voluntary Third-Party Assurance (vTPA) Programme Assessment Tool

Disclaimer

Foreword

This vTPA programme assessment tool was developed by UNIDO under a regional project to pilot and learn about the use of vTPA programmes in West Africa (STDF/PG/665), which was funded by the Standards and Trade Development Facility (STDF). This project was implemented by UNIDO, in cooperation with the public and private sector in Mali and Senegal, from 2020 to 2024.

The project in West Africa piloted and learned about use of the Codex Principles and Guidelines for the Assessment and Use of Voluntary Third-Party Assurance Programmes (CXG 93-2021) in a developing country context. There were synergies with two other STDF-funded regional vTPA projects – notably a project in Central America (STDF/PG/682) led by the Inter-American Institute for Cooperation on Agriculture (IICA) in Belize and Honduras, and a project in East Africa led by Land O' Lakes Venture 37 in Rwanda and Uganda (STDF/PG/842) – as well as with other UNIDO-supported work in the Near East.

These projects brought together diverse public and private stakeholders involved in food safety management at the country level, as well as diverse international and regional partners, including through the online vTPA Partnership Platform, managed by UNIDO. This publication benefits from insights shared by various partners, including through a regional workshop organized by UNIDO in Cairo in 2023. More information is available on the STDF website.

vTPA Programme Assessment Tool

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1. Introduction

1.1 Background

The purpose of this assessment tool is to provide a high-level overview of the factors which need to be considered by the Competent Authority (CA)[1] prior to, during and after assessment of a voluntary Third-Party Assurance (vTPA) programme. Reliable vTPA programme information / data may be used in general to better risk-profile sectors, and in some circumstances individual Food Business Operators 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 (CXG 93-2021 A4).

In line with the Codex Principles and Guidelines for National Food Control Systems[2] all aspects of a National Food Control System (NFCS) should be transparent and open to scrutiny by all stakeholders, while respecting legal requirements to protect confidential information as appropriate. Transparency relating to the use of vTPA programmes by CAs can be achieved through clear documentation and communication.

This assessment tool is based on the Codex Principles and Guidelines for the Assessment and Use of vTPA Programmes[3], hereafter referred to as the Codex Guidelines, ISO/IEC 17021[4] and ISO/IEC 17065[5]. The assessment tool includes guidance on best practice, flow-diagrams, checklists and 'tips' for CAs to use when assessing the suitability of vTPA programmes.

In order to ensure 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 (CXG 93-2021 G14 (2a)).

Before an assessment of any vTPA program, the CA should:

- Consider how vTPA programme information / data might be used to benefit the NFCS.

- Publish details of their intent to use vTPA Programmes and their intended purpose (i.e., to inform prioritization of official controls).

- Consult key stakeholders on the approach.

- Outline finalised vision in national policy & strategy (as relevant).

- Identify all vTPA programmes that address food safety and could support smarter data driven prioritisation of official control activities.

- Prioritise vTPA programmes based on official control needs.

- Have robust internal processes required to ensure transparency, data protection, confidentiality, avoidance of conflict-of-interest etc.

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1   Competent authority also known as the regulatory authority, is the authority responsible for the enforcement of legislation.

2   Codex Principles and Guidelines for National Food Control Systems - CAC/GL 82-2013

3   Codex Principles and Guidelines for the Assessment and Use of vTPA Programmes - CXG 93-2021

4   International Standard: ISO/IEC 17021-1:2015 Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements

5   International Standard ISO/IEC 17065:2012 Conformity assessment – Requirements for bodies certifying products, processes and services.

1.2 Scope of the Codex Guidelines

The Codex 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 the intended use of the vTPA programme information / data and should only apply assessment criteria that are relevant to that purpose (CXG 93-2021 A3).

The Codex 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 (CXG 93-2021 B6). They are intended to assist competent authorities within their national boundaries in the effective assessment and transparent use of reliable vTPA programme information / data to support their NFCS objectives (CXG 93-2021 B5).

Figure 1.2-1 outlines the boundaries of the Codex Guidelines (CXG 93-2021 B7-10).

Competent authorities may choose to establish an arrangement with a vTPA owner to use the information / data generated by the vTPA to support their regulatory controls. If they choose to do so, they must satisfy themselves that the information / data they intend to use is both reliable and fit for purpose (CXG 93-2021 A2).

Figure 1.2-1 vTPA Assessment Boundaries

1. 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

2. 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

3. 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

4. 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.

1.3 Roles and Responsibilities

Figure 1.3-1 outlines the organisations involved in vTPA programmes and their interactions, and **Table 1.3.1** outlines their roles and responsibilities. The roles and responsibilities of all of these organisations 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 (CXG 93-2021 E12).

Figure 1.3-1 Organisations involved in vTPA programmes and their interactions
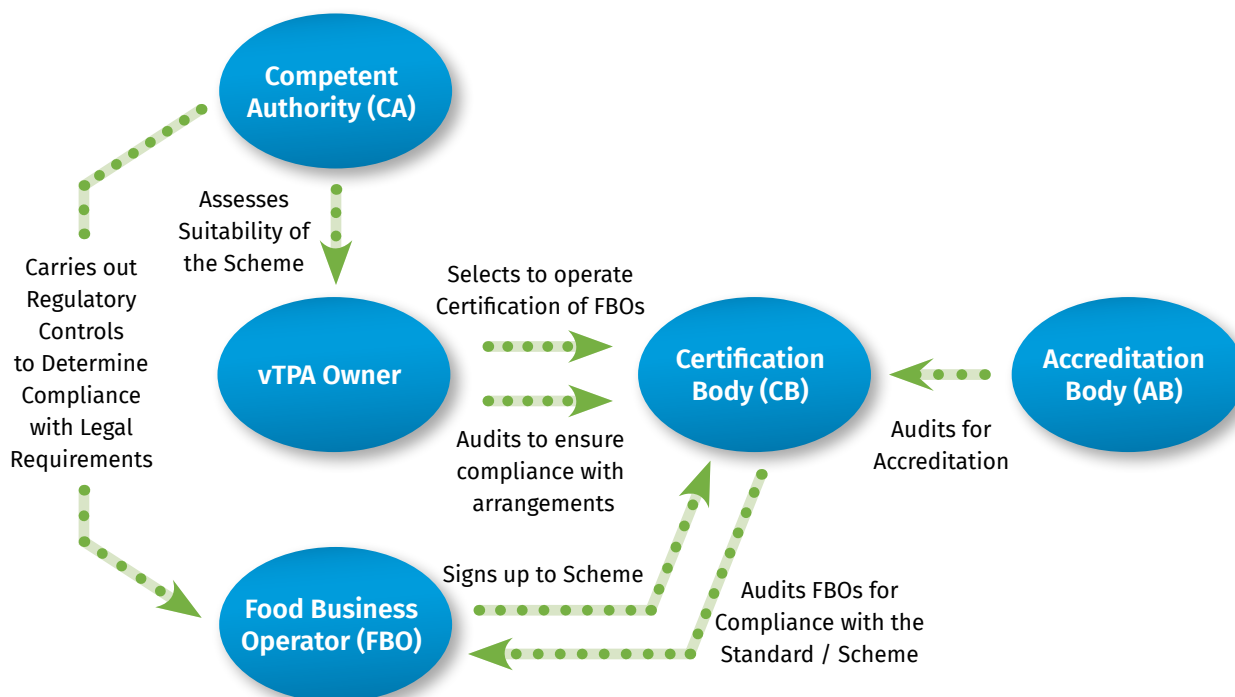
Table 1.3-1 Roles and Responsibilities

Category	Responsibility
Competent Authority	The Codex Principles and Guidelines for National Food Control Systems, CAC/GL 82-2013 establishes the premise of CAs taking into account quality assurance systems in their national food control system (NFCS). CAs 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.
	Competent Authorities (CAs) (CXG 93-2021 E12(1))
	a. Have statutory responsibilities for regulatory requirements set down in the national food control systems (NFCS), as recommended in CAC/GL 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 or not.
	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 supervise and 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.

