for ease of reference and can now be deleted with the reference to the relevant Codex document numbers retained.
- The numbering system was revised to include numbers for all sections/provisions.

Section C. Definitions

- A number of comments were received on the definitions section, seeking to either simplify the section or, for definitions derived from ISO texts, to elaborate further and include additional text from ISO/IEC standards. The co-chairs would like to make proposals to streamline the text and minimize the potential for inconsistencies with other Codex texts, for setting precedents, or for definitions to become outdated as source texts are revised.
 - Definitions of commonly used terms and dictionary definitions: the co-chairs recall that some definitions, e.g., procedure, attestation, assurance, integrity, credibility, were deemed useful to include in the draft document in the early stages of its development to aid understanding of what for some was a new approach at the time. The co-chairs are of the view that these have served their purpose and are now well understood so can be deleted. We bring to the attention of the EWG that these terms are used throughout existing CCFICS texts and the committee has not previously deemed it necessary to develop or include definitions. For example, “procedure” is used upward of 70 times in existing CCFICS texts and attestation is used upwards of 25 times.
 - Definitions sourced from ISO texts: a number of definitions were derived from ISO/IEC 17000:2004 and simplified/adapted to the needs of this document. To some extent this approach reflects the “eco-system” in which vTPA programmes operate. Several comments have suggested including additional clarifications from the ISO documents into the definitions. The co-chairs would like to bring to the attention of the EWG that ISO/IEC 17000:2004 was replaced with ISO17000:2020, with a number of revisions to the definitions. This illustrates one of the challenges of including external references in Codex texts. These external references may change again in the future in a manner that is no longer consistent with the intent when the definitions were included in the Codex text. The chairs suggest maintaining the essential definitions and including a footnote to indicate that specific definitions were adapted from relevant ISO texts, e.g., ISO 17000:2020 for the purposes of this text.
 - Inclusion of additional text from ISO/IEC 17000:2004: A number of comments were received suggesting inclusion of the “Note to Entry” texts that are associated with most ISO/IEC 17000:2004 definitions. These notes include explanatory material or references to additional definitions. The co-chairs note that the additional text proposed in these comments has already become outdated due to the recent update of the ISO document to the 2020 version. Inclusion of the “Notes to entry” would lead to incorporation of significantly more ISO text in the Codex document than what was deemed necessary by previous physical working groups and CCFICS24. As mentioned above, the chairs recommend limiting the definitions to the essential information needed to explain particular terms for the purposes of the draft guidelines and not to duplicate text contained in the ISO standard, again noting the advice from CCEXEC78.

- **Certification vs Conformity Assessment:** A number of comments were received proposing to delete “certification”/“certification body” and replace it with “conformity assessment body” in some definitions and the text for consistency with ISO terminology. The co-chairs would offer the following reflections and way forward for EWG participants’ consideration:
 - The draft guidelines are not intended to duplicate ISO texts and definitions. A number of definitions were found useful and were adapted to the needs of this text.
 - Conformity assessment is a series of activities, which may include inspections, audits, testing, and certification activities, etc. These activities are conducted by conformity assessment bodies/certification bodies.
 - It is our understanding that the term “certification bodies” is a more commonly used terminology in third party quality assurance programmes and has a similar meaning to “conformity assessment bodies”. The latter term is less commonly used.
 - The co-chairs propose retaining use of the term “certification body” in the text and include a clarification in the definition that, for the purpose of these guidelines, it has the same meaning as “conformity assessment body”.

Section G: Regulatory approaches

The co-chairs noted some members suggested the inclusion of some additional bullets in this section, for example, regarding a competent authority’s observing a vTPA audit. The co-chairs note that the document provides the flexibility for competent authorities to determine an approach suited to their intended use.

Appendix 3

The revised text and questions to the reactivated EWG's participants that formed the basis of the consultation between 3 November 2020 and 3 January 2021.

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

(At Step 6/7)

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 ~~these aspects of~~ 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)⁸ 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 of vTPA programmes 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/data and should only apply assessment criteria that are relevant to that purpose.
4. Reliable vTPA programme 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 programme information/data from FBOs i.e. emphasising that the decision to use vTPA programme 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

⁸CAC 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.~~

certification bodies⁹ 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 those that described in these guidelines when considering how to take into account vTPA programmes in their risk-based targeting of regulatory controls.

C: DEFINITIONS¹⁰

For the purposes of this document, the following definitions apply:

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. (*Adapted from ISO/IEC 17000:2020 Source: ISO/IEC 17000:2004*)

Accreditation body: authoritative body that performs accreditation (*Adapted from ISO/IEC 17000:2020 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*) Third party conformity assessment body operating certification services. (*Adapted from: ISO/IEC 17065:2102*) (*Note: "schemes" replaced by "services" to avoid confusion with the overall operation of the vTPA programme.*)

Note: For the purposes of this document, the term "certification body" has the same meaning as "conformity assessment body"

Conformity assessment: ~~demonstration that specified requirements relating to a product, process, system, person or body are fulfilled.~~ (*Adapted from ISO/IEC 17000:2020 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**. (*Adapted from ISO/IEC 17000:2020 Source: ISO/IEC 17000:2004*)

Specified requirement: need or expectation that is stated. (*Adapted from ISO/IEC 17000:2020 Source: ISO/IEC 17000:2004*)

⁹CAC/GL 20-1995: Principles for Food Import and Export Certification ~~Officially recognized inspection systems and officially recognized certification systems are systems which have been formally approved or recognized by a government agency having jurisdiction.~~

¹⁰ Based (in part) on EN ISO/IEC 17000 'Conformity assessment – Vocabulary and general principles'

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 conformity ~~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 17065:2012)~~

D: PRINCIPLES

11. When considering the potential role of vTPA programmes and the potential contribution ~~they~~ their information/data 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.

Principle 3 Transparency of policies and processes

- Any arrangement to use vTPA programme 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 82-2013¹¹.

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 programme 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 programme 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 programme compliance information/data, competent authorities should ensure that their approach is consistent with international rights and obligations.

The co-chairs noted differing views on whether to retain or delete text referring to international rights and obligations. During the previous EWG, one member proposed to move the text from Section G to the Section on Principles. In Add.1 comments, two members suggested deletion of this principle since these are key responsibilities of competent authorities and reminders are not needed in Codex texts. Other members suggested revisions to the text. The co-chairs would like to seek the views of EWG participants on the following:

¹¹ 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.

1) Should Principle 8 be retained in the document or deleted? Please provide a rationale in support of your response.

2) If you support retaining the text, please indicate if you are in support of the proposed revisions:

Principle 8 Rights and obligations

- In developing an appropriate approach to ~~leverage~~ make use of the vTPA ~~compliance~~ conformity information/data, competent authorities should ensure that their approach is consistent with ~~international~~ applicable 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 reliable vTPA programme information/data in their NFCS relating to protecting the health of consumers and ensuring fair practices in the food trade.

1) Competent Authorities

- Have statutory responsibilities for regulatory requirements set down in the NFCS, as recommended in CAC/GL 82-2013 and authorised by relevant national legislation.
- May consider using information/data generated by vTPA programmes to support meeting the objectives of their NFCS.
- 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.
- ~~Need to~~ Should clearly describe the use of a vTPA programme information/data within their NFCS.
- ~~d. (bis). Should have mechanisms in place to verify the continued credibility and reliability of vTPA programme and restrict its use when information/data provided is false or otherwise lacks credibility (Note: point d, was split into two points, and reworded to better convey the intended concepts).~~
- Should ensure any arrangements to use vTPA programme information/data is fully transparent.
- ~~Have to~~ Should protect against potential conflicts of interest.

The co-chairs note that point f was discussed and agreed upon by the previous working group (refer to CX/FICS 20/25/4). However, revisions to this point were proposed in Add.2, on the output of the previous EWG, by two Codex members. The co-chairs are of the view that both proposed revisions have merit. The co-chairs note that the current text lacks clarity and the sentence is incomplete since it does not indicate who or what the competent authority should protect with respect to conflict of interest. The co-chairs would like to seek the view of the EWG on the following options:

Option 1: maintain the text as originally drafted, i.e.,

Should protect against potential conflicts of interest.

Option 2: Revise the text as follows, based on comments received:

Should ~~Have to protect against~~ recognize potential conflicts of interests and their impact on the reliability of the information/data of the vTPA programme

EWG members are kindly asked to indicate whether they support the proposed revisions or the original text, and to provide a rationale with their response.

- g. ~~Have to~~ Should ensure and maintain the confidentiality of data shared by the vTPA owner.

The co-chairs recall that point g was discussed and agreed upon by the previous EWG (refer to CX/FICS 20/25/4). The co-chairs are of the view that two changes are essential, 1) the revision proposed by Japan to replace “have to” with “should” since this is consistent with Codex terminology, and 2) inclusion of “information” for consistency of terminology in the document, where “information/data” is used throughout. Other revisions were proposed: to delete “ensure”, include “appropriate” and “according to the legislative framework of the country”. The co-chairs would like to seek the view of the EWG on the following options for point g (with the revision regarding “should” and “information” accepted). The co-chairs remind the participants that the previous EWG had recommended deleting “appropriate” and “according to the legislative framework of the country”.

The members of the EWG are invited to indicate which option they find more suitable and to provide a rationale with their response.

Option 1: maintain the text as originally drafted, i.e.,

Should ensure and maintain the confidentiality of data shared by the vTPA owner

Option 2: revise the text as follows, based on comments received:

g. Should ~~ensure and~~ maintain the appropriate confidentiality of information/data shared by the vTPA owner, according to the legislative framework of the country.

