Joint FAO/WHO Food Standards Programme
Codex Committee on Food Import and Export Inspection and Certification Systems
Twenty-Fourth Session
Brisbane, Australia, 22–26 October 2018

Proposed Draft Principles and Guidelines for the Assessment and Use of Voluntary Third-Party Assurance Programmes
(At Step 3)

Prepared by an electronic working group1 (EWG) led by the United Kingdom with Canada and Mexico


Introduction

1. At its 23rd session CCFICS considered a discussion paper and accompanying new work project document on regulatory approaches to third party assurance schemes in food safety and fair practices in food trade (CX/FICS 17/23/8). The Committee broadly acknowledged the importance of the topic and supported the commencement of new work as proposed whilst also expressing the following views:
   i. Competent authorities in various countries were increasingly considering and using third-party assurance schemes to better inform their risk profiling of food businesses so as to more effectively target resources within their National Food Control System (NFCS).
   ii. Using third-party assurance schemes could enhance but not replace NFCSs, and the standards used in such schemes should take into account international standards, such as those of Codex.
   iii. Using third-party assurance schemes had the potential to enable a competent authority and industry to improve food-safety outcomes, while allowing each stakeholder to operate within its defined roles and responsibilities.
   iv. Developing guidance on how and under which conditions a competent authority could make use of third-party assurance schemes in its NFCS was very timely, may prevent potential barriers to trade and could benefit from the experience of those countries already using such schemes.
   v. It was important to establish principles to: ensure the integrity, competency and voluntary nature of third-party assurance schemes; allow for the consideration of such schemes by national competent authorities but not require their use; and provide for the use by competent authorities of the regulatory elements of such schemes within their national boundaries.
   vi. Guidance on the use of third-party assurance schemes should: cover the dual mandate of Codex, not be limited to food safety; make reference to the Guidelines for the Design, Operation,

---

1Membership of Electronic Working Group:
Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997); and be consistent with other CCFICS texts.

2. Taking account of the above the Committee made a number of in-session changes to the project document and in expressing broad support for the work agreed to:
   a. start new work on developing guidelines on regulatory approaches to third-party assurance schemes in food safety and fair practices in the food trade, and to submit the revised project document (Appendix V) for approval to CAC40; and
   b. establish an EWG, with the possibility of convening physical meetings, chaired by the United Kingdom and co-chaired by Canada and Mexico, working in English only, that, subject to approval of the new work by CAC40, would prepare proposed draft guidelines for circulation for comments and for consideration at CCFICS24.

3. Under a separate AOB agenda item the Chair led a discussion about the “Enhancement of participation” and recalled that the Committee had agreed to establish two EWGs, with the possibility of convening physical meetings, to develop guidance on “Use of Systems Equivalence” and “Regulatory Approaches to Third-Party Assurance Schemes”. To ensure broad participation among members, he proposed holding the two Physical Working Groups (PWG) in advance of CCFICS24, scheduled for October 2018, in two different locations – in Chile, in November/December 2017, and in Ireland or the United Kingdom, in April/May 2018. He further proposed combining the PWGs via a webinar or similar modality to facilitate the participation, with real-time responses, of a range of countries that may not be able to participate physically. This experimental approach would be assessed after 12 months. Following discussion, the Committee agreed:

   a. Two intersessional PWGs would be held on an experimental basis, one in Latin America (Chile) and one in Europe (Ireland or the United Kingdom), to make progress in developing guidance documents on the “Use of Systems Equivalence” and “Regulatory Approaches to Third-Party Assurance Schemes”;
   b. Each PWG would last four days, with the time split equally between the two work items; and
   c. Both PWGs would be broadcast via webinar to enable broader participation.

Approach and sequencing of the work

4. A first draft of the proposed guidance was prepared by the UK with support from Canada and Mexico and circulated to EWG members on 11 November 2017. Comments on this first draft were not sought as the co-chairs considered that the early first draft would benefit from discussion at the first PWG meeting that was due to take place in Chile one month later. The PWG took place in Santiago Chile between 8 – 11 December 2017. The PWG was attended by delegations from 33 Codex members and observers² the Chair of CCFICS and the Codex Secretariat, with several delegations participating via webinar technology.

5. The outputs from the Santiago PWG were used to produce a second draft which was then circulated to EWG members for comment on 21 March 2018. Comments were received from 15 members and 5 observers. These comments were consolidated and considered by the co-chairs in advance of the second PWG which took place in Edinburgh, Scotland, between 28 – 31 May 2018. The PWG in Edinburgh was attended by delegations from 25 Codex members and 6 observers³ the Chair of CCFICS and the Codex Secretariat, with 7 delegations participating via webinar technology.