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Category	Responsibility
Food Business Operator	Food business operators (FBOs) have the primary role and responsibility for managing the food safety of their products and services, and for complying with regulatory requirements relating to food under their control. FBOs must be able to demonstrate to CAs 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 (CXG 93-2021 A1). *Food Business Operators (FBOs)* (CXG 93-2021 E12(2)) a. Have the primary role and responsibility for managing the food safety of their products and services 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, services or production systems to relevant stakeholders. d. Own the information / data generated by the vTPA programme. Note: The FBO consents that data pertaining to vTPA programmes can be shared with parties agreed with the vTPA owner (e.g. Regulators, retailers or potential clients). e. Has no conflicts of interest with the operation of the vTPA programme.
vTPA Owner	*Voluntary Third-Party Assurance (vTPA) Owners* (CXG 93-2021 E12(3)) a. Are responsible for implementing the governance arrangements of a vTPA programme, which may include utilising national, regional, and/or 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 CAs. *Note:* The sharing of data and information is based on permission from the FBO and respecting confidentiality agreements. c. Have mechanisms to share information / data with the CA, according to the process established by the vTPA owners and the CA. d. Have policies and processes when sharing vTPA programme information / data with CAs such as notification to the FBO. e. Have policies and processes to alert the CA of any significant public health risks or consumer deception associated with non-conformities by an FBO. 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.
Certification Body	*Certification Bodies (CBs)* a. Are responsible for and shall retain authority for decisions relating to certification. This includes the granting, maintaining, renewing, extending, reducing, suspending, and withdrawing of certification. b. Provide updates to FBOs on certification activities and requirements. c. Are responsible for safeguarding impartiality in its certification functions and for ensuring that the policy on safeguarding impartiality and related procedures and other systems are effectively implemented. d. Ensure there are technical personnel competent for the development and establishment of the certification body's internal systems and for certification activities. e. Establish, document, implement and maintain processes and procedures for ensuring fulfilment of requirements specified in ISO/IEC 17065 (or ISO/IEC 17021, e.g. management of impartiality. f. Are responsible for information sharing between the vTPA owners and FBOs.

Category	Responsibility
Accreditation Body	**Accreditation Bodies (Abs)** a. Are responsible for ensuring that certification bodies, and other conformity assessment bodies meet established standards. b. Ensure compliance with codes of ethics/conduct when providing assessment services. c. Examine the competence of the certification body's staff. d. Verify the scope of a certification body's services based on sector specific standards.

1.4 The Assessment Tool

The assessment tool has been developed to support Competent Authorities in carrying out an assessment of vTPA programmes as set down in the Codex Guidelines. The assessment tool outlines best practices in the areas covered by each of the criteria from the Codex Guidelines and lists areas for consideration when making an assessment of each criterion to determine if the criterion is being met, or if key elements are missing.

Section 3 of this document outlines the guiding principles for the assessment process and six pre-steps that are recommended to be carried out to make a high level evaluation about which vTPA programmes should undergo a full assessment. **Section 4** details the assessment process which uses the criteria from the Codex Guidelines and describes best practices in each of these areas. **Section 5** includes information on the post assessment process, and outlines policy areas for consideration by the CA. **Figure 1.4-1** below outlines the complete process.

This document is a simplified version of the Assessment Tool that does not include all the details. For complete and detailed information, please refer to the original version of the document.

Figure 1.4-1 The assessment process using this assessment tool

Pre-steps
- Formation of Committee*
- Approach vTPA owner
- Initial Agreement
- Feasibility Study
- Feedback to vTPA owner
- Outcome

Assessment
Assessment of:
- Governance Arrangements
- Certification Bodies
- Standard Setting Process
- Conformity Assessment
- Management of Non-Conformity
- Data Sharing
- Outcome

Post Assessment
- Decision-Making
- Feedback to vTPA owner
- Agreement
- Information Sharing
- Data Management
- On-going Verification

* The assessment is proportionate to intended use, so a committee may not be appropriate in all circumstances.

2. Definitions

For the purposes of this document, the following definitions apply (CXG 93-2021 C):

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)

Audit:
> is a systematic and functionally independent examination to determine whether activities a
> nd 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 and ISO/IEC 17021).

Competent authority (CA)
> The national body or authority legally designated with the statutory responsibility for
> the regulatory requirements set out in the national food control systems (NFCS).

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. (CXG 93-2021)

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. (CXG 93-2021)

Voluntary Third-Party Assurance Programme:
> An autonomous programme 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. (CXG 93-2021)

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

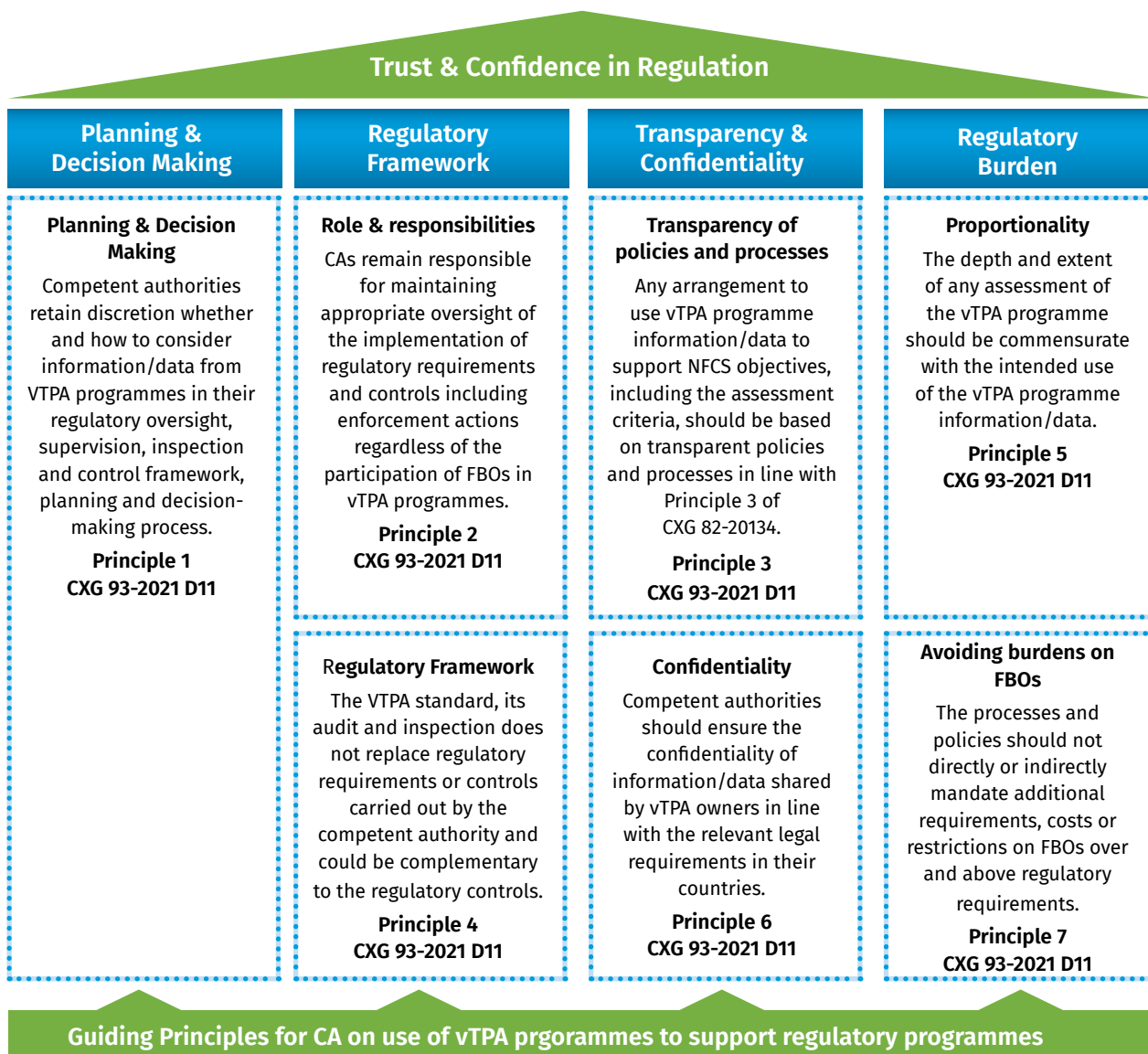# 3. Principles & Pre-Steps for Competent Authorities

3.1 Guiding Principles

Building and maintaining trust and credibility in the regulatory control system is important. 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 seven principles from the Codex Guidelines (CXG 93-2021 D11).