2) 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.
- 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.
- May elect to participate in vTPA programmes to meet business needs, demonstrate ~~conformance~~ conformity with relevant food safety standards, and provide independent assurance of the integrity of their products or production systems to relevant stakeholders ~~buyers~~.
- Owns the information/data generated by the vTPA programme.
- Has no conflicts of interest with the operation of the vTPA programme.

3) Voluntary Third-Party Assurance Owners

- Are responsible for implementing the governance arrangements of a vTPA programme, which may include utilising national/international standards and independent accredited audit and certification.
- Are accountable to participating FBOs to disclose the potential sharing of information/data generated by the vTPA programme with competent authorities.
- ~~Have mechanisms to share~~ Sharing information/data generated by the vTPA programme owners for use by with the competent authority, according to the process established by the vTPA programme owners and the competent authority.
- Have policies and processes when sharing vTPA programme information/data with competent authorities such as notification to the FBO and ~~protections for proprietary information~~.
- Have policies and processes 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).

The co-chairs note that the Add.2 comments broadly support the continued inclusion of the adjective “significant” though note one member has suggested its deletion owing to its subjectivity. Other comments suggest some reordering and for there to be a more explicit link to “non-compliance/conformity” rather than or alongside public health. One member and one observer organisation raised a more fundamental point and argue that there needs to be a definition to quantify what is meant by “significant public health risk”.

The co-chairs recall that the term “significant public health risk” was in square brackets at the conclusion of CCFICS24, which established an EWG to address text in brackets. The outcome of the previous EWG supported maintaining the phrase “significant public health risk” in the document and also did not see the need for a definition (refer to CX/FICS 20/25/4). However, given that this sub-bullet continues to attract attention from some members the co-chairs are keen to seek the views to determine a way forward:

- 1) Do EWG members support the current wording (contained in CX/FICS 20/25/4)?
 - a. If not, please provide alternative wording and rationale for the EWG’s consideration.
- 2) Do EWG members support adding a definition for “significant public health risk”?
 - a. If yes, please provide a proposed definition with rationale and source information (if available) for the EWG’s consideration.
 - b. If no, please explain why not.

- f. Have policies and processes appropriate systems in place to protect against potential conflicts of interest between vTPA 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 information/data from vTPA programmes ~~in~~ to help inform their NFCS should satisfy themselves that the vTPA programme 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 programme 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 and ensure that the vTPA programme has implemented them in a comprehensive way to assure successful outcomes.

1) Governance Arrangements

- a. Are the governance arrangements and responsibilities within the vTPA programme clearly defined and documented?
- b. Are the oversight arrangements structured to avoid potential conflicts of interest?
- c. Does the vTPA programme have management controls to ensure consistent and effective implementation and maintenance?
- d. Does the vTPA programme have an accreditation arrangement with an accreditation body with international standing¹², recognition and credibility? If not, how does the vTPA ~~programme~~ owner ensure that certification ~~accreditation~~ bodies have the capacity and competency to perform effectively?”

2) Accreditation of Certification Bodies

- a. Does the vTPA programme have an independent process to ensure the use of appropriately accredited certification bodies?
- b. Is the certifying body accredited for the vTPA programme according to the relevant accreditation standard?
- c. Is the accreditation of certification bodies for the vTPA programme subject to a periodic review and renewal?
- d. Does the accreditation body assess the certifying body for the vTPA programme using relevant and internationally recognized standards¹³?

¹² For example, the International Accreditation Forum (IAF) and the International Laboratory Accreditation Co-operation (ILAC).

¹³ Examples include: ISO/IEC 17020, ISO/IEC 17065 or ISO/IEC 17021-1 supplemented with ISO/TS 22003, ISO/IEC 17011

- d. ~~Is the certifying body accredited for the vTPA programme according to the relevant accreditation standard? (Note: moved to become point b., for flow).~~

3) Standard Setting Process

- a. Do the vTPA programme owners set their own standards or utilise national or international standards for assurance?
- b. To what extent are the vTPA standards consistent with Codex or other relevant international standards and/or applicable national regulatory requirements?
- c. Do the vTPA standards contain specified requirements to protect consumers in relation to food safety and fair practices in food trade?
- d. Have the vTPA standards been developed through a transparent consultative process with relevant experts **and stakeholders** reflecting the range of business processes within the target sector?
- e. Are the vTPA standards open, transparent in governance and subject to continuous improvement by regular review to keep them up to date?
- f. ~~To what extent are the vTPA standards consistent with Codex or other relevant international standards and/or applicable national regulatory requirements? (Note: moved to become point b., for flow)~~
- f. Are the vTPA standards written in a way that they can be assessed for **conformity** ~~conformance~~?

4) Conformity Assessment

- a. Does the vTPA programme have written **procedures** ~~policies~~ on frequency, methodology, announced and unannounced audits and competency requirements for certification bodies?
- b. 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?
- c. Does the vTPA programme have procedures in place to ensure that auditors have and maintain the required auditor competence?
- d. Does the vTPA programme have a transparent system to identify FBOs that conform to the standard (e.g. certification)?

5) Responses to Non-**Conformity** ~~Conformance~~

- a. Do the vTPA programme **governance** arrangements include clearly defined procedures for dealing with non-conformities against the **vTPA programme** standards, failures to **implement corrective actions to rectify non-conformities**, and other situations where sanctions (**e.g., withdrawal of certification of the FBO**) might be required?
- b. Do the **governance** arrangements include a system for review of audit reports, **review of decisions relating to non-conformities** ~~on interpretation and~~, **potential use of sanctions**, and a procedure for appeal?

6) Data Sharing and Information Exchange

- a. 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, **for example through a publicly accessible database**?
- b. Subject to national privacy legislation, **will does** the vTPA programme owner inform the competent authority immediately when they become aware of a significant risk to public health or consumer deception? (Note: this will need to take account of members' views on the term "significant public health risk".)
- c. Does the vTPA owner have permission to share FBO data with competent authorities and is this in accordance with national data protection obligations? (Note: this was previously point g; moved from below for more logical flow of questions)
- d. ~~Will~~ **Does** the vTPA programme owner **inform** ~~notify~~ the competent authority of any FBO that ceases to participate **either directly or via a web-accessible platform**?

- e. ~~Will~~ **Does** 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, information sharing and accreditation arrangements?
- f. ~~Will~~ **Does** the vTPA programme owner share information/data relating to conformity ~~conformance~~ with the standard where the standard aligns with regulatory requirements to inform the NFCS?
- g. If the data available is in electronic form are there adequate arrangements for maintaining the security of the data?
~~g. Does the vTPA owner have permission to share FBO data with competent authorities and is this in accordance with national data protection obligations? (Note: moved up for better flow of questions)~~
- h. Does the vTPA owner have a protocol in place for information/data retention?

G: REGULATORY APPROACHES FOR THE USE OF vTPA PROGRAMME 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 programme information/data. It also contains examples of the practical uses that can be made by competent authorities of vTPA programme information/data to support their NFCS objectives.

1) Process considerations

- a. Information/data from a vTPA programme may be considered for use by a competent authority after an appropriate assessment of ~~its~~ the vTPA programme's credibility and integrity as informed by the criteria in this guidance.
- b. Competent authorities need only apply relevant assessment criteria commensurate with their intended use of vTPA programme 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. Where an arrangement is in place between a competent ~~Competent~~ authority ~~ies that have arrangements with~~ and a vTPA owner, the vTPA owners should establish a process es for the sharing of relevant information/data with the competent authority and processes for handling findings of non-conformities, including alerting the competent authority of any significant public health risk or consumer deception. *(Note: this will need to take account of members' views on the term "significant public health risk".)*
- e. Competent authorities should have ~~may need to establish~~ transparent procedures to verify the reliability of the vTPA programme information/data that they ~~it~~ intends to use ~~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 The competent authority may consider the need for any intervention ~~needed~~.
- g. Competent authorities may compare ~~comparable~~ relevant 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 arrangement ~~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 arrangement ~~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 programme audits that are 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).~~

2) Policy options

- a. In order to validate the suitability of an assurance system, including a review of the vTPA programme governance arrangements ~~requirements~~ and ~~its~~ their operation, the competent authority may consider

- the value of comparing the vTPA standards requirements with relevant international standards and/or relevant national regulatory requirements. *(Note: This was previously point b. Re-ordered for flow)*
- b. 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. *(Note: was previously point c. Re-ordered for flow)*
 - c. Competent authorities may choose to verify the reliability of vTPA programme information/data through for example a comparison of conformity ~~conformance~~ data from the vTPA programme with their official compliance information/data. *(Note: This was previously point a. Re-ordered for flow and edited for clarity)*
 - 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 similar or higher levels of compliance with relevant regulatory requirements.
 - f. The suitability and extent to which competent authorities use vTPA programme information/data will be determined by the depth of any assessment of the integrity and credibility of the vTPA programme.
Audit information/data generated by the vTPA programme and FBO certification status may be used to determine the food safety or consumer deceptions risks associated with the participating FBOs, to inform NFCS planning and adjust frequency or intensity of regulatory oversight, and hence, help prioritise resources to higher risk areas. *(Note: Removes duplication by combining d, h & i)*
 - g. vTPA programme information/data indicating a trend could be used to target specific interventions such as focused inspections or national training/information programs where the vTPA programme 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 4**The co-chairs analysis and proposals to the responses received from the reactivated EWG's participants to the 2 Nov 2020 consultation contained in Appendix 3.**

Comments were received from : Australia, Canada, Chile, France, Japan, Islamic Republic of Iran, Morocco, Peru, Singapore, the United States, the European Union, the Global Food Safety Initiative (GFSI), the International Accreditation Forum (IAF), and the International Council of Beverages Associations (ICBA).

