CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

Food and Agriculture Organization of the United Nations

World Health Organization

**PRINCIPLES AND GUIDELINES FOR THE ASSESSMENT
AND USE OF VOLUNTARY THIRD-PARTY ASSURANCE PROGRAMMES**

CXG 93-2021

Adopted in 2021.

A.   PREAMBLE

1.   Food business operators (FBOs) have the primary role and responsibility for managing the food safety of their products and for complying with regulatory requirements relating to food under their control. Competent Authorities require FBOs to demonstrate that they have effective controls and procedures in place to protect the health of consumers and ensure fair practices in food trade. Many FBOs use quality assurance systems, including voluntary third-party assurance (vTPA) programmes to reduce supply chain risks and confirm food safety outcomes.

2.   The Codex *Principles and Guidelines for National Food Control Systems*[1] 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 bodies[2] 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. 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.   DEFINITIONS[3]

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 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)*

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[1]   CXG 82-2013: *Principles and Guidelines for National Food Control Systems*.
[2]   CXG 20-1995: *Principles for Food Import and Export Certification*.

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

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 17065:2012*).

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

Governance: the processes and arrangements through which organizations 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. (*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.

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 82-2013[4].

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.

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

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 food business operators**

- 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.

## 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 CXG 82-2013.

b.	May consider using information/data generated by vTPA programmes to support meeting the objectives of their NFCS.

c.	Establish and implement regulatory controls, including frequency/intensity, 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.

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

f.	Should have mechanisms in place to verify the continued credibility and reliability of vTPA programme information/data.

g.	Should recognize potential conflicts of interest and their impact on the reliability of the information/data of the vTPA programme.

h.	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.

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).

f.	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 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 standing[5], 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**

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

   b. Is the certification 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 certification body for the vTPA programme using relevant and internationally recognized standards[6]?

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)?

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[5] For example, the International Accreditation Forum (IAF) and the International Laboratory Accreditation Co-operation (ILAC), ISO/IEC 17011.

[6] Examples include: ISO/IEC 17020, ISO/IEC 17065 or ISO/IEC 17021-1 supplemented with ISO/TS 22003

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?

    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 in relation to food safety and fair practices in food trade.

    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.