These are presented in **Figure 3.1-1** under the following four key pillars:
- Regulatory Framework
- Planning and Decision Making
- Transparency and Confidentiality
- Regulatory Burden

Figure 3.1-1 Guiding principles for CAs on building trust and confidence in vTPA programmes

Trust & Confidence in Regulation

Planning & Decision Making	Regulatory Framework	Transparency & Confidentiality	Regulatory Burden
Planning & Decision Making Competent authorities retain discretion whether and how to consider information/data from VTPA programmes in their regulatory oversight, supervision, inspection and control framework, planning and decision-making process. **Principle 1** **CXG 93-2021 D11**	**Role & responsibilities** CAs 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 2** **CXG 93-2021 D11**	**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 82-20134. **Principle 3** **CXG 93-2021 D11**	**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 5** **CXG 93-2021 D11**
	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 4** **CXG 93-2021 D11**	**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 6** **CXG 93-2021 D11**	**Avoiding burdens on FBOs** The processes and policies should not directly or indirectly mandate additional requirements, costs or restrictions on FBOs over and above regulatory requirements. **Principle 7** **CXG 93-2021 D11**

Guiding Principles for CA on use of vTPA prgorammes to support regulatory programmes

CAs should be guided by these principles when considering the potential role of vTPA programmes and the potential contribution of their information / data may make to determining FBOs compliance with regulatory requirements and broader NFCS objectives.
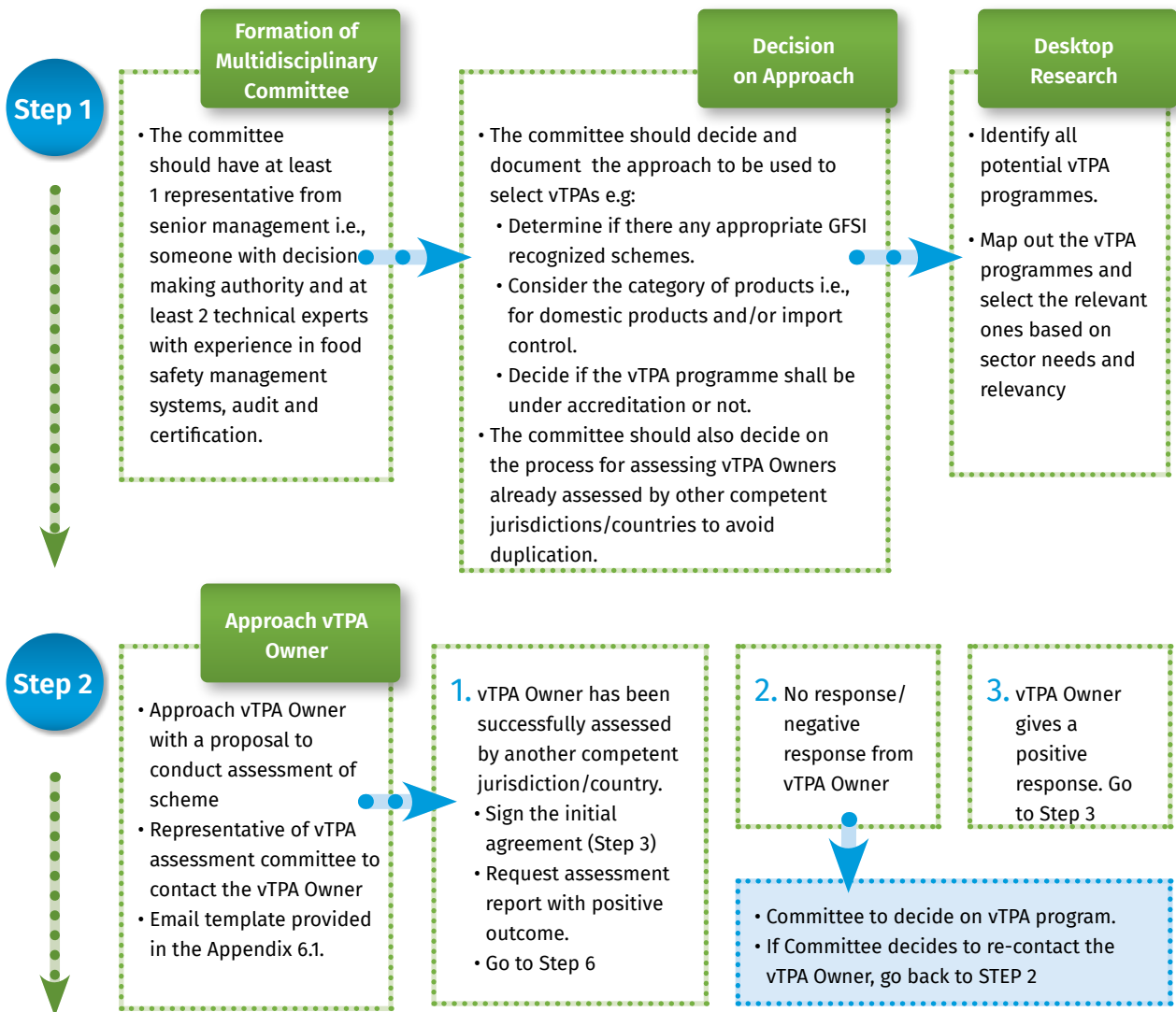
3.2 Pre-steps

This section outlines six pre-steps which CA should undertake as part of their initial validation of a vTPA programme. These pre-steps are necessary to ensure the effective and efficient use of CA resources in the assessment of vTPA programmes.

The pre-steps are presented in **Figure 3.2-1 and cover the following:**
- Primary selection of the vTPA programme
- Preliminary engagement with the vTPA programme owner
- Initial high-level feasibility study

If the findings from the feasibility study are favourable, the CA will then progress to a more in-depth assessment, using the assessment guidelines outlined in **Section 4 of this assessment tool.**

Figure 3.2-1 Pre-steps schematic

Step 1

Formation of Multidisciplinary Committee
- The committee should have at least 1 representative from senior management i.e., someone with decision making authority and at least 2 technical experts with experience in food safety management systems, audit and certification.

Decision on Approach
- The committee should decide and document the approach to be used to select vTPAs e.g:
  - Determine if there any appropriate GFSI recognized schemes.
  - Consider the category of products i.e., for domestic products and/or import control.
  - Decide if the vTPA programme shall be under accreditation or not.
- The committee should also decide on the process for assessing vTPA Owners already assessed by other competent jurisdictions/countries to avoid duplication.

Desktop Research
- Identify all potential vTPA programmes.
- Map out the vTPA programmes and select the relevant ones based on sector needs and relevancy

Step 2

Approach vTPA Owner
- Approach vTPA Owner with a proposal to conduct assessment of scheme
- Representative of vTPA assessment committee to contact the vTPA Owner
- Email template provided in the Appendix 6.1.

1. vTPA Owner has been successfully assessed by another competent jurisdiction/country.
   - Sign the initial agreement (Step 3)
   - Request assessment report with positive outcome.
   - Go to Step 6

2. No response/ negative response from vTPA Owner

3. vTPA Owner gives a positive response. Go to Step 3

- Committee to decide on vTPA program.
- If Committee decides to re-contact the vTPA Owner, go back to STEP 2

Step 3

Initial Agreement

- After receiving a positive response from the vTPA Owner, draft an initial agreement between both parties to ensure confidentiality.
- Both parties should sign the initial agreement to ensure confidentiality
- Template of initial agreement provided in **Appendix 6.2.**

Step 4

Feasibility Study

- Request high-level documents to support high level feasibility study which focuses on 'red flag' areas for competent authority including:
  - Request for evidence of approval / recognition or benchmarking of vTPA, e.g: by accreditation bodies / IAF, GFSI, CA's
  - Ability of vTPA Owner to share relevant data i.e., data protection and retention policy
  - Alignment of vTPA program with relevant national legislation by mapping of the vTPA standard against existing relevant standards (Codex, other international and regional standards) & relevant national legislation
  - Number of FBOs participating in the scheme
- Perform a gap analysis to identify gaps in regulatory requirements
- Feasibility study report provided in **Appendix 6.3.**

Step 5

Feedback

- Provide feedback to vTPA scheme owner on outcome including any non-conformances detected
- Feedback email template provided in **Appendix 6.1.**

Step 6

In depth Assessment

- If findings of initial feasibility study are favorable, progress with a more in-depth assessment as per assessment tool

4. Assessment of Credibility & Integrity of vTPA Programme

CAs 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 (CXG 93-2021 F13). Following on from a favourable result in the feasibility study in the pre-steps, the next stage in the process is to carry out a full assessment or partial assessment of the credibility and integrity of the vTPA programme (CXG 93-2021 F13).

The Codex Guidelines present six areas to assess the credibility and integrity of vTPA programmes (CXG 93-2021 F13). These areas are presented in **Figure 4-1** below.

Figure 4-1 vTPA Programme Assessment Criteria

VTPA Program Assessment Criteria

Governance Arrangements | Certification Bodies | Standard Setting Process | Conformity Assessment | Management of Non-Conformity | Data Sharing

The Codex Guidelines outline the criteria in each of these areas to be assessed. When carrying out the assessment, the competent authority should select from the six areas those criteria 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 (CXG 93-2021 F13).

The following sections outline best practices for each of the criteria in the six areas to be examined during the assessment. These best practices can be considered by the CA to assist in making a determination as to whether the practices in-place achieve the intention of the criterion to an extent which is suitable given the intended use of the vTPA programme.

4.1 Governance Arrangements

Good governance is essential for a company or organization to achieve its objectives and drive improvement, as well as maintain legal and ethical standing in the eyes of shareholders, customers, regulators and the wider community.

All governance arrangements and responsibilities within the vTPA programme should be clearly defined and documented. There should be arrangements in-place to deal with conflicts of interest, to ensure consistency, effective implementation and maintenance of the vTPA programme and to define how certification of the programme is done (accredited certification body, non-accredited certification body, independent auditor).