Co-chairs' overarching comments/analysis and recommendations

The co-chairs thank the participants in the electronic working group (EWG) for their continued engagement in this work and would like to offer the following summary for the EWG's consideration:

- There appears to be consensus with the approach and revisions to the text proposed by the co-chairs, based on the analysis of comments received in CX/FICS 20/25/4 Add.1 and CX/FICS 20/25/4 Add.2. As such, these revisions have been incorporated into the revised draft Guidelines presented in Appendix 3.
- A few editorial comments were received from EWG participants, most of which enhance clarity of the text and are reflected in red font and underlined text in the updated version of the draft Guidelines in Appendix 3.
- The responses received from EWG participants on the specific questions have been compiled and analyzed by the co-chairs, and are available below, along with the co-chairs' proposals for a way forward for each question. The co-chairs' proposals are also reflected in the revised draft Guidelines in Appendix 3.
- An EWG participant provided comments regarding the terminology used in the text, i.e., where the term "vTPA" is used in lieu of "scheme" or "conformity assessment scheme", and also provided suggestions for the definitions of different categories of standards. The WG participant also recommend that a number of criteria to assess the credibility and integrity of vTPA programmes be added to the text. The co-chairs recognize and appreciate the efforts in providing recommendations and suggestions. The co-chairs note that the terminology (e.g., vTPA) and the definitions used in the text were the outcome of significant discussions in previous CCFICS meetings, physical working groups, EWG and Plenary. With respect to the recommendations to include additional criteria, the co-chairs note that the text is intentionally written in a manner that provides flexibility for competent authorities and to serve as a starting point (Section F para 13). It follows that the criteria included in the text are examples and so are not exhaustive, hence, competent authorities may use additional criteria that they deem necessary in their evaluation of vTPA programmes.
- One EWG participant provided comments relevant to the Spanish version of the text:
 - With respect to preference in the use of the terms "arrangement" (arreglo) vs "agreement" (acuerdo) in the text.
 - In section F.13. 3).c., replace "security" with "safety".

The importance of accuracy and consistency of translation will be brought to the attention of CCFICS25.

- An EWG participant proposed revising the title of the document to "*Principles and Guidelines for **Competent Authorities to Assess** ~~the Assessment and Use of Voluntary Third Party Assurance Programmes~~*". The co-chairs appreciate the suggestion but would note that it is well understood that Codex texts are intended for use by competent authorities. Hence, the co-chairs recommend maintaining the title as currently found in Appendix 1 for brevity.
- An EWG member was of the view that the following two bullet points in Section G., 14., 2) Policy Options, overlap:
 - d. *Competent authorities may reduce levels and/or frequency of official inspection where there is verification through their official data that participation in a vTPA programme is achieving similar or higher levels of compliance with relevant regulatory requirements.*

- f. *Audit information/data generated by the vTPA programme and FBO certification status may be used to help determine the food safety or consumer deceptions risks associated with the participating FBOs, to inform NFCS planning and adjust frequency or intensity of regulatory oversight, and hence, help prioritise resources to higher risk areas.*

The co-chairs view the two points as separate. Bullet d describes an approach where the competent authority verifies the vTPA information/data against its official information/data to compare conformity/non-conformity with compliance/non-compliance. Bullet f describes how the vTPA information/data alone may be used once its credibility and integrity has been established. The co-chairs therefore recommend maintaining two separate bullets.

- EWG participants are invited to take note of the summary above and the analysis of comments and co-chair's views and recommendations below when preparing for discussion of the revised text at CCFICS25. The co-chairs are open to further high-level feedback by XX March to help inform preparations for CCFICS25

General comments

AUSTRALIA*

Australia agrees that it is not appropriate to reference specific industry-led and funded certification bodies such as GFSI, however, we would note that competent authorities of an exporting country may wish to consider the use of vTPAs that have been recognised by an international organization that benchmarks food safety standards.

The use of these vTPA's could facilitate acceptance of certification issued by these bodies by importing country competent authorities. Noting that paragraph 10 of the scope clearly states These guidelines do not constitute approval, recognition or endorsement of vTPA programmes. It follows that competent authorities may choose approaches other than those described in these guidelines when considering how to take into account vTPA programmes in their risk-based targeting of regulatory controls. It is highly likely that competent authorities may not have the resources or capacity to undertake an assessment of every vTPA used by their trading partners and therefore the use of vTPAs recognised by international organisations may assist in the facilitation of trade.

CANADA

Canada supports the current version of this text and thanks the EWG for the opportunity to provide responses to the questions.

CHILE

Se prefiere cambiar "arreglo" por "acuerdo".

INTERNATIONAL ACCREDITATION FORUM (IAF)

IAF Food Working Group would like to thank the Chair, Co-Chairs and EWG members for their efforts for the draft guidelines. Here are our general comments:

A: PREAMBLE

Comment in relation to VOLUNTARY THIRD-PARTY ASSURANCE (vTPA):

It is important a common vocabulary is used, and new definitions are not created unnecessarily. vTPA would be considered as a new acronym. The common vocabulary is 'scheme' or 'conformity assessment scheme'. If the term vTPA is published by Codex, it is enabling duplicate definitions meaning the same thing. If the term 'scheme' implies scheming, changing the name to vTPA will not solve the problem of being untrustworthy. If a scheme owner purpose is truly about safe food for consumers, then 'scheme' is not a perceived reputational threat and should be used in this guideline instead of vTPA. A common vocabulary is the foundation and essential for public-private harmonization.

References-

The Conformity Assessment Toolbox CASCO

https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_building-trust.pdf

Annex 2 <https://www.iso.org/sites/cascoregulators/documents/Annex%20%20-%20Conformity%20assessment%20-%20Conformity%20assessment%20schemes.pdf>

C: DEFINITIONS

Comment in relation to consideration of definitions for standards:

It is important to distinguish between different types of standards. See example document, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities: CIRCULAR NO. A-119 <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-119-1.pdf>

Example definitions:

“Voluntary consensus standards” are standards developed or adopted by voluntary consensus standards bodies, both domestic and international.

“Industry standards” are standards developed in the private sector but not in the full consensus process, typically requiring a financial contribution (e.g. standard owner fees). Also referred to as private standards.

“Government standards” are standards developed by the government for its own uses.

CIRCULAR NO. A-119 is a US government document instructing their agencies (including the US Food and Drug Administration) to adopt “voluntary consensus standards” before relying upon “industry standards” and / or developing “government standards”. For this reason, it is important to distinguish between different types of standards used by Food business operators (FBOs).

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

Comment on

1) Governance Arrangements

b. Are the oversight arrangements structured to [add text] avoid payment from vTPA PROGRAMMES (scheme owners) and other potential conflicts of interest?

Rationale: Consider oversight arrangement receiving payments from vTPA PROGRAMMES (scheme owners) they are responsible for overseeing and / or in a position of authority? Governance must ensure impartiality and neutrality. Any form of payment could result in bias where oversight arrangement is supportive of poor performing vTPA PROGRAMMES (scheme owners) due their financial relationship.

Add new criteria

e. Does the oversight arrangement communicate to competent authorities their financial accounts?

Rationale: if oversight arrangement is a corporate led multi-stakeholder initiative, do they provide full visibility to how they receive their income and what this income is spent on e.g. Lobbying government.

f. Does the oversight arrangement communicate to competent authorities as part of their business continuity or crisis management process?

Rationale: Oversight arrangement voting to prevent remote auditing during a pandemic. Competent authorities can decide whether to exclude a vTPA PROGRAMME (scheme owner) under the oversight arrangement from their risk-profile model. This drives consequences if an oversight arrangement or vTPA PROGRAMME (scheme owner) votes to make decisions that could be interpreted as self-interest or not aligned with the regulator’s inspection model.

g. Does the oversight arrangement demonstrate impartiality and neutrality?

Rationale: Are voting rights restricted to a small group of individuals or companies? Or are voting rights evenly distributed amongst key stakeholders which include could include National Standards Bodies, Certification Body Associations and Accreditation Bodies? (could also be grouped into b. potential conflicts of interest)

6) Data Sharing and Information Exchange

Add new criteria

i. Does the vTPA PROGRAMME (scheme owner) notify the competent authority if their status changes from a non-profit organization to a for-profit organization?

Rationale: For profit vTPA PROGRAMME (scheme owner) must demonstrate to competent authorities they continue to work in the best interests of the industry they serve, and not switch to operating out of self-interest e.g. to increase revenue from scheme owner fees.

j. Does the vTPA PROGRAMME (scheme owner) share information/data relating to performance, when there are reported recalls, withdrawals, and regulatory inspection issues?

Rationale: Many vTPA PROGRAMMES (scheme owners) mandate reporting of recalls and withdrawals but do not mandate reporting of regulatory inspection issues. This data is often not shared by the vTPA PROGRAMME (scheme owner). Consideration that not all standards are created equal. If requirements are benchmarked for equivalency, the performance of the vTPA PROGRAMME (scheme owner) can still vary in relation to average number recalls and withdrawals.

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

Comment on

2) Policy options

Add new criteria

j. Competent authorities may define a risk-profile based on the type of standard e.g. “voluntary consensus standard” compared to an “Industry standard” or “private standard”.

Rationale: A voluntary consensus standard may demonstrate neutrality and impartiality because companies or individuals cannot become members. Whereas “Industry standards” or “private standards” may have exclusive oversight arrangements with restricted voting rights which may lead to undue influence.