6. All of the working papers for the Edinburgh meeting were shared electronically via an open google drive folder Edinburgh pWG, including presentations from the session and the tabulated consolidated EWG comments to help inform discussions on the draft during the session.

²Australia, Argentina, Belgium, Bolivia, Canada, Chile, Colombia, Costa Rica, Denmark, Ecuador, European Union, Guyana, Guatemala, Honduras, India, Indonesia, Japan, Jamaica, Mexico, New Zealand, Nicaragua, Norway, Panama, Paraguay, Thailand, South Africa, United Kingdom, USA, Uruguay, FAO, CGF, ICMA, SSAFE.
³Australia, Argentina, Belgium, Canada, Chile, European Union, France, Finland, India, Italy, Ireland, Japan, Mexico, New Zealand, Netherlands, Norway, Peru, Philippines, Spain, Switzerland, Thailand, United Kingdom, Uruguay, USA, CGF, FAO, ICBA, OIE, SSAFE, WTO.
Draft text submitted at Step 3

7. The proposed text submitted for discussion at Step 3 builds on extensive discussion and input through two physical working groups and one electronic working group, which have engaged over 43 members and 15 observer organisations.

8. At the highest level the working groups have helped provide a clear focus for the guidelines, the purpose of which is to set out how voluntary Third-Party Assurance (vTPA) programmes can help support NFCS objectives, in line with paragraph 54 of Principles and Guidelines for national food control systems (CXG 82-2013) which foresee national food control systems taking account of quality assurance systems.

9. In terms of the structure of the guidance, the working groups have made comments on every part of the proposal. In particular the working groups helped develop principles from a blank sheet of paper, a preamble which introduces and frames the guidance, a scope which is clear and succinct, criteria in the form of questions that allow for an objective and proportionate assessment of the credibility and integrity of vTPA programmes, and a clearer description of policy options and process considerations to guide competent authorities in any decision and approach.

10. The current draft also picks up on concerns around the degree of prescription in the earlier drafts, particularly in relation to the perceived requirement for a full and in-depth assessment of the credibility and integrity of vTPA programmes for all regulatory approaches. A new principle was added (7) to address these concerns, along with some examples of regulatory approaches that do not require such a full assessment.

11. The structure of the guidelines has evolved during the working group stages with sections being moved around and/or merged. The title of the document also now differs from that contained in the project document. The changes introduced reflect the wide-ranging discussions during the two pWG’s and written comments from members of the eWG. Comments to improve the structure further are welcome, including on the position of Section G which could for example be positioned before Section F.

Recommendations

12. Attached for the consideration of the Committee (Appendix 1) is the proposed Draft Principles and guidelines for the assessment and use of voluntary third-party assurance.

13. The Committee is invited to:
   i. Consider the proposed draft presented at Step 3 in Appendix 1.
   ii. Propose amendments to the draft.
   iii. Consider whether to recommend to CAC42 advancement of the amended text to Step 5.
PROPOSED DRAFT of Principles and guidelines for the assessment and use of voluntary third-party assurance programmes

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 those 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. As a result, 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) foresee competent authorities taking into account quality assurance systems in their national food control system. However, before competent authorities can take account of vTPA programmes 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, specifically whether the information/data they generate is reliable and supportive of NFCS objectives. The focus of the guidelines is vTPA programmes that are accredited, and have audit and certification arrangements independent of the programme owner. The guidelines also seek to raise awareness and understanding of the potential value and contribution vTPA programmes can make to NFCS objectives by illustrating the role it plays in helping FBOs demonstrate compliance.

4. The guidelines provide a framework and criteria for assessing the integrity and credibility of governance structures and the reliability of information/data generated by vTPA programmes. When carrying out such an assessment, competent authorities should be guided by their intended use of vTPA programmes and should only apply assessment criteria that are proportionate and relevant to their approach.

5. Reliable vTPA data may be used to better risk-profile individual FBOs, or sectors. 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 of official inspections. Conversely, poorly performing FBOs, or sectors, may be subject to increased official inspection or targeted interventions based on trends identified through the information/data shared by the vTPA owner.

6. The document does not constitute any approval, recognition or endorsement of vTPA programmes. It follows that competent authorities may choose approaches other than that described in these guidelines when considering how to take into account vTPA programmes in their risk-based targeting of regulatory controls.

B: SCOPE

7. 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. Its focus is the structure, governance and components of vTPA programmes that align and support NFCS objectives relating to protecting consumer health and ensuring fair practices in food trade.

8. The guidelines do not compel competent authorities to take account of vTPA programme outcomes nor does it mandate the use of vTPA information/data by FBOs.