Also it is important to note that the governance arrangements for second-party and third-party assurance programmes are different.

Second-Party vTPA programmes are owned and governed by an organisation with a pre-existing relationship with FBO. These include customers, consumer, and industry associations. Thus, certification activities are conducted by parties having an interest in the FBO, or by other individuals on their behalf to ensure that they are meeting their requirements. These requirements may include special control over certain processes, requirements for pollution prevention or compliance evaluation, requirements for specific documentation, or any other requirements that are of special interest to the

organisation.

Third party certification is carried out by an independent organisation, and can be used to:
- Demonstrate compliance with national, regional or international standards and regulations
- Demonstrate independent validation and verification of their commitment to food safety
- Increase credibility and acceptance with retailers, consumers, and regulators

4.1.1 GOVERNANCE ARRANGEMENTS AND RESPONSIBILITIES

CXG 93-2021 F13 Criterion 1a:
Are the governance arrangements and responsibilities within the vTPA programme clearly defined and documented?

Table 4.1.1-1 below outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.1.1-1 Best practices in the area of governance arrangements and responsibilities.

Best practice in this area:	How this can be assessed:
The vTPA owner shall be a legal entity, or a partnership of legal entities, and shall have the authority to establish and amend the vTPA Programme.	• Evidence should be provided to prove registration of the vTPA owner as a legal entity, for example, certificate from government body showing they are a registered business, document showing they registered with the tax authorities for the country.
The vTPA owner shall implement a documented management system.	• The vTPA owner will provide evidence that there is a documented management system in-place, i.e. a series of documents describing and supporting the operation of their processes.
The vTPA owner shall have a process/procedure for complaints and appeals. The process / procedure shall be communicated to certification bodies and FBOs.	• A complaints process / procedure and an appeals process / procedure are in-place. • There is a process / procedure for communicating this information to certification bodies and FBOs. • Correspondence on complaints and appeals is available.
The vTPA Programme shall be developed and maintained with the participation of technically competent stakeholders, and/or be subjected to formal review by such parties and determined as appropriate. The Programme shall be subjected to extensive stakeholder consultation during its development and normative documents shall be established by consensus and issued using a formalised and documented approval process.	• Processes / procedures for development and review of standards will be in-place and will include formal sign-off / approval of the standard. • These processes / procedures will include how consultation with technically competent stakeholders takes place. • The standard will include information on the frequency of review. • Records of meetings and correspondence with stakeholders are available.
There shall be a periodic internal review of the vTPA programme.	• Details of the frequency of review should be specified in the standard. • A process / procedure for internal review of vTPA programmes is available. Minutes from meetings and correspondence relating to reviews should be available.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 1a:** Are the governance arrangements and responsibilities within the vTPA programme clearly defined and documented?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA owner				

4.1.2 CONFLICTS OF INTEREST

CXG 93-2021 F13 Criterion 1b:
Are the oversight arrangements structured to avoid potential conflicts of interest?

Table 4.1.2-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.1.2-1 Best practices to avoid potential conflicts of interest.

Best practice in this area:	How this can be assessed:
vTPA owner shall not provide consultancy on their programme.	• The vTPA owner provides evidence of the role of the vTPA owner and confirms it does not have a role in providing consultancy services on these programmes.
The vTPA owner and certification bodies / independent auditor shall not provide any product or services, which could compromise the integrity, confidentiality and/ or implementation of programme.	• The vTPA owner provides evidence that it will not provide any product or services, which could compromise the integrity, confidentiality and/ or implementation of programme. • Agreement between the vTPA and the certification body includes a clause that they shall not provide any product or services, which could compromise the integrity, confidentiality and/ or implementation of programme. • The vTPA owner will carry out checks to ensure compliance with these terms of the agreement.
The vTPA owner shall ensure that the functions of any of its related entities do not affect the implementation of its certification programme.	• The vTPA owner provides evidence that confirm its functions and those of related entities do not compromise implementation of certification programme.
The vTPA owner shall ensure that the certification bodies / independent auditors require all personnel involved with the certification process to sign a contract, which commits them to: • Comply with the rules of the certification, particularly to confidentiality and independence from commercial or personal interests • Declare any issues in relation to personal conflicts of interest.	The agreement between the vTPA owner and the certification body/ independent audit require all personnel involved with the certification process to sign a contract which commits them to: • Comply with the rules of certification, particularly to confidentiality and independence from commercial or personal interests • Declare any issues in relation to personal conflicts of interest.
The vTPA programme shall have procedures/processes in place for declaring and addressing conflicts of interest.	• Procedures/processes for declaring and addressing conflicts of interest are in-place and declaration records are available. • Review any cases of potential conflict of interest cases and how they were handled.
The vTPA programme shall not be developed, managed, or owned by a Certification Body or group of Certification Bodies or by an independent auditor involved in certification.	• The vTPA owner provides evidence that assurance programmes are developed, managed, and owned, in a way that guarantees independence from the certification process.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 1b:** Are the oversight arrangements structured to avoid potential conflicts of interest?				
Fit for Purpose?	Yes		No	
What are the missing elements?				

Additional Information required from vTPA Owner	

4.1.3 ENSURE CONSISTENT AND EFFECTIVE IMPLEMENTATION AND MAINTENANCE

CXG 93-2021 F13 Criterion 1c:
Does the vTPA programme have management controls to ensure consistent and effective implementation and maintenance?

Table 4.1.3-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.1.3-1 Best practice to ensure consistent and effective implementation and maintenance.

Best practice in this area:	How this can be assessed:
The vTPA owner shall regularly collate and compare audit findings from certification bodies / independent auditors to identify 'outliers' (e.g., comparison of audit findings by geographical region, industry sector etc...).	• Processes / procedures are in place to compare audit findings from certification bodies / independent auditors, at a defined frequency. • Records of this comparison taking place are available and show whether any outliers have been identified.
The vTPA owner shall review 'outliers' to determine root cause (e.g., inconsistencies in auditing).	• Records of the investigation of any outliers detected to determine their root cause and any actions taken are available.
The vTPA owner shall provide feedback to certification bodies / independent auditors regarding subjective / ambiguous requirements	• Correspondence to certification bodies / independent auditors regarding subjective/ambiguous requirements are available.
The vTPA owner shall ensure normative documents are reviewed and re-issued as appropriate to remain current and address stakeholders' expectations.	• Processes / procedures are in place for the review of normative documents. • Records of the review, and correspondence with re-issued documents are available.
The vTPA owner shall inform key stakeholders, of any changes to the programme, in particular those changes that are relevant to the recognition status.	• Correspondence with key stakeholders on any changes to the programme is available.
There shall be timely notification and appropriate transition periods to enable members and auditors address changes/amendments to the vTPA programme requirements.	• Processes / procedures specify the notification and transition periods for changes/amendments to the vTPA programme requirements.
vTPA owners shall review auditors, technical reviewers, and other technical staffs' competence and provision of appropriate support materials (e.g., checklists) to ensure consistent approach to audits	• Records of the review of technical competence are available, i.e. qualifications and on-going training programmes. • Appropriate support materials are available (preferably on-line).

Outcome of Assessment of **CXG 93-2021 F13 Criterion 1c:** Does the vTPA programme have management controls to ensure consistent and effective implementation and maintenance?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA Owner				

4.1.4 ACCREDITATION ARRANGEMENT

CXG 93-2021 F13 Criterion 1d:

Does the vTPA programme have an accreditation arrangement with an accreditation body with international standing, recognition and credibility? If not, how does the vTPA owner ensure that certification bodies have the capacity and competency to perform effectively?

There are three different scenarios for this criterion:

- The Certification bodies are **accredited** by an accreditation body.
- **Table 4.1.4-1** outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.
- The Certification bodies are **not accredited** by an accreditation body. The vTPA owner needs to ensure they have the capacity and competency to perform effectively. Additional monitoring by the CA may be required to ensure certification is in accordance with best practice.
- **Table 4.1.4-2** outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.
- Certification is carried out by **independent auditors.** The vTPA owner needs to ensure they have the capacity and competency to perform effectively. Additional monitoring by the CA may be required to ensure certification is in accordance with best practice.
- **Table 4.1.4-3** outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

*4.1.4-1 Best practices regarding the accreditation arrangements for **accredited certification bodies.***

Best practice in this area:	How this can be assessed:
The vTPA owner shall ensure that all activities resulting in the issuing of certificates are delivered by certification bodies accredited by an accreditation body that is a member of the International Accreditation Forum (IAF) and signatories to the Multilateral Recognition Arrangement (MLA) for the appropriate scope. All the IAF MLA signatories demonstrate conformance with ISO / IEC 17011[6].	• This will be specified in policy documents for the vTPA owner. • Appropriate records on accreditation of the certification bodies, and membership of IAF and MLA for accreditation bodies are on-file.
There is a mechanism for the vTPA owner to be informed by the Accreditation Body if an accredited certification body has its accreditation withdrawn or suspended.	• A mechanism for the vTPA owner to be informed by the Accreditation Body if an accredited certification body has its accreditation withdrawn or suspended is in-place. • Correspondence relating to this is available.
The vTPA owner shall define clear scope(s) of accreditation for the Certification Bodies.	• This will be specified in the agreement between the vTPA owner and the certification bodies
The vTPA owner shall ensure that the scope of accreditation of certification bodies shall be publicly available.	• The vTPA owner's website could include a link to the website for the accreditation body showing up-to-date information on accreditation status of certification bodies.