MOROCCO

Morocco proposes to revise the title as follows: “PRINCIPLES AND GUIDELINES FOR COMPETENT AUTHORITIES **TO ASSESS AND USE THE** VOLUNTARY THIRD-PARTY ASSURANCE PROGRAMMES”

SINGAPORE

Singapore would like to thank the Co-Chairs for the work done to revise the draft guidelines. We would like to submit our responses to the questions below, as well as comments to Section G as shown below.

[In reference to Section G, sub-section 2) Policy Options]: we note that the text in red under (f) was drafted with the intention of removing duplication from (d), (h) & (i). However, we feel that there is still overlap between this and the text in (e), with regard to the level/frequency/intensity of regulatory oversight by the competent authority.

Collated responses to the specific questions and co-chairs' analysis and proposals

Text	Question to EWG members	EWG Response & Rationale
<p>D: PRINCIPLES</p> <p>Principle 8 Rights and obligations</p> <p>In developing an appropriate approach to leverage the vTPA <u>programme</u> compliance information/data, competent authorities should ensure that their approach is consistent with international rights and obligations.</p>	<p>The co-chairs noted differing views on whether to retain or delete text referring to international rights and obligations. During the previous EWG, one member proposed to move the text from Section G to the Section on Principles. In Add.1 comments, two members suggested deletion of this principle since these are key responsibilities of competent authorities and reminders are not needed in Codex texts. Other members suggested revisions to the text. The co-chairs would like to seek the views of EWG participants on the following:</p> <p>1) Should Principle 8 be retained in the document or deleted? Please provide a rationale in support of your response.</p> <p>2) If you support retaining the text, please indicate if you are in support of the proposed revisions:</p> <p>Principle 8 Rights and obligations</p> <p>In developing an appropriate approach to leverage <u>make use of</u> the vTPA compliance <u>conformity</u> information/data, competent authorities should ensure that their approach is consistent with international <u>applicable</u> rights and obligations.</p>	<p>AUSTRALIA</p> <p>Response – support principle 8 being retained.</p> <p>Rationale – the principle confirms and clarifies that a competent authority will observe country specific rights and obligations.</p> <p>CANADA</p> <p>Canada would recommend deleting Principle 8. Countries have international rights and obligations with which they have to abide regardless of Codex texts. We do not believe it is necessary to include principles in Codex texts to remind countries of their rights and obligations. We do not see why this particular text merits inclusion of such a reminder.</p> <p>CHILE</p> <p>Mantener el principio. Si bien es redundante, el Codex tiene un mandato claro para establecer normas de carácter internacional, y el principio 8 reafirma este mandato de manera clara y directa, apoyando y recordando a los países la relevancia que tiene el multilateralismo. Además, el texto otorga claridad respecto a las garantías que las autoridades competentes deben asegurar para el éxito de estos programas.</p> <p><i>[Google translation: Keep the principle. Although it is redundant, Codex has a clear mandate to establish standards of an international character and principle 8 reaffirms this mandate clearly and directly, supporting and reminding countries of the relevance of multilateralism. In addition, the text provides clarity regarding the guarantees that the competent authorities must ensure for the success of these programs].</i></p> <p>FRANCE</p> <p>Retain – The principle gives clarity to the text and should be retained. The proposed revisions can be supported (deletion of international, replaced with “applicable”).</p> <p>IRAN</p> <p>1. Principle 8 would be preferably retaining, since a developing approach is better to be along with the international rights and obligations.</p> <p>2. We are in support of “international applicable” rights and obligations.</p>

Text	Question to EWG members	EWG Response & Rationale
		<p>JAPAN</p> <p>It is the responsibility of the competent authority and does not need to be included in the text.</p> <p>MOROCCO</p> <p>Morocco support <u>deleting this principle</u>.</p> <p>Rationale: This principle deals with the rights and obligations of competent authorities, and the phrase "... their approach is consistent with applicable rights and obligations" uses the term "applicable «which is very vague. We believe that the sentencing of this principle will generate divergent interpretations by members. In addition, this confusion will be accentuated because of the diversity of the national legislations of different countries.</p> <p>Also, Morocco asks to review the wording of the main principles (except 3, 4 and 5) because they have more to do with the obligations of the competent authorities than to principles. Indeed, the principle is a proposition, value or rule that has to be or usually is to be followed by all stakeholders in the implementation of these directives.</p> <p>We also believe that the volunteering of this program should be established as a principle and not as much as scope.</p> <p>PERU</p> <p>Respuesta: 2. Se apoya la conservación del texto con las revisiones propuestas. El principio aclara que las autoridades competentes velan por la consistencia del uso de información con los derechos y obligaciones de cada país. [<i>Google translation: Support retaining the principle with the proposed revisions. The principle clarifies that the competent authorities ensure the consistency of the use of information with the rights and obligations of each country</i>].</p> <p>SINGAPORE</p> <p>1) We would like to retain Principle 8, as being aligned with international rights and obligations is a fundamental principle for all competent authorities, and this should remain even as competent authorities make use of vTPA programme(s).</p> <p>2) With regard to the proposed revisions, we would like to retain the word "international" in addition to "applicable", as the word "international" is important to reflect international food trade and rights and obligations of countries in relation to each other.</p>

Text	Question to EWG members	EWG Response & Rationale
		<p>United States</p> <p>1) U.S. response: The principle should be retained.</p> <p>2) U.S. response: Support the revision replacing <compliance> with <conformity> to ensure uniformity and consistency with terminology throughout the document.</p> <p>European Union</p> <p>The EU can accept deleting this principle as it is indeed implicit that CA should always respect international rights and obligations. If the principle is kept, then the EU supports the revised text but suggests retaining the term “international” as the meaning of the new suggested term “applicable” is rather obscure.</p> <p>GFSI</p> <p>Principle should be retained</p> <p>Propose to keep the principle with the initial writing:</p> <p>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.</p> <p>ICBA</p> <p>Response: ICBA proposes to retain the Principle 8, with a slightly revised wording:</p> <p>In developing an appropriate approach to leverage <u>make use of</u> the vTPA compliance <u>conformity</u> information/data, competent authorities should ensure that their approach is consistent with international rights and obligations.</p> <p>Rationale: It is important for this Codex Guidance to be grounded firmly in rights and obligations that are internationally adhered to, since vTPA will facilitate the cross-border food trade and not just within country trade. This principle underscores continuity of Codex Principles which are globally applicable.</p> <p>IAF</p> <p>Principle should be retained. Support the proposed revisions</p>

Text	Question to EWG members	EWG Response & Rationale
<p>CO-CHAIRS' ANALYSIS AND PROPOSAL:</p> <p>Most comments support retaining the principles, with the rationale, where given, that it is useful to remind countries of their rights and obligations. Some comments support deletion of the principle since countries have to respect rights and obligations irrespective of this text. Comments on the proposed revisions to the text were limited, although there is some support to retain “international” in the text and replace “compliance” with conformity. Further, one participant suggested that wording of other principles be reviewed although no specific proposals were received.</p> <p>Based on the comments received, the co-chairs propose retaining principle 8 with the following wording:</p> <p>Principle 8 Rights and obligations</p> <p>In developing an appropriate approach to make use of leverage of vTPA programme conformity information/data, competent authorities should ensure that their approach is consistent with applicable international rights and obligations.</p>		

Text	Question to EWG members	EWG Response & Rationale
<p>E: ROLES, RESPONSIBILITIES AND RELEVANT ACTIVITIES</p> <p>1) Competent Authorities</p> <p>f. Have to <u>Should</u> protect against potential conflicts of interest</p>	<p>The co-chairs note that point f was discussed and agreed upon by the previous working group (refer to CX/FICS 20/25/4). However, revisions to this point were proposed in Add.2, on the output of the previous EWG, by two Codex members. The co-chairs are of the view that both proposed revisions have merit. The co-chairs note that the current text lacks clarity and the sentence is incomplete since it does not indicate who or what the competent authority should protect with respect to conflict of interest. The co-chairs would like to seek the view of the EWG on the following options:</p> <p>Option 1: maintain the text as originally drafted, i.e.,</p> <p><u>Should</u> protect against potential conflicts of interest.</p> <p>Option 2: Revise the text as follows, based on comments received:</p> <p><u>Should</u> Have to protect against <u>recognize</u> potential conflicts of interests <u>and their impact on the</u></p>	<p>AUSTRALIA</p> <p>Response – support option one.</p> <p>Rationale - competent authorities, under good governance, should protect against conflicts of interest. Option 2 includes superfluous text.</p> <p>CANADA</p> <p>Canada prefers a combination of the text found in Option 1 & Option 2:</p> <p><u>Should protect against</u> <u>recognize</u> potential conflicts of interest.</p> <p>Or</p> <p><u>Should protect against</u> <u>take into account</u> potential conflicts of interest.</p> <p>Canada agrees that “protect against” is not the ideal text to describe the roles, responsibilities and relevant activities of competent authorities. Canada prefers “recognize” or “take into account” to provide additional flexibility to competent authorities.</p> <p>Canada believes the impact on the reliability of information/data of the vTPA programme is already covered in the document and is discussed previously in this</p>