9. 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 bodies that certify to a regulatory standard for which compliance is mandatory.

---

4CAC 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.

5CAC/GL 20-1995: Officially recognized inspection systems and officially recognized certification systems are systems which have been formally approved or recognized by a government agency having jurisdiction.
The guidelines are not intended to apply to private standards that are the subject of contractual arrangements between buyers and sellers, and does not apply to components of vTPA programmes that are outside the scope or requirements of the NFCS.

C: DEFINITIONS

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

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

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

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

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

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


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

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

Governance: the processes and arrangements through which organisations are administered, in particular how they are directed, controlled and led including the way management systems are structured and separated to avoid potential conflicts.[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 honest and having strong moral principles. (Source: Oxford English dictionary)

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

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

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

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

Voluntary Third-Party Assurance Programme: A non-governmental or autonomous scheme comprising of the ownership of a standard that utilises national/international requirements; a governance structure for certification and enforcement, and in which FBO participation is voluntary. [Source: new]

D: PRINCIPLES

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

**Principle 1 [Decision making and planning]**

- Competent authorities retain discretion whether or not to consider information/data from vTPA programmes in their regulatory oversight, inspection and control framework, planning and decision-making process.

---

6 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  [Process and policies]
- Where the competent authority has assessed vTPA arrangements and identified information/data that aligns and indicates compliance with relevant regulatory requirements and NFCS objectives, the competent authority should establish a process for information/data sharing and handling of non-compliances with the vTPA owner to alert the competent authority of any significant public health risk.

Principle 4  [Regulatory framework]
- The vTPA standard, its audit and inspection does not replace regulatory requirements or controls carried out by the competent authority.

Principle 5  [Proportionality]
- The actions of the competent authority to make use of vTPA information/data should not directly or indirectly mandate additional requirements, costs or restrictions on FBOs over and above regulatory requirements.

Principle 6  [Transparency]
- Competent authorities should make their approach to the use of vTPA programmes, including the assessment process and criteria publicly available in line with Principle 3 of CAC/GL 82-2013.

Principle 7  [Assessment]
- The depth and extent of any assessment of the vTPA programme should be commensurate with the intended use of the vTPA information/data.

E: ROLES, RESPONSIBILITIES AND RELEVANT ACTIVITIES:

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

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 taking account of information/data generated by vTPA programmes to support the objectives of their NFCS and inform the design, implementation, monitoring and review activities to verify FBO compliance levels.

c. Have ultimate responsibility for the delivery and frequency/intensity of regulatory controls and enforcement action for all FBOs regardless of whether a FBO participates in a vTPA programme.

d. Need to clearly describe the use of a vTPA programme within their NFCS.

e. Should ensure any arrangements to use vTPA information/data is fully transparent.

f. Have to protect against potential conflicts of interest.

g. Have to maintain appropriate confidentiality of data.

h. Should be able to impose sanctions where false information/data is given to them by the vTPA owner.

---

7 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.
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 those aspects of food under their control.

b. Need to demonstrate that they have effective controls and procedures in place to protect the health of consumers and ensure fair practices in food trade.

c. May elect to participate in vTPA programmes to meet business needs, demonstrate compliance with relevant food safety standards, and provide independent assurance of the integrity of their products or production systems to buyers.

d. Owns the information/data generated by the vTPA programme.

VOLUNTARY THIRD-PARTY ASSURANCE OWNERS

a. Are responsible for implementing the governance arrangements of a vTPA programme, which will include utilising national/international standards and independent accredited audit and certification.

b. Are accountable to FBOs that participate in vTPA programmes.

c. May choose to share information/data generated by the vTPA programme for use by the competent authority.

d. Will have appropriate systems in place to protect against potential conflicts of interest between TPA owners, auditors and FBOs, and be able to demonstrate adherence to data protection obligations.

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

13. Competent authorities that choose to take account of vTPA programmes in their NFCS should satisfy themselves that the private 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 private 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.

Governance Arrangements

1) Are the governance arrangements and responsibilities within the vTPA programme clearly defined and documented?

2) Are the oversight arrangements structured to avoid potential conflicts of interest?

3) Does the vTPA programme have management controls to ensure consistent and effective implementation and maintenance.

4) Does the vTPA programme have an accreditation arrangement that adheres to the International Accreditation Forum’s (IAF) Multilateral Recognition Arrangement or the International Laboratory Accreditation Co-operation (ILAC)?

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

Accreditation of Certification Bodies

1) Does the vTPA programme have an independent process to ensure the use of appropriately accredited certification bodies?