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6   ISO / IEC 17011:2017 Conformity Assessment — Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies

The vTPA owner shall ensure that certification bodies seeking accreditation for the programme shall be accredited within 12 months from the date of application to an accreditation body. In the event that accreditation is not granted within 12 months, the vTPA owner shall ensure that the certification body contract shall be terminated, and potential actions reviewed. In situations where there is a delay, the certification body shall provide a plan to the vTPA owner for approval to achieve accreditation.	• Processes / procedures are in-place for the vTPA owner to assess certification bodies and shall include timeline for achieving accreditation and what is done if this timeline is not achieved. • The agreement between the vTPA owner and the certification body shall include timeline for achieving accreditation and what is done if this timeline is not achieved. Where appropriate, there will be correspondence between vTPA owner and certification body terminating the contract due to non-compliance with this requirement or setting out a plan to deal with a delay in accreditation.

*Table 4.1.4-2 Best practices to ensure **non-accredited certification bodies** have the capacity and competency to perform effectively.*

Best practice in this area:	How this can be assessed:
If accreditation of the certification body is not required by the vTPA programme owner, evidence must be provided to ensure that the certification body has the required capacity and competency to perform effectively, and controls are in place to ensure compliance.	• Processes / procedures are in-place for vTPA owner to assess suitability of a non-accredited certification body. • Records are available of the assessment of capacity, competence, and controls in-place to ensure compliance.
The vTPA owner shall have a process to ensure that certification bodies shall be experienced within the relevant sector, and have a good reputational standing within the country	• Records are available for the assessment done by the vTPA owner to evaluate the experience and reputational standing of the non-accredited certification body.
The vTPA owner shall ensure that certification bodies meet the requirements of the relevant accreditation standard such as ISO 17065 and ISO 17021, see Section 4.2.1.	• Records are available for the assessment done by the vTPA owner to evaluate whether the certification body meets the requirements of the relevant accreditation standard, such as ISO 17065 and ISO 17021

Also note requirements regarding auditor competence in Section 4.4.3.

*Table 4.1.4-3 Accreditation arrangement Best practices to ensure **independent auditors** have the capacity and competency to perform effectively.*

Best practice in this area:	How this can be assessed:
If independent auditors are used by the vTPA owner, evidence must be provided to ensure that they have the capacity and competency to perform effectively, and controls in place for ensuring compliance.	• Processes / procedures in-place for the vTPA owner to assess suitability of an independent auditor. • Records are available of this assessment to verify their capacity, competence and controls in-place to ensure compliance.
Issues regarding liability and insurance should also be addressed.	• The agreement between the vTPA owner and the independent auditor includes a clause on liability and insurance. • Evidence of suitable insurance is on-file.

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The auditor should be experienced within the relevant sector with a good reputational standing within the country and meet key requirements of the relevant accreditation standard regarding qualification and experience such as ISO 17065 and ISO 17021, see Section 4.2.1.	• Records are available on the assessment of the experience and reputational standing of an independent auditor. • Records are available for the assessment done by the vTPA owner to evaluate whether the independent auditor meets the requirements of the relevant accreditation standard, such as ISO 17065 and ISO 17021.

Also note requirements regarding auditor competence in Section 4.4.3.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 1d** Does the vTPA programme have an accreditation arrangement with an accreditation body with international standing, recognition and credibility? If not, how does the vTPA owner ensure that certification bodies have the capacity and competency to perform effectively?						
Select Type of Certification Auditor	Accredited Certification Body		Non-Accredited Certification Body		Independent Auditor	
Fit for Purpose?		Yes		No		
What are the missing elements?						
Additional Information required from vTPA Owner						

4.2 Accreditation of Certification Bodies

Certification bodies are independent organizations that carry out a conformity assessment against specified requirements (or vTPA standard). The certification body will award a certificate to the organization to show that they comply once they have achieved the requirements set out in the standard.

vTPA owners should ensure that all arrangements between the vTPA owner and the certification body are in accordance with

the following:
- Arrangements are clearly defined and documented,
- The certification process is carried out in accordance with relevant standards
- Arrangements are monitored on an on-going basis.
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The vTPA owner should have an independent process to ensure certification bodies have the capacity and competency to perform effectively. Ideally this can be achieved through selecting accredited certification bodies. However, there may be circumstances were vTPA programmes are audited by **non-accredited certification bodies** or **independent auditors**.

The outcome of these audits may still be suitable for consideration by the CA if the vTPA owner has suitable mechanisms in-place to ensure the **non-accredited certification body / independent auditor** has capacity and competency to perform the certification process effectively.

The CA will need to consider what elements needs to be in-place to ensure certification in accordance with best practice outlined in the relevant ISO standards (ISO / IEC 17065 or ISO / IEC 17021 with ISO / TS 220037). The CA also needs to consider the additional risks in utilizing information / data from an audit by a **non-accredited certification body / independent auditor** and how these risks can be controlled through monitoring by the CA.

4.2.1 INDEPENDENT PROCESS

CXG 93-2021 F13 Criterion 2a:
Does the vTPA programme have an independent process to ensure the use of appropriately accredited certification bodies?

There are two different scenarios for this criterion:

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7   ISO / TS 22003-1:2022 Food safety – Part 1: Requirements for bodies providing audit and certification of food safety management systems.

- The use of Certification Bodies that are accredited by an accreditation body.
  Table 4.2.1-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

- The use of Certification bodies or Independent Auditors that are not accredited by an accreditation body. Additional monitoring by the CA may be required to ensure certification is in accordance with best practice.
  Table 4.2.1-2 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

*Table 4.2.1-1 Best practice regarding an independent process to ensure the use of appropriately **accredited certification bodies.***

Best practice in this area:	How this can be assessed:
There shall be a procedure/process for selection of appropriately qualified accredited certification bodies. This process shall include the following steps: • Formation of selection team (multidisciplinary) • Development of evaluation criteria & scoring system • Pre-qualification questionnaire • Issue request for tenders • Initial evaluation • Development of shortlist • Interviews /presentations • Selection of certification body	• The vTPA owner will have processes / procedures in-place for selecting qualified accredited certification bodies. This process will include the following steps: • Formation of selection team (multidisciplinary) • Development of evaluation criteria & scoring system • Pre-qualification questionnaire • Issue request for tenders • Initial evaluation • Development of shortlist • Interviews /presentations • Selection of certification body • Records of how this happens will be available.
The certification body shall demonstrate the following performance and descriptive requirements: • Impartiality • Competence • Responsibility • Openness • Confidentiality • Responsiveness to complaints • Risk-based approach (ISO/IEC 17021-1:2015 (E) – Section 4.1.3)	• Fulfilment of these requirements are demonstrated through accreditation.
The vTPA owner shall have contractual and enforceable arrangements with the accredited certification bodies.	• Contractual and enforceable arrangements are in-place between the vTPA owner and the accredited certification bodies.
The vTPA owner shall ensure that a list of active certification bodies is publicly available without request. This list shall include the scope of activities of the certification bodies and their accreditation status.	• The vTPA owner's website should maintain an up-to-date list of active certification bodies, the scope of their activities, and link to accreditation body's website showing their accreditation status.
The vTPA owner shall ensure that IAF MD4[8] is included as a normative reference for their programme(s).	• IAF MD4 is included as a normative reference for the programmes developed.
The vTPA owner shall require that certification bodies notify them of any withdrawal or suspension of their accreditation.	• The scheme documents or the agreement between the vTPA owner and certification body includes a clause that the certification body shall inform the vTPA owner of any withdrawal or suspension of accreditation.
The vTPA owner shall ensure that certification bodies make the following information available at all times: ☐ Evaluation procedures and certification processes ☐ Details of complaints, appeals and disputes procedures ☐ A comprehensive list of all certified organisations	• The scheme documents or the agreement between the vTPA owner and certification body includes a clause that the certification body shall make the following information available at all times: • Evaluation procedures and certification processes • Details of complaints, appeals and disputes procedures • A comprehensive list of all certified organisations • Copies of this information is available on the vTPA owner's system.