Text	Question to EWG members	EWG Response & Rationale
	<p><u>reliability of the information/data of the vTPA programme</u></p> <p>EWG members are kindly asked to indicate whether they support the proposed revisions or the original text, and to provide a rationale with their response.</p>	<p>section, under paragraph 12. 1) d. (bis): <u>“Should have mechanisms in place to verify the continued credibility and reliability of vTPA programme.”</u></p> <p>FRANCE</p> <p>Option 2 - vTPAs imply an arrangement between 2 private bodies: conflict of interest can arise. Therefore, it makes more sense to recognize these potential conflicts of interest and assess their impact on the reliability of the information of the vTPA</p> <p>IRAN</p> <p>Option 2 as it is more complete and explains about the potential conflicts of interest.</p> <p>JAPAN</p> <p>Option 1 – It does not indicate who or what the competent authority should protect with respect to conflict of interest.</p> <p>Option 2 – The content that the competent authority should understand is clear and supports option2</p> <p>MOROCCO</p> <p>Morocco support the revised text (Option 2) <u>but with some changes</u> (Morocco changes are in blue and highlighted in yellow):</p> <p><u>Should have to protect against recognize potential detect, report and manage conflict of interest risks and their impact on the reliability of the information/data of the vTPA programme.</u></p> <p>Rationale:</p> <p>The text proposed by Morocco comes to complete and clarify the final purpose of the competent authority by detecting, reporting, and managing conflict of interest risks. All of these actions aim to protect against potential conflicts of interest.</p> <p>PERU</p> <p>Respuesta: Opción 2. El hecho de establecer una tercera parte implica la posibilidad de un conflicto de intereses; por tanto, al reconocer este posible conflicto es necesario evaluar su impacto en la confiabilidad del vAPT. [Google translation: Option 2.</p> <p><i>Establishing a third party implies the possibility of a conflict of interest; therefore, recognizing this potential conflict, it is necessary to evaluate its impact on the reliability of the vTPA].</i></p>

Text	Question to EWG members	EWG Response & Rationale
		<p>SINGAPORE</p> <p>We would support Option 2, as it spells out with greater clarity what the competent authority should do when it comes to potential conflicts of interest. Being able to recognise the potential conflicts of interest and then making an assessment on their impact on reliability of information/data would then provide guidance to the competent authority as to whether they should continue using the information/data from the particular vTPA programme(s). In contrary, Option 1 does not provide any details on how the competent authority should protect against the potential conflicts of interest.</p> <p>UNITED STATES</p> <p>U.S. response: Option 2.</p> <p>Rationale: The edit including the impact that conflicts of interest have on the reliability of information provides clarity.</p> <p>EUROPEAN UNION</p> <p>The EU supports option 2 as the revised text adds clarity.</p> <p>GFSI</p> <p>Option 1</p> <p>ICBA</p> <p>Response: ICBA agrees with Option 1, as it empowers Competent Authority to protect against potential conflicts of interest.</p> <p>Rationale: We believe that Option 2 is weaker and only about “recognition” and no action is directed as a result of such recognition, therefore, we do not support Option 2.</p> <p>IAF</p> <p>Option 2: recognize potential conflicts means the competent authorities must take this into consideration.</p>

Text	Question to EWG members	EWG Response & Rationale
<p>CO-CHAIR ANALYSIS AND PROPOSAL:</p> <p>Most comments received support Option 2, as proposed by the EWG Co-chairs on the basis that the text provides further clarity. Suggested revisions were also proposed by Canada and Morocco.</p> <p>Given the balance of comments support Option 2, the co-chairs propose the following:</p> <p>E: ROLES, RESPONSIBILITIES AND RELEVANT ACTIVITIES</p> <p>1) <u>Competent Authorities</u></p> <p>f. Should protect against recognize potential conflicts of interest and their impact on the reliability of the information/data of the vTPA programme.</p>		

Text	Question to EWG members	EWG Response & Rationale
<p>E: ROLES, RESPONSIBILITIES AND RELEVANT ACTIVITIES</p> <p>1) <u>Competent Authorities</u></p> <p>g. Have to Should ensure and maintain the confidentiality of data shared by the vTPA owner.</p>	<p>The co-chairs recall that point g was discussed and agreed upon by the previous EWG (refer to CX/FICS 20/25/4). The co-chairs are of the view that two changes are essential, 1) the revision proposed by Japan to replace “have to” with “should” since this is consistent with Codex terminology, and 2) inclusion of “information” for consistency of terminology in the document, where “information/data” is used throughout. Other revisions were proposed: to delete “ensure”, include “appropriate” and “according to the legislative framework of the country”. The co-chairs would like to seek the view of the EWG on the following options for point g (with the revision regarding “should” and “information” accepted). The co-chairs remind the participants that the previous EWG had recommended deleting “appropriate” and “according to the legislative framework of the country”.</p> <p>The members of the EWG are invited to indicate which option they find more suitable and to provide a rationale with their response.</p>	<p>AUSTRALIA</p> <p>Response - support option 2 with deletion of ‘appropriate’.</p> <p>Rationale – additional text provides legislative governance around information/data shared. However, do not support the inclusion of ‘appropriate’ as its inclusion may not support transparency. It makes the obligation too subjective.</p> <p>CANADA</p> <p>Canada prefers Option 2, with the deletion of “ensure and” and the addition of “information/data” to add clarity and precision to the sentence. However, Canada can support both Options.</p> <p>IRAN</p> <p>Option 1, would be preferred</p> <p>In option 2 could make challenges and conflicts between different countries and is against harmonization of international principles and guidelines</p> <p>JAPAN</p> <p>Support option 2 for clarity.</p> <p>FRANCE</p> <p>Option 1 - The second part of the suggestion (according to the legislative framework of the country) is implicit. Furthermore, some recognition programmes</p>

Text	Question to EWG members	EWG Response & Rationale
	<p>Option 1: maintain the text as originally drafted, i.e.,</p> <p><u>Should</u> ensure and maintain the confidentiality of data shared by the vTPA owner</p> <p>Option 2: revise the text as follows, based on comments received:</p> <p>g. <u>Should</u> ensure and maintain the <u>appropriate</u> confidentiality of <u>information</u>/data shared by the vTPA owner, <u>according to the legislative framework of the country.</u></p>	<p>may one day go beyond national borders (EU for example), the term “country” could therefore be restrictive.</p> <p>MOROCCO</p> <p>Morocco support the revised text (Option 2), but without including “appropriate”. Then the sentence will be:</p> <p>g. <u>Should</u> ensure and maintain the appropriate confidentiality of <u>information</u>/data shared by the vTPA owner, <u>according to the legislative framework of the country.</u></p> <p>Rationale:</p> <p>Morocco considers that the term "appropriate confidentiality" is very vague and would give rise to differences regarding the level (max and min) of appropriate. It could be understanding that "appropriate confidentiality" is a “light confidentiality”. This adjective is likely to create confusion. However, confidentiality is confidentiality without needing to qualify it with.</p> <p>For the last sentence, “<u>according to the legislative framework of the country.</u>” we are agreeable to the amendments made, insofar as the revised text recalls the regulatory framework on which the competent authority is based to ensure confidentiality.</p> <p>PERU</p> <p>Respuesta: Opción 2. El texto adicional establece la gobernabilidad de cada país con respecto a la confidencialidad de la información en el marco de la vAPT. Por otro lado, sugerimos que el termino “adecuado” sea eliminado, por ser un termino muy abierto para implementarlo; por tanto las redacción seria: “...confidencialidad de la información...” [Google translation: Option 2. The additional text establishes the governance of each country with respect to the confidentiality of the information under the vAPT. On the other hand, we suggest that the term "adequate" be eliminated, as it is a very open term to implement it; therefore the wording would be: "... confidentiality of information ...].</p> <p>SINGAPORE</p> <p>We would prefer Option 1, as it is understood that the maintenance of confidentiality of data will be done in accordance to the country’s legislative framework. However, we would recommend to add in the word “information” to be consistent, i.e. “information/data”</p>

Text	Question to EWG members	EWG Response & Rationale
		<p>UNITED STATES U.S. response: Option 2</p> <p>EUROPEAN UNION The EU supports the original text as it is crisp and to the point.</p> <p>GFSI Option 1</p> <p>ICBA Response: ICBA supports Option 2, with deletion of word “appropriate”. The use of term appropriate lends a level of subjectivity. <u>Should ensure and maintain the appropriate confidentiality of information/data shared by the vTPA owner, according to the legislative framework of the country.</u></p> <p>Rationale: The use of term “appropriate” lends subjectivity and its inclusion will not support transparency.</p> <p>IAF Option 1.</p>