2) Is the accreditation of certification bodies subject to a periodic review and renewal?

3) Does the Accreditation Body assess the certifying body using the relevant standards including ISO/IEC 17020, ISO/IEC 17065 or ISO/IEC 17021-1 supplemented with ISO/TS 22003?

4) Is the certifying body accredited for the vTPA programme according to the relevant accreditation standard?

Standard Setting Process
1) Do the vTPA standards contain specified requirements to protect the health of consumers in relation to food safety and fair practices in food trade?

2) Have the vTPA standards been developed through a transparent consultative process with relevant experts reflecting the range of business processes within the target sector?

3) Are the vTPA standards subject to a regular review to keep them up to date?

4) To what extent are the vTPA standards consistent with Codex or other relevant international standards and/or applicable national regulatory requirements?

5) Are the vTPA standards written in a way that they can be assessed for conformance?

Conformity Assessment

1) Does the vTPA programme have written policies on frequency, methodology, announced and unannounced audits and competency requirements for accreditation and certification bodies?

2) Does the vTPA programme require a conformity assessment against the standard on a defined regular basis, e.g. annual audit of participating FBOs following an appropriate quality assurance framework?

3) Does the vTPA programme have procedures in place to ensure that auditors have and maintain the required auditor competence?

4) Does the vTPA programme have a transparent system to identify FBOs that conform to the standard (e.g. certification)?

Responses to Non-Conformance

1) Do the vTPA programme arrangements include clearly defined procedures for dealing with non-conformities against the standards, failures to rectify non-conformities, and other situations where sanctions might be required?

2) Do the arrangements include a system for review of audit reports, decisions on interpretation and sanctions, and a procedure for appeal?

Data Sharing and Information Exchange

1) Is there an up-to-date list of participating FBOs (including their status) that are certified or verified as conforming to the vTPA standard, and is this information available to the competent authority? Is the information available in the public domain?

2) Subject to national privacy legislation, will the vTPA programme owner inform the competent authority immediately or when they become aware of a significant risk to public health or fraud?

3) Will the vTPA programme owner notify the competent authority of any FBO that ceases to participate?

4) Will the vTPA programme owner agree to notify the competent authority of any changes made to the vTPA programme, including but not limited to: the standard, governance, certification and accreditation arrangements?

5) Will the vTPA programme owner share information/data relating to compliance with the standard where the standard aligns with regulatory requirements to inform the NFCS?

6) If the data available is electronic form are there adequate arrangements for maintaining the security of the data?

7) Does the vTPA owner have permission to share FBO data and is this in accordance with national data protection obligations?

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

14. This section provides examples of necessary considerations and the practical uses that can be made by competent authorities of vTPA information/data to support their NFCS objectives.

Process considerations

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

c. Where there is a positive assessment outcome the competent authority may choose to enter into an arrangement with the vTPA owner by mutual consent.

d. Competent authorities should have transparent procedures in place to verify the reliability of the vTPA information/data that it intends using.

e. 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 consider the need for and type of any intervention needed.

f. Competent authorities may compare comparable regulatory audit data with that generated by the vTPA audits to verify consistency and reliability.

g. In addition to specific and critical information detailed in any voluntary agreement, there should be routine information exchanged to demonstrate that the vTPA programme continues to operate in line with its agreed governance.

h. Where competent authorities choose not to enter into an agreement with the vTPA owner they may access the information/data directly from the FBO.

i. The competent authority should identify the information/data from the vTPA audits that is of most value to its NFCS objectives and agree the access arrangements for those elements. Key elements are identified in para 38 (“Data Sharing and Information Exchange” above).

**Policy options**

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

b. Competent authorities may choose to verify the reliability of vTPA information/data through for example a comparison of the compliance data from the vTPA with their official inspection information/data.

c. In order to validate the suitability of an assurance system, including a review of the vTPA requirements and its operation the competent authority may consider the value of comparing the vTPA requirements with relevant international standards and/or relevant national regulatory requirements.

d. 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 fair practices in food trade.

e. 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.

f. Competent authorities may reduce levels of official inspection where there is verification through their official inspection data that participation in a vTPA programme is achieving higher levels of compliance with relevant regulatory requirements.

g. The suitability and extent to which competent authorities use vTPA information/data will be determined by the depth of any assessment of the integrity and credibility of the vTPA programme.

h. vTPA information/data indicating a trend could be used to target specific interventions such as focused inspections or national training/information programs where the vTPA information/data helps identify a systemic issue.

i. 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.
Competent authorities may use the additional information/data from vTPA audits to help prioritise regulatory resources to higher risk areas to better protect the health of consumers in relation to food safety and fair practices in food trade.