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8   IAF MD 4:2022 – IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes

Best practice in this area:	How this can be assessed:
The vTPA owner shall ensure that certification bodies notify the vTPA owner of changes to ownership, management personnel and management structure or constitution in a timely manner	• The scheme documents or the agreement between the vTPA owner and certification body includes a clause that the certification bodies notify the vTPA owner of any changes to ownership, management personnel and management structure or constitution in a timely manner.
There shall be timely notification and appropriate transition periods to enable members and auditors address changes/amendments to the vTPA programme requirements.	• The scheme documents or the agreement between the vTPA owner and certification body shall specify notification and appropriate transition periods to enable members and auditors address changes/amendments to the vTPA programme requirements.

Table 4.2.1-2 Best practice regarding an independent process to ensure the use of appropriate qualified certification bodies (non- accredited) or independent auditors.

Best practice in this area:	How this can be assessed:
NON-ACCREDITED CERTIFICATION BODIES / INDEPENDENT AUDITORS	
There shall be a procedure/process for selection of appropriately qualified certification bodies. It should include the following steps: • Formation of selection team (multidisciplinary) • Development of evaluation criteria & scoring system • Pre-qualification questionnaire • Issue request for tenders • Initial evaluation • Development of shortlist • Interviews /presentations • Selection of certification body	• The vTPA owner will have processes / procedures in-place for selecting qualified certification bodies. These processes / procedures will include the following steps: • Formation of selection team (multidisciplinary) • Development of evaluation criteria & scoring system • Pre-qualification questionnaire • Issue request for tenders • Initial evaluation • Development of shortlist • Interviews /presentations • Selection of certification body • Records of how this happens will be available.
The certification body / independent auditor shall demonstrate the following performance and descriptive requirements: • Impartiality • Competence • Responsibility • Openness • Confidentiality • Responsiveness to complaints • Risk-based approach ISO/IEC 17021-1:2015 (E) – Section 4.1.3	• Certification bodies (non-accredited) and independent auditors need to provide evidence of how they will comply with these requirements. • The vTPA owner needs to have processes and procedures to evaluate compliance with these requirements.
The vTPA owner shall have contractual and enforceable arrangements with the certification body (non-accredited) or the independent auditor.	• Contractual and enforceable arrangements are in-place between the vTPA owner and the certification body (non-accredited) or the independent auditor.
The vTPA owner shall ensure that a list of active certification bodies / independent auditors for the vTPA programme is publicly available without request. This list shall include the scope of activities of these certification bodies / independent auditors.	• The vTPA owner's website should maintain an up-to-date list of active certification bodies and independent auditors, and the scope of their activities.

Best practice in this area:	How this can be assessed:
NON-ACCREDITED CERTIFICATION BODIES / INDEPENDENT AUDITORS	
The vTPA owner will outline the relevant requirements of ISO / IEC 17065 or ISO / IEC 17021 with ISO / TS 22003	• Relevant requirements, such as those outlined in ISO / IEC 17065 or ISO / IEC 17021 with ISO / TS 22003 are referenced in the contract or in the scheme documents.
The vTPA owner will outline the relevant requirements of IAF MD4	• Relevant requirements, such as those outlined in IAF MD4 are referenced in the contract or in the scheme documents.
The vTPA owner shall ensure that certification body (non-accredited) or independent auditor make the following information available at all times: • Evaluation procedures and certification processes • Details of complaints, appeals and disputes procedures • A comprehensive list of all certified organisations	• The scheme documents or the agreement between the vTPA owner and certification body (non-accredited) or independent auditor includes a clause that the certification body shall make the following information available at all times: • Evaluation procedures and certification processes • Details of complaints, appeals and disputes procedures • A comprehensive list of all certified organisations • Copies of this information is available on the vTPA owner's system.
The vTPA owner shall ensure that certification body (non-accredited) or independent auditor notify the vTPA owner of any changes to ownership, management personnel and management structure or constitution in a timely manner	The scheme documents and / or the agreement between the vTPA owner and certification body (non-accredited) or independent auditor includes a clause that the certification body (non-accredited) or independent auditor notifies the vTPA owner of any changes to ownership, management personnel and management structure or constitution in a timely manner.
There shall be timely notification and appropriate transition periods to enable members and auditors address changes/amendments to the vTPA programme requirements.	The scheme documents and / or the agreement between the vTPA owner and certification body (non-accredited) or independent auditor shall specify notification and appropriate transition periods to enable members and auditors address changes/amendments to the vTPA programme requirements.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 2a:**
Does the vTPA programme have an independent process to ensure the use of appropriately accredited certification bodies?
OR
Does the vTPA programme have an independent process to ensure the use of appropriately qualified certification bodies (non-accredited) or independent auditors?

Select Type of Auditor:	Accredited Certification Body		Non-Accredited Certification Body		Independent Auditor	
Fit for Purpose?			Yes		No	
What are the missing elements?						
Additional Information required from vTPA Owner						

4.2.2 RELEVANT ACCREDITATION STANDARD

CXG 93-2021 F13 Criterion 2b:
Is the certification body accredited for the vTPA programme according to the relevant accreditation standard?

There are two different scenarios for this criterion:

- The use of Certification Bodies that are accredited by an accreditation body.
  Table 4.2.2-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

- The use of Certification bodies or Independent Auditors that are not accredited by an accreditation body. The assessment here will be to determine if certification is carried out in accordance with the relevant international (ISO) standards.
  Table 4.2.2-2 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.2.2-1 Relevant accreditation standard Accreditation of certification bodies to the relevant accreditation standard (accredited certification bodies).

Best practice in this area:	How this can be assessed:
The vTPA programme shall include a certification process based on one of the following standards: ISO / IEC 17065 or ISO / IEC 17021 with ISO / TS 22003	• Evidence is available that the certification process of the vTPA programme is based on the relevant ISO standards.
The vTPA programme owner shall ensure that all activities resulting in the issuing of certificates are delivered by certification bodies accredited by accreditation bodies members of the International Accreditation Forum (IAF) and signatories to the Multilateral Recognition Arrangement (MLA) for the appropriate scope.	• Evidence is available that the certification bodies are accredited, and that this accreditation is by accreditation bodies which are members of IAF and signatories to MLA.

Table 4.2.2-2 Certification in-line with the relevant accreditation standard for non-accredited certified bodies or independent auditors.

Best practice in this area:	How this can be assessed:
The vTPA programme owner shall ensure that all activities resulting in the issuing of certificates are delivered by the certification bodies (non-accredited)/ independent auditor in-line with the requirements of ISO / IEC 17065 or ISO / IEC 17021 with ISO / TS 22003	• Evidence is available that the certification process of the vTPA programme is based on the relevant ISO standards.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 2b:** Is the certification body accredited for the vTPA programme according to the relevant accreditation standard? OR Is the non-accredited certification body / independent auditor carrying out certification in-line with the relevant accreditation standard?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA Owner				

4.2.3 PERIODIC REVIEW

CXG 93-2021 F13 Criterion 2c:
Is the accreditation of certification bodies for the vTPA programme subject to a periodic review and renewal?

There are two different scenarios for this criterion:

- The use of Certification Bodies that are accredited by an accreditation body.
  Table 4.2.3-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

- The use of Certification Bodies or Independent Auditors that are not accredited by an accreditation body. The assessment here will be to determine if the vTPA owner undertakes periodic review of the arrangements with the certification body (non-accredited) or the independent auditor to ensure capacity and competency to perform effectively is maintained.
  Table 4.2.3-2 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

*Table 4.2.3-1 Periodic review Periodic review and renewal of **accredited certification bodies.***

Best practice in this area:	How this can be assessed:
Accreditation of certification bodies shall be subject to renewal	• Accreditation certificates should include dates accreditation awarded / renewed and date accreditation expires.
Accreditation of certification bodies shall be subject to periodic review / surveillance	• Information from the accreditation body should show the frequency of review and surveillance of accreditation.

Table 4.2.3-2 Periodic review and renewal of certification bodies (non-accredited)/ independent auditors.