Text	Question to EWG members	EWG Response & Rationale
<p>CO-CHAIRS ANALYSIS AND PROPOSAL:</p> <p>EWG participants’ views were divided with respect to how best to construct this bullet. Those supporting option 1 indicated that the addition of “according to the legislative framework of the country” is unnecessary or counter to international harmonization, while those in support of option 2 took the view that it provides clarity to the text. Further, three participants suggested deletion of the term “appropriate”, since it may be considered as subjective. One participant in support of Option 1 was of the view that the word “country” could be limiting in the future since vTPA application could extend beyond the border of a country in the future. After reviewing all comments received, the co-chairs would like to provide the following clarifications and suggestions:</p> <ul style="list-style-type: none"> - The term “according to the legislative framework of the country” is for some members implicit, however others consider it adds clarity. Since its inclusion does not break anything (by making something implicit explicit) the co-chairs recommending retaining the term as per option 2. - Some participants in support of option 2 also suggested deletion of “appropriate” from the sentence arguing that it was subjective. The co-chairs are of the view that the inclusion of “appropriate” may be redundant since competent authorities are required to adhere to their respective regulatory frameworks which generally lay out criteria around confidentiality of data. The co-chairs recommend deletion of “appropriate”. - One participant in support of option 1 was of the view that inclusion of the word “country”, as found in option 2 could be limiting since some recognition programmes may one day go beyond national borders. While the co-chairs recognise that some vTPA programmes operate in more than one country, Section B Scope, para 5 makes it clear that the guidance is intended for use by competent authorities <u>within their national boundaries</u>. <p>Based on the analysis of the comments, the co-chairs would recommend an amended version of option 2, with the deletion of the word “appropriate”, as follows</p> <p>E: ROLES, RESPONSIBILITIES AND RELEVANT ACTIVITIES</p> <p>1) <u>Competent Authorities</u></p> <p>g. Should ensure and maintain the confidentiality of information/data shared by the vTPA owner, according to the legislative framework of the country.</p>		
<p>E: ROLES, RESPONSIBILITIES AND RELEVANT ACTIVITIES</p> <p>3) <u>Voluntary Third-Party Assurance Owners</u></p> <p>e. Have policies and processes to ensure a vTPA owner alerts the competent authority of any significant public health risks or consumer deception</p>	<p>The co-chairs note that the Add.2 comments broadly support the continued inclusion of the adjective “significant” though note one member has suggested its deletion owing to its subjectivity. Other comments suggest some reordering and for there to be a more explicit link to “non-compliance/conformity” rather than or alongside public health.</p> <p>One member and one observer organisation raised a more fundamental point and argue that there needs to be a definition to quantify what is meant by “significant public health risk”.</p> <p>One member and one observer organisation raised a more fundamental point and argue that</p>	<p>AUSTRALIA</p> <p>Response – do not support either option and suggest the following alternative text</p> <p>e. Have policies and processes to alert the competent authority of any critical non-conformances significant public health risks or consumer deception found through independent audit of the associated with non-conformities by the FBO(s).</p> <p>Rationale – using ‘critical non-conformances’ avoids subjectivity with ‘significant public health risk’ and aligns with the terminology in audit reports, which is globally recognized.</p> <p>CANADA</p> <p>1) Canada supports the current wording.</p> <p>2) Canada does not support including a definition for “significant public health risk”. Canada believes that not including a definition provides the appropriate flexibility to</p>

Text	Question to EWG members	EWG Response & Rationale
<p>associated with non-conformities by the FBO(s).</p>	<p>there needs to be a definition to quantify what is meant by “significant public health risk”.</p> <p>The co-chairs recall that the term “significant public health risk” was in square brackets at the conclusion of CCFICS24, which established an EWG to address text in brackets. The outcome of the previous EWG supported maintaining the phrase “significant public health risk” in the document and also did not see the need for a definition (refer to CX/FICS 20/25/4). However, given that this sub-bullet continues to attract attention from some members the co-chairs are keen to seek the views to determine a way forward:</p> <ol style="list-style-type: none"> 1) Do EWG members support the current wording (contained in CX/FICS 20/25/4)? <ol style="list-style-type: none"> a. If not, please provide alternative wording and rationale for the EWG’s consideration. 2) Do EWG members support adding a definition for “significant public health risk”? <ol style="list-style-type: none"> a. If yes, please provide a proposed definition with rationale and source information (if available) for the EWG’s consideration. b. If no, please explain why not. 	<p>Members to determine what constitutes a “significant public health risk” in the national context.</p> <p>CHILE</p> <ol style="list-style-type: none"> 1) Se apoya la redacción actual. 2) No se apoya agregar una definición. <p>El riesgo significativo ha de ser determinado por cada país en base a su nivel adecuado de protección y a sus leyes, reglamentos y situaciones particulares. [Google translate: The significant risk must be determined by each country based on its appropriate level of protection and its laws, regulations and particular situations.]</p> <p>IRAN</p> <ol style="list-style-type: none"> 1) Yes. The current wording is supported. 2) Yes. Having a precise definition for “significant public health risk”: <p>A significant public health risk occurs when the FBO is not successful to provide its food safety management system so the products is not safe for intended use.</p> <p>JAPAN</p> <ol style="list-style-type: none"> 1) Support the current wording. 2) It is difficult to quantitatively define what is "significant". It is on a case-by-case basis and varies by country or region. <p>FRANCE</p> <ol style="list-style-type: none"> 1) YES 2) YES. <p>Not to be confused with “significant hazard” as defined in the revised GENERAL PRINCIPLES OF FOOD HYGIENE CXC 1-1969.</p> <p>A significant public health risk occurs when the FBO has lost control of the safety of his products.</p> <p>The FBO fails to fulfil his roles in terms of food safety as defined in CXC 1-1969</p> <p>« FBOs should apply the hygienic practices and food safety principles set out in this document to:</p>

Text	Question to EWG members	EWG Response & Rationale
		<ul style="list-style-type: none"> ○ develop, implement and verify processes that provide food that is safe and suitable for its intended use; ○ ensure personnel are competent as appropriate to their job activities; ○ build a positive food safety culture by demonstrating their commitment to providing safe and suitable ○ food and encouraging appropriate food safety practices; ○ contribute to maintaining confidence in domestically and internationally traded food; and ○ ensure that consumers have clear and easily understood information to enable them to identify the presence of food allergens, protect their food from contamination, and prevent the growth/survival of foodborne pathogens by storing, handling and preparing food correctly.” <p>In other words, the FBO’s Food hygiene system (Prerequisite programmes, supplemented with control measures at CCPs, as appropriate, that when taken as a whole, ensure that food is safe and suitable for its intended use) is dysfunctional and fails to control food safety hazards.</p> <p>MOROCCO</p> <p>Morocco proposes a new wording:</p> <p>e. Have policies and processes to ensure a vTPA owner alerts the competent authority of any significant public health risks risk profile or consumer deception associated with non-conformities by the FBO(s).</p> <p><u>Rationale:</u></p> <p>Morocco considers that the term “Risk profile” is better suited in this configuration. The “Risk profile” means the description of the food safety problem and its context. (Reference: FAO and WHO, 2019 - Codex Alimentarius Procedural Manual.</p> <p>To our knowledge, the term “significant public health risks” does not have a definition with international consensus and will be probably subject to interpretation by members.</p> <p>PERU</p> <p>Apoyamos la redacción actual, y no es necesario definir “riesgo significativo para la salud pública”, toda vez que se entiende que los titulares deben conocer la normas como: GENERAL PRINCIPLES OF FOOD HYGIENE CXC 1-1969,</p>

Text	Question to EWG members	EWG Response & Rationale
		<p>adopted in 1969. Amended in 1999. Revised in 1997, 2003, 2020; la cual contempla la aplicación del sistema HACCP a lo largo de toda la cadena alimentaria, y su aplicación debe basarse en pruebas científicas de peligros para la salud humana. [Google translation : We support the current wording, and it is not necessary to define “significant risk to public health”, since it is understood that the licensees must know the standards such as: GENERAL PRINCIPLES OF FOOD HYGIENE CXC 1-1969, adopted in 1969. Amended in 1999 Revised in 1997, 2003, 2020; which contemplates the application of the HACCP system throughout the entire food chain, and its application must be based on scientific evidence of dangers to human health].</p> <p>SINGAPORE</p> <p>1) We are agreeable to the amendments made as shown.</p> <p>2) We do not support having a definition for “significant public health risk” as each country may define this differently, based on their own identified hazards and thresholds.</p> <p>UNITED STATES</p> <p>1) U.S. response: This is an important point to include in this guideline and we offer the following alternative for consideration by the EWG:</p> <p>e. (bis) Have policies and processes to alert the competent authority of any non-conformance that is likely to lead or contribute to an imminent or serious risk to public health or consumer detriment.</p> <p>2) U.S. response: We do not support adding a definition for significant public health risk. Previous discussions around the formalized definition of this term have not been successful (e.g., it was suggested that if a specific point was not included in the definition then it meant that it was not a significant public health issue/risk.)</p> <p>EUROPEAN UNION</p> <p>The EU supports the original text. There is no need to develop a definition for a “significant public health risk” because it is up to the CA to define what is meant by this term depending on their national circumstances. Moreover, developing an all encompassing definition for this term would probably be a mission impossible</p> <p>GFSI</p> <p>The vTPA does not evaluate a public health risk but the conformity to a predefined standard. As a consequence, GFSI proposes to change “Have policies and processes to ensure a vTPA owner alerts the competent authority of any</p>

Text	Question to EWG members	EWG Response & Rationale
		<p>significant public health risks or consumer deception associated with non-conformities by the FBO(s).”</p> <p>By “Have policies and processes to alert the competent authority where sanctions are taken against a FBO as a result of non-conformities (e.g. withdrawal of certification)”.</p> <p>ICBA</p> <p>Response: ICBA proposes the following text to replace existing text:</p> <p>e. Have policies and processes to ensure a vTPA owner alerts the competent authority of any significant public health risks high risk non-conformities and associated consumer deception associated with non-conformities by the FBO(s).</p> <p>Rationale: vTPA owners should highlight all significant non-conformities and not just those that lead to public health risk/s. It should be noted that vTPA owners are not expected to carry out public health risk assessment.</p> <p>IAF</p> <p>Support of current wording.</p>