Best practice in this area:	How this can be assessed:
The vTPA owner will have a mechanism for the on-going review of certification bodies (non-accredited) or independent auditors to ensure capacity and competency to perform effectively is maintained.	• A review mechanism is included in the scheme documents and/or the agreement between the vTPA owner and the certification body (non-accredited) or independent auditor. • A review procedure/process is in-place. • Reports on these reviews are available.
The vTPA owner shall implement a risk-based programme to monitor and regularly review the performance of certification bodies (non-accredited) or independent auditors, and their compliance to the programme's requirements.	• Evidence on how they use a risk-based approach to decide frequency of review of certification bodies (non-accredited) or independent auditors to be provided by the vTPA owner.
The vTPA owner shall implement a risk-based programme of assessments of performance on audit and auditor records.	• Evidence on how they use a risk-based approach to assess performance to be provided by the vTPA owner.
The vTPA owner shall define and monitor Key Performance Indicators (KPIs) for certification bodies (non-accredited) or independent auditors including complaints, results of desktop assessments and office visits. The KPIs shall be communicated to and reviewed with the certification bodies (non-accredited) or independent auditors at least once a year.	• The vTPA owner shall have processes / procedures in-place to define and monitor KPIs for certification bodies. • Records of the review of these KPIs shall be available. • Correspondence between the vTPA owner and the certification body on KPIs, at least once a year, shall be available.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 2c** Is the accreditation of certification bodies for the vTPA programme subject to a periodic review and renewal? OR Is there periodic review and renewal of non-accredited certification bodies / independent auditors by vTPA owners?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA owner				

4.2.4 ACCREDITATION TO THE RELEVANT STANDARD

CXG 93-2021 F13 Criterion 2d:
Does the accreditation body assess the certification body for the vTPA programme using relevant and internationally recognized standards?

This criterion only applied to Certification Bodies that are accredited by an accreditation body.

Table 4.2.4-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.2.4-1 Accreditation to the relevant standard.

Best practice in this area:	How this can be assessed:
The vTPA owner shall ensure accreditation to relevant regional and internationally recognized standards.	• Evidence on how determine accreditation to relevant regional and internationally recognized standards is in-place.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 2d** Does the accreditation body assess the certification body for the vTPA programme using relevant and internationally recognized standards?				
Applicable		Not-Applicable		
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA owner				

4.3 Standard Setting Process

There should be a clearly defined process for developing the vTPA standard, it should include input from all stakeholders with relevant expertise and experience in relation to the sector to which the standard relates, and it should be transparent and open for continuous improvement. The CA can evaluate the process for development of standards used by vTPA owner by examining the criteria in this section.

4.3.1 DEVELOP OWN STANDARDS OR USE NATIONAL OR INTERNATIONAL STANDARDS

CXG 93-2021 F13 Criterion 3a:
Do the vTPA owners set their own standards or utilise national or international standards for assurance?

Table 4.3.1-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.3.1-1 Best practices regarding the development of own standards or the use national or international standards.

Best practice in this area:	How this can be assessed:
Where the vTPA owners set their own standard, they shall be developed in accordance with applicable legislative requirements / best practice.	• The applicable legislative requirements and best practice are referenced in the standards. • The process / procedure for developing standards specifies standards are in accordance with legislative requirements / best practice.
Where the vTPA standard is based on another standard / scheme* (i.e., 'source' standard / programme), the vTPA owner should ensure that: • Due diligence has been undertaken to ensure the 'source' standard / scheme is fit for purpose (e.g., ensures food safety and does not cause any barriers to trade). • The requirements and the conformance criteria of the 'source' standard / programme are appropriate to the scope of the vTPA programme • Procedures/processes are in place to monitor / track changes in the 'source' standard / programme and to amend the vTPA programme, as appropriate	• The process / procedure for developing standards specifies where a source programme is used that it is evaluated for suitability and appropriateness, and include procedures to monitor for changes /updates to ensure the vTPA programme is amended accordingly.

Other standards /schemes include:

- Regional / International / GFSI benchmarked programmes (e.g. BRCGS, IFS, FSSC 22000, SQF, GLOBAL G.A.P.) & other international programmes / standards (e.g. ISO standards)
- National Programmes (e.g. Codes of Practice)
- Sector/industry/value-chain specific programmes

Outcome of Assessment of **CXG 93-2021 F13 Criterion 3a** Do the vTPA owners set their own standards or utilise national or international standards for assurance?				
Develop own standard		Utilise national/ international source standard		
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA owner				

4.3.2 STANDARDS CONSISTENT WITH CODEX OR OTHER RELEVANT INTERNATIONAL STANDARDS AND/OR APPLICABLE NATIONAL REGULATORY REQUIREMENTS

CXG 93-2021 F13 Criterion 3b:
To what extent are the vTPA standards consistent with Codex or other relevant international standards and/or applicable national regulatory requirements?

Table 4.3.2-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.3.2-1 Best practice to ensure vTPA programmes are aligned with codex or other relevant international standards and/ or applicable national regulatory requirements.

Best practice in this area:	How this can be assessed:
The scope of the vTPA standard should clearly outline its relationship with other standards (e.g., Codex, other relevant international standards) & applicable national regulatory requirements	• The standard should include reference to applicable Codex standards and other relevant international standards • The standard should include reference to applicable national regulatory requirements
The vTPA programme should state that "As a minimum meeting all applicable legislative requirements is a mandatory requirement" of the standard.	• The vTPA programme states that "As a minimum meeting all applicable legislative requirements is a mandatory requirement" of the standard.
Horizon scanning of the external environment should be conducted to track changes in the policy environment, other national/international standards, applicable national regulatory requirements. This is essential to future-proof the vTPA programme.	• Processes / procedures in-place to identify and assess the impact of trends and changes/updates in the policy and regulatory environment and in changes to international standards.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 3b** To what extent are the vTPA standards consistent with Codex or other relevant international standards and/or applicable national regulatory requirements?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA owner				

4.3.3 SPECIFIED REQUIREMENTS TO PROTECT CONSUMERS

CXG 93-2021 F13 Criterion 3c:
Do the vTPA standards contain specified requirements to protect consumers in relation to food safety and fair practices in food trade?

Table 4.3.3-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.3.3-1 Best practice to determine if vTPA standards contain specific requirements to protect consumers in relation to food safety and fair practices in food trade.

Best practice in this area:	How this can be assessed:
Any specified requirements to protect consumers in relation to food safety and fair practices in food trade should be based on evidence and risk (the risk analysis paradigm should be at the core of decision making).	• Processes / procedures in-place to ensure all food safety and fair trade requirements of the standard should be based on evidence and risk.
Food safety requirements should be proportionate (i.e., consumer protection is critical; however, unnecessary burdens should not be placed on the FBO)	• Processes / procedures in-place to ensure all food safety requirements are proportionate. • Identify food safety requirements that go beyond national food safety law requirements • Assess potential impacts these may have on FBOs • Record outcomes (keep track of any challenges for FBOs or positive outcomes in support of FBOs activity).
There shall be clear differentiation between mandatory requirements and best practices.	• The standard itself clearly differentiates between mandatory requirements and best practices. • Processes / procedures in-place to develop new standards specifies this requirement for a clear distinction between mandatory requirements and best practice.
The vTPA standard should not create any barrier to food trade	• vTPA standards to be aligned to national or international food safety requirements not to create barriers to trade. • Processes / procedures are in-place to monitor and record cases in which standards created barriers to trade and to update/review standards that cause unnecessary trade restrictions.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 3c:** Do the vTPA standards contain specified requirements to protect consumers in relation to food safety and fair practices in food trade?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA Owner				

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4.3.4 TRANSPARENT CONSULTATIVE PROCESS

CXG 93-2021 F13 Criterion 3d:
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?

Table 4.3.4-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.3.4-1 Best practice in relation to a transparent consultative process.

Best practice in this area:	How this can be assessed:
The vTPA owner shall ensure due consideration to comments received from stakeholders during the consultation.	• Records of consultations outcomes show how inputs and feedbacks are incorporated in the process of developing a vTPA standard.
The vTPA owner shall inform key stakeholders of any changes to the vTPA standard	• Processes / procedures are in-place for communicating changes to vTPA standards to stakeholders. • Correspondence to prove this happens is available.
The vTPA owner shall ensure that stakeholders and other interested parties can make effective contact to clarify any interpretation	• Correspondence channel for clarification of any interpretation is available and clearly communicated to stakeholders and other interested parties.
The vTPA standard shall be developed and maintained in consultation with technically competent representatives of direct stakeholders, and be subjected to formal review	• Processes / procedures are in-place to develop and maintain vTPA standards in consultation with relevant stakeholders and subjected to formal review. • Correspondence with stakeholders is available.
The vTPA standard shall be subjected to extensive stakeholder consultation during its development.	• Processes / procedures are in-place for stakeholder consultation during the development of a vTPA standard. • Records of consultations outcomes and correspondence with key stakeholders are available.
The vTPA programme's normative documents shall be established by consensus and issued using a formalised and documented approval process.	• Processes / procedures are in-place for the establishment and issuing of approved normative documents. • Evidence to prove this happens is available.
Normative documents shall be appropriately controlled, reviewed and publicly available.	• Processes / procedures are in-place for the control, review, and publication of normative documents.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 3d:** 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?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA Owner				

4.3.5 OPEN, TRANSPARENT IN GOVERNANCE AND SUBJECT TO CONTINUOUS IMPROVEMENT

CXG 93-2021 F13 Criterion 3e:
Are the vTPA standards open, transparent in governance and subject to continuous improvement by regular review to keep them up to date?