Text	Question to EWG members	EWG Response & Rationale
<p>CO-CHAIRS ANALYSIS AND RESPONSE:</p> <p><u>In response to the first question</u>, whether EWG participants support the current wording i.e., “e. Have policies and processes to alert the competent authority of any significant public health risks or consumer deception associated with non-conformities by the FBO(s)”</p> <p>By way of background and to add context, the co-chairs recall that this text was placed in square brackets by CCFIC24 and so was the subject of further consideration by the previous EWG. In moving the text forward the co-chairs felt it was important to retain the term “significant public health risk” in this section as it was simultaneously being deleted from Principle 3. [Extract from EWG report: <i>The Co-chairs 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.</i>]</p> <p>Further, the term has been used in some form throughout the development of the text and is based on the practical experience of those countries that have implemented the approach. In those countries the term serves as both a filter and a safety net. A filter so that official resources are not diverted to duplicate what is already part of the vTPA governance arrangements (see Section F, para 5 of the guidelines) which include the monitoring of corrective actions for all non-conformities identified. A safety net because where competent authorities are using vTPA information/data they may have reduced their official inspection frequency. This means they may not have visited an FBO for a longer period, so the timeliness of alerts becomes an important factor.</p> <p>Turning to the comments, the co-chairs note that a majority of EWG members continue to support the current wording and the inclusion of the adjective “significant”. However, several members have suggested alternative wording that changes the emphasis from public health to non-conformity. It is however reassuring that the suggested alternatives do not alter the overall intent of the bullet, that there should be a mechanism for prompt alerts to competent authorities when potential serious risks are identified during a vTPA audit. Whilst the co-chairs are open to reordering the text, e.g. the USA’s suggested amendment, for the reasons provided above the co-chairs suggest retaining the wording as originally drafted in the knowledge that the issue will likely be discussed during CCFIC25.</p> <p>E: ROLES, RESPONSIBILITIES AND RELEVANT ACTIVITIES</p> <p>3) Voluntary Third-Party Assurance Owners</p> <p>e. Have policies and processes to alert the competent authority of any significant public health risks or consumer deception associated with non-conformities by the FBO(s).</p> <p><u>In response to the second question</u>, whether EWG participants support inclusion of a definition of “significant public health risk”?</p> <p>All but two EWG participant did not support including a definition of “significant public health risk” or did not respond to the question. One participant was of the view that a definition should be included but did not propose a specific definition. Another participant proposed a definition for consideration. Based on the majority of EWG participants’ views, a definition has not been included.</p>		

Appendix 5

The output from the work of the reactivated EWG (track change version) including embedded co-chair rationale for the revisions. (see Appendix 1 for the clean version)

**DRAFT PRINCIPLES AND GUIDELINES FOR THE ASSESSMENT
AND USE OF VOLUNTARY THIRD-PARTY ASSURANCE PROGRAMMES (Updated text – track changes)
(At Step 6/7)**

A: PREAMBLE

13. 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. 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.
14. The Codex Principles and Guidelines for National Food Control Systems (NFCS) (CAC/GL 82-2013)¹⁴ 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.
15. 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 of vTPA programmes 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/data and should only apply assessment criteria that are relevant to that purpose.
16. Reliable vTPA programme 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

17. 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.
18. 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.
19. The guidelines do not oblige competent authorities to use vTPA programme outcomes nor do they mandate the use of vTPA programme information/data from FBOs i.e. emphasising that the decision to use vTPA programme information/data by the competent authority is voluntary.
20. 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 bodies¹⁵ that certify to a regulatory standard for which compliance is mandatory.

¹⁴CAC GL 82-2013: Principles and Guidelines for National Food Control Systems.

¹⁵CAC/GL 20-1995: Principles for Food Import and Export Certification.

21. 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.
22. These guidelines do not constitute approval, recognition or endorsement of vTPA programmes. Competent authorities may choose approaches other than those described in these guidelines when considering how to take into account vTPA programmes **information/data** in their risk-based targeting of regulatory controls. **[US proposal to include “information/data, to add clarity to what is being taken into account. Co-chairs agree with the proposal and rationale].**

C: DEFINITIONS¹⁶

For the purposes of this document, the following definitions apply:

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 **certification/conformity** assessment body conveying formal demonstration of its competence to carry out specific tasks. (*Adapted from ISO.IEC 17000:2020*) **Proposal from Chile. The Co-chairs agree with suggested change which is consistent with the note added to the definition of “certification body” below.**

Accreditation body: authoritative body that performs accreditation (*Adapted from ISO.IEC 17000:2020*)

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: Third party conformity assessment body operating certification services. (*Adapted from: ISO/IEC 17065:2102*).

Note: For the purposes of this document, the term “certification body” has the same meaning as “conformity assessment body”.

Conformity assessment: demonstration that specified requirements are fulfilled. (*Adapted from ISO.IEC 17000:2020*)

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.

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. (*CAC/GL 20-1995*)

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**. (*Adapted from ISO.IEC 17000:2020*)

Specified requirement: need or expectation that is stated. (*Adapted from ISO.IEC 17000:2020*)

vTPA Standard: specified requirements contained in the vTPA programme.

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 conformity with the standard, and in which FBO participation is voluntary.

vTPA Owner: Person or organisation responsible for developing and maintaining a specific vTPA programme. (*Source: Adapted from ISO IEC 17065:2012*)

D: PRINCIPLES

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

¹⁶ Based (in part) on EN ISO/IEC 17000 ‘Conformity assessment – Vocabulary and general 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.

Principle 3 Transparency of policies and processes

- Any arrangement to use vTPA programme 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 82-2013¹⁷.

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 programme 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 programme 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 make use leverage of vTPA programme conformity information/data, competent authorities should ensure that their approach is consistent with applicable international rights and obligations. *[Revisions made pursuant to the analysis of responses submitted by EWG participants].*

E: ROLES, RESPONSIBILITIES AND RELEVANT ACTIVITIES

24. 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 reliable vTPA programme information/data in their NFCS relating to protecting the health of consumers and ensuring fair practices in the food trade.

1) Competent Authorities

- Have statutory responsibilities for regulatory requirements set down in the NFCS, as recommended in CAC/GL 82-2013 and authorised by relevant national legislation.
- May consider using information/data generated by vTPA programmes to support meeting the objectives of their NFCS.
- 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.
- Should clearly describe the use of a vTPA programme information/data within their NFCS.

¹⁷ 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.

- d. (bis). Should have mechanisms in place to verify the continued credibility and reliability of vTPA programme information/data.
- m. Should ensure any arrangements to use vTPA programme information/data is fully transparent.
- n. Should ~~protect against~~ recognize potential conflicts of interest and their impact on the reliability of the information/data of the vTPA programme. *[Revisions made pursuant to the analysis of responses submitted by EWG participants].*
- o. Should ~~ensure and~~ maintain the confidentiality of information/data shared by the vTPA owner, according to the legislative framework of the country. *[Revisions made pursuant to the analysis of responses submitted by EWG participants].*

2) Food Business Operators (FBOs)

- f. 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.
- g. Need to demonstrate that they have effective controls and procedures in place to address regulatory requirements ~~protect the health of consumers and ensure fair practices in food trade.~~ *[US proposed revision to add clarity to the objective for effective controls and procedures. The co-chairs find merit with this proposal and suggest endorsing the revision. This section addresses the responsibilities of food business operators, and it would be more appropriate to indicate that they have to comply with regulatory requirements instead of repeating the mandate of Codex, i.e., protect the health of consumers and ensure fair practices in the food trade].*
- h. May elect to participate in vTPA programmes to meet business needs, demonstrate ~~conformance~~ conformity with relevant food safety standards, and provide independent assurance of the integrity of their products or production systems to relevant stakeholders.
- i. Owns the information/data generated by the vTPA programme.
- j. Has no conflicts of interest with the operation of the vTPA programme.

3) Voluntary Third-Party Assurance Owners

- f. Are responsible for implementing the governance arrangements of a vTPA programme, which may include utilising national/international standards and independent accredited audit and certification.
- g. Are accountable to participating FBOs to disclose the potential sharing of information/data generated by the vTPA programme with competent authorities.
- h. Have mechanisms to share information/data with the competent authority, according to the process established by the vTPA owners and the competent authority.
- i. Have policies and processes when sharing vTPA programme information/data with competent authorities such as notification to the FBO.
- p. Have policies and processes to alert the competent authority of any significant public health risks or consumer deception associated with non-conformities by the FBO(s). *[Agreement to retain the existing text pursuant to the analysis of responses submitted by EWG participants, and not to define "significant public health risk"].*
- j. Have policies and processes in place to protect against potential conflicts of interest between vTPA 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 information/data from vTPA programmes to help inform their NFCS should satisfy themselves that the vTPA programme 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 programme 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 and ensure that the vTPA programme has implemented them in a comprehensive way to assure successful outcomes. *[proposal from Japan to replace "help inform" with "support" for consistency. The co-chairs are of the view that "help*

inform” would be a better term to use. Should “support” be used, then the word “objectives” should be added after “NCFS” for completeness of the sentence

1) Governance Arrangements

- e. Are the governance arrangements and responsibilities within the vTPA programme clearly defined and documented?
- f. Are the oversight arrangements structured to avoid potential conflicts of interest?
- g. Does the vTPA programme have management controls to ensure consistent and effective implementation and maintenance?
- h. Does the vTPA programme have an accreditation arrangement with an accreditation body with international standing¹⁸, recognition and credibility? If not, how does the vTPA owner ensure that certification bodies have the capacity and competency to perform effectively?”

2) Accreditation of Certification Bodies

- e. Does the vTPA programme have an independent process to ensure the use of appropriately accredited certification bodies?
- f. Is the certifying body accredited for the vTPA programme according to the relevant accreditation standard?
- g. Is the accreditation of certification bodies for the vTPA programme subject to a periodic review and renewal?
- h. Does the accreditation body assess the certifying body for the vTPA programme using relevant and internationally recognized standards¹⁹?

3) Standard Setting Process

- g. Do the vTPA owners set their own standards or utilise national or international standards for assurance?
- h. To what extent are the vTPA standards consistent with Codex or other relevant international standards and/or applicable national regulatory requirements?
- i. Do the vTPA standards contain specified requirements to protect consumers in relation to food safety and fair practices in food trade?
- j. Have the vTPA standards been developed through a transparent consultative process with relevant experts and stakeholders reflecting the range of business processes within the target sector?
- k. Are the vTPA standards open, transparent in governance and subject to continuous improvement by regular review to keep them up to date?
- l. Are the vTPA standards written in a way that they can be assessed for conformity?

4) Conformity Assessment

- e. Does the vTPA programme have written procedures on frequency, methodology, announced and unannounced audits and competency requirements for certification bodies?
- f. 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?
- g. Does the vTPA programme have procedures in place to ensure that auditors have and maintain the required auditor competence?
- h. Does the vTPA programme have a transparent system to identify FBOs that conform to the standard (e.g. certification)?

¹⁸ For example, the International Accreditation Forum (IAF) and the International Laboratory Accreditation Co-operation (ILAC).

¹⁹ Examples include: ISO/IEC 17020, ISO/IEC 17065 or ISO/IEC 17021-1 supplemented with ISO/TS 22003, ISO/IEC 17011

5) Responses to Non-Conformity

- c. Do the vTPA programme governance arrangements include clearly defined procedures for dealing with non-conformities against the vTPA programme standards, failures to implement corrective actions to rectify non-conformities, and other situations where sanctions (e.g., withdrawal of certification of the FBO) might be required?
- d. Do the governance arrangements include a system for review of audit reports, review of decisions relating to non-conformities, potential use of sanctions, and a procedure for appeal?

6) Data Sharing and Information Exchange

- i. 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, for example through a publicly accessible database?
- j. Subject to national privacy legislation, does the vTPA owner inform the competent authority immediately when they become aware of a significant risk to public health or consumer deception?
- k. Does the vTPA owner have permission to share FBO information/data with competent authorities and is this in accordance with national data protection obligations? *[Proposal from Japan to add "information" for consistency. The co-chairs agree with the proposal since it enhances consistency of terminology in the text.*
- l. Does the vTPA owner inform competent authority of any FBO that ceases to participate either directly or via a web-accessible platform?
- m. Does the vTPA owner agree to notify the competent authority of any changes made to the vTPA programme, including but not limited to: the standard, governance, certification, information sharing and accreditation arrangements?
- n. Does the vTPA owner share information/data relating to conformity with the standard where the standard aligns with regulatory requirements to inform the NFCS?
- o. If the data available is in electronic form are there adequate arrangements for maintaining the security of the data?
- p. Does the vTPA owner have a protocol in place for information/data retention?

G: REGULATORY APPROACHES FOR THE USE OF vTPA PROGRAMME 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 information/data from vTPA programmes information/data. It also contains examples of the practical uses that can be made by competent authorities of vTPA programme information/data to support their NFCS objectives. *[Editorial revision proposed by Japan]. [co-chair proposal to simplify the second sentence: It also contains practical examples of how vTPA programme information/data could be used by competent authorities to support their NFCS objectives.*

1) Process considerations

- k. Information/data from a vTPA programme may be considered for use by a competent authority after an appropriate assessment of the vTPA programme's credibility and integrity as informed by the criteria in this guidance.
- l. Competent authorities need only apply relevant assessment criteria commensurate with their intended use of vTPA programme information/data.
- m. Where there is a positive assessment outcome the competent authority may choose to enter into an arrangement with the vTPA owner by mutual consent.
- n. Where an arrangement is in place between a competent authority and a vTPA owner, the vTPA owners should establish processes for the sharing of relevant information/data with the competent authority and processes for handling findings of non-conformities, including alerting the competent authority of any significant public health risk or consumer deception.

- o. Competent authorities should have transparent procedures to verify the reliability of the vTPA programme information/data that they intend to use.
- p. 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. The competent authority may consider the need for any intervention.
- q. Competent authorities may compare relevant regulatory audit data with that generated by the vTPA audits to verify consistency and reliability.
- r. In addition to specific and critical information detailed in an arrangement 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.
- s. Where competent authorities choose not to enter into an arrangement with the vTPA owner they may access the information/data directly from the FBO.
- t. The competent authority should identify the information/data from the vTPA programme audits that are of most value to support its NFCS objectives and agree upon the access arrangements for those elements. *Editorial proposal from Japan to add "support" in order to enhance consistency. The co-chairs agree with the proposal and have made an additional edit to improve sentence construction.*

2) Policy options

- h. In order to validate the suitability of an assurance system, including a review of the vTPA programme governance arrangements and their operation, the competent authority may consider the value of comparing the vTPA standards with relevant international standards and/or relevant national regulatory requirements.
- i. 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. *[US proposal to replace "focus on" by "prioritize". The co-chairs recommend maintaining the existing terminology which is consistent with the scope of the guidelines (Section B, para 6) and the emphasis on the parts of the vTPA standard that mirror regulatory requirements.]*
- j. Competent authorities may choose to verify the reliability of vTPA programme information/data through for example a comparison of conformity data from the vTPA programme with their official compliance information/data.
- k. Competent authorities may reduce the intensity levels and/or frequency of official inspection where there is verification through their official data that participation in a vTPA programme is achieving similar or higher levels of compliance with relevant regulatory requirements. *[Proposal from Japan to add "and/or frequency". Rationale: Frequency of official inspection may be reduced, we do not need to limit "level". The co-chairs support this edit and have added "intensity" for consistency with other sections of the text. As an example, vTPA conformity data may verify official inspection data which indicates compliance with pre-requisite requirements which might allow the competent authority to adjust its inspection approach accordingly.]*
- l. The suitability and extent to which competent authorities use vTPA programme information/data will be determined by the depth of any assessment of the integrity and credibility of the vTPA programme.
- m. Audit information/data generated by the vTPA programme and FBO certification status may be used to help determine the food safety or consumer deceptions risks associated with the participating FBOs, to inform NFCS planning and adjust frequency or intensity of regulatory oversight, and hence, help prioritise resources to higher risk areas. *[Editorial revision from the US. The co-chairs support the proposal.]*
- n. vTPA programme information/data indicating a trend could be used to target specific interventions such as focused inspections, targeted sampling and testing, or national training/information programs where the vTPA programme information/data helps identify a systemic issue. *[Proposal from Japan to add "targeted sampling and testing" as another example of specific interventions. The co-chairs support the proposal.]*

Appendix 6**Chronology/timeline of work**

Milestones	Description	Output
CCFICS23 (May 2017)	New work endorsed for the development of guidance on regulatory approaches to third party assurance schemes in food safety and fair practices in food trade. Recommendation to establish an EWG and to hold 2 physical working groups and pilot virtual participation via web-streaming, to draft the guidelines	Project document available in REP17/FICS, Appendix V
CAC40 (July 2017)	Approved the new work proposal forwarded by CCFICS23.	REP17/CAC, August 2017, paras 96-97.
EWG (Summer/Autumn 2017)	EWG launched to prepare a first draft to be considered at the PWG in Chile, in December 2017.	Report of working group meetings available in CX/FICS 18/24/6
Web-streamed Physical WG meeting (Santiago, Chile, 8-11 December 2017)		
Web-streamed Physical WG meeting (Edinburgh, UK, 28-31 May, 2018)		
CCFICS24 (October 2018)	Forwarded the proposed draft <i>principles and guidelines for the assessment and use of voluntary third-party assurance programmes</i> for adoption at Step 5 Established an EWG to address comments in square brackets and comments at Step 6.	REP19/FICS, paras 41-53, and Appendix III
CAC42 (July 2019)	Adopted the <i>Draft Principles and Guidelines for the Assessment and Use of voluntary Third-Party Assurance (vTPA)</i> at Step 5	REP19/CAC, July 2019, paras 76-79
	<i>Draft Principles and Guidelines for the Assessment and Use of voluntary Third-Party Assurance (vTPA)</i> circulated for comments at Step 6 (CL 2019/93/OCS-FICS)	Comments available in CX/FICS 20/25/4 Add.1
EWG (Summer/Autumn 2019)	Launch of EWG established by CCFICS24 to address text in square brackets and comments received at Step 6.	EWG report published as CX/FICS 20/25/4.

Milestones	Description	Output
	Due to timing issues, the EWG could not address comments at Step 6. Only text in brackets was addressed.	Circulated for comments in advance of CCFICS25 (CL 2020/26/OCS-FICS). Comments received available in CX/FICS 20/25/4 Add.2
CCFICS25, 27 April – 1 May 2020, Hobart, Tasmania	POSTPONED	
EWG re-activated (November 2020 – February 2021).	Consider comments in CX/FICS 20/25/4 Add.1 and CX/FICS 20/25/4 Add.2 to advance the work in preparation for the re-scheduled meeting of CCFICS25	<p>Appendix 1: The output from the work of the reactivated EWG comprising a clean text for discussion at CCFICS25.</p> <p>Appendix 2: The co-chairs' analysis and summary of the comments submitted by members and observers in CX/FICS 20/25/4 Add.1 and CX/FICS 20/25/4 Add.2.</p> <p>Appendix 3: The revised text and questions to the reactivated EWG's participants that formed the basis of the consultation between 3 November 2020 and 3 January 2021.</p> <p>Appendix 4: The co-chairs analysis and proposals to the responses received from the reactivated EWG's participants to the consultation contained in Appendix 3.</p> <p>Appendix 5: Output from the reactivated EWG comprising of a track change version of the text with embedded co-chair rationale for the revisions.</p>