Table 4.3.4-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.3.5-1 Best practice in relation to openness, transparency and continuous improvement.

Best practice in this area:	How this can be assessed:
A transparent process should be in place to facilitate continuous improvement of the vTPA standard to ensure it: • Aligns with relevant changes in policy / regulatory requirements. • Aligns with relevant changes in the 'source' standard / programme, if appropriate. • Operates optimally, remains fit for purpose, and achieves an acceptable standard of compliance.	• Processes / procedures are in-place to facilitate continuous improvement of the vTPA standard, details of how this is done is available to all stakeholders.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 3e:** Are the vTPA standards open, transparent in governance and subject to continuous improvement by regular review to keep them up to date?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA owner				

4.3.6 SUITABILITY FOR CONFORMITY ASSESSMENT

CXG 93-2021 F13 Criterion 3f:
Are the vTPA standards written in a way that they can be assessed for conformity?

Table 4.3.6-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.3.6-1 Best practice in relation to suitability for conformity assessment.

Best practice in this area:	How this can be assessed:
The specific requirements of the standard should be non-ambiguous to ensure clarity for FBOs and consistency during audit.	• Policy is in-place regarding the use of agreed-upon language, aligned with national / international requirements language. • Guidance is provided where requirements need further explanation. • Areas were clarification is sought are reviewed to consider if an update/change is required.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 3f:** Are the vTPA standards written in a way that they can be assessed for conformity?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA owner				

4.4 Conformity Assessment

Conformity assessment is the process whereby certification bodies (accredited and non-accredited) or independent auditors verify conformity by FBOs with the requirements of the scheme standard, through audits. vTPA owners need to ensure conformity assessment is being carried out using suitable audit methodology, at an appropriate frequency, by auditors with the required competency and using a transparent system.

The CA can assess suitable conformity assessment processes are in-place by using the criteria in this section.

4.4.1 CONFORMITY ASSESSMENT METHODOLOGY

CXG 93-2021 F13 Criterion 4a:
Does the vTPA programme have written procedures on frequency, methodology, announced and unannounced audits and competency requirements for certification bodies (accredited and non-accredited) and independent auditors?

Table 4.4.1-1 outlines best practices in this area to consider to see if the vTPA programme meets this criterion.

Table 4.4.1-1 Best practices regarding written procedures on frequency, methodology, announced and unannounced audits and competency requirements.

Best practice in this area:	How this can be assessed:
AUDIT METHODOLOGY	
The vTPA programme should clearly define the audit methodology required.	• Written procedures on frequency of audits. • Written procedures on audit methodology to be used. • Specification as to whether audits shall be announced or unannounced
Competency requirements are clearly specified.	• Competency requirements are clearly specified in the written procedures, audit checklists.
Comprehensive records of audit findings should be maintained (to include date, name of auditor, scope of audit, audit findings, timescales for rectification)	• Records of audit findings are available.
The vTPA owner shall have a process in place for monitoring the performance of the audits	• Records for monitoring the performance of the audits are available.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 4a:** Does the vTPA programme have written procedures on frequency, methodology, announced and unannounced audits and competency requirements for certification bodies (accredited and non-accredited) and independent auditors?			
Fit for Purpose?	Yes		No
What are the missing elements?			
Additional Information required from vTPA Owner			

4.4.2 CONFORMITY ASSESSMENT ON A REGULAR BASIS

CXG 93-2021 F13 Criterion 4b:
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?

Table 4.4.2-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.4.2-1 Best practices regarding conformity assessment on a regular basis.

Best practice in this area:	How this can be assessed:
The frequency of conformity assessments must be at least once a year.	• Processes / procedures are in-place for audit programming which show that the frequency of assessment is at least once a year, is risk based and considers previous history.
Audit programming should be risk based with minimum frequencies defined and should consider previous history.	

Outcome of Assessment of **CXG 93-2021 F13 Criterion 4b:** 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?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA Owner				

4.4.3 AUDITOR COMPETENCE

CXG 93-2021 F13 Criterion 4c:
Does the vTPA programme have procedures in place to ensure that auditors have and maintain the required auditor competence?

Table 4.4.3-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.4.3-1 Best practices regarding auditor competence.

Best practice in this area:	How this can be assessed:
Competency requirements for auditors, technical reviewers, and staff of certification bodies shall be clearly defined	• Roles, descriptions and qualifications are clearly defined in documented procedures.
Auditors shall be impartial, competent and maintain relevant sector knowledge.	• Roles, descriptions and qualifications are clearly defined in documented procedures. • Training programmes to maintain auditor competence are in-place.
The vTPA owner shall have a process in place for ensuring auditor competence.	• Records from the assessment of auditor competence are available. • Records of training to maintain auditor competence are available.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 4c:** Does the vTPA programme have procedures in place to ensure that auditors have and maintain the required auditor competence?				
Fit for Purpose?	Yes		No	
What are the missing elements?				

Additional Information required from vTPA owner	

4.4.4 CLEARLY IDENTIFY FBOS THAT CONFORM TO THE STANDARD

CXG 93-2021 F13 Criterion 4d:
Does the vTPA programme have a transparent system to identify FBOs that conform to the standard (e.g. certification)?

Table 4.4.4-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.4.4-1 Best practices regarding the identification of FBOs that conform to the standard.

Best practice in this area:	How this can be assessed:
An up-to date list of FBOs conforming to the vTPA standard should be available, preferably on-line.	• The vTPA owner's website should maintain an up-to-date list of FBOs conforming to the vTPA standard

Outcome of Assessment of **CXG 93-2021 F13 Criterion 4d:** Does the vTPA programme have a transparent system to identify FBOs that conform to the standard (e.g. certification)?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA owner				

4.5 Responses to Non-Conformity

Non-conformances detected during conformity assessment need to be addressed in a consistent, effective, transparent way. The vTPA owner shall have a processes in-place for reviewing processes, audit reports, decisions relating to non-conformities, the use of sanctions and any appeals. The CA will review these processes.

4.5.1 DEALING WITH NO-CONFORMITIES, FAILURE TO IMPLEMENT CORRECTIVE ACTION AND APPLYING SANCTIONS

CXG 93-2021 F13 Criterion 5a:
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?

Table 4.5.1-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.5.1-1 Best practices for dealing with non-conformities, failure to implement corrective actions and applying sanctions.

Best practice in this area:	How this can be assessed:
Conformance Criteria: Each requirement should be differentiated based on risk (e.g., critical criteria where conformance is mandatory for certification; general criteria where partial conformance is possible for certification; requirements for best practice where compliance is not mandatory for certification)	• The standard itself should clearly show critical criteria where conformance is mandatory for certification; general criteria where partial conformance is possible for certification; requirements for best practice where compliance is not mandatory for certification. • Documented procedures, checklist etc for the certification body should align with the categorisation of criteria in the standard.

Best practice in this area:	How this can be assessed:
Audited Scoring/Assessment: A scoring system/ assessment criteria should be provided for each conformance criteria, as applicable (i.e., for full conformance, major non-conformance; partial non-conformance).	• Processes / procedures from the certification body should detail the scoring system and conformance criteria being used.
Corrective actions shall be specified for each non-conformance and should be based on the risk posed by non-compliance.	• Processes / procedures from the certification body should detail the specific corrective actions that are to be taken for each non-conformance, and these should be based on risk.
There shall be a procedure/process for dealing with repeat non-conformities.	• Processes / procedures from the certification body will include information on how repeat non-conformities are dealt with.
There shall be a procedure/process for dealing with failure to rectify non-conformities.	• Processes / procedures from the certification body will include action to be taken when the FBO fails to rectify nonconformities. • Audit reports will include a timeline for addressing non-conformities.
There shall be a procedure/process for verifying corrective action.	• Processes / procedures from the certification body will specify how and when corrective actions are verified. • Records will show this process is in-place.
There shall be a defined process/procedure for the application of sanctions.	• Processes / procedures from the certification body will specify how and when sanctions are applied. • Records will show this process is in-place.
The vTPA owner should have a procedure/process for when certification should be withheld or suspended and circumstances in which it might be re-instated.	• The scheme documents or the agreement between the vTPA owner and the certification body will specify when certification should be withheld or suspended and circumstances in which it might be re-instated. • Processes / procedures from the certification body will specify when certification should be withheld or suspended and circumstances in which it might be re-instated.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 5a:** 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?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA owner				

4.5.2 REVIEW OF AUDITS

CXG 93-2021 F13 Criterion 5b:
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?

Table 4.5.2-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.5.2-1 Best practice regarding review of audit reports, decisions relating to non-conformities, and potential use of sanctions, and appeals.

Best practice in this area:	How this can be assessed:
The vTPA owner shall specify the requirements on the governance of audit findings (including decisions relating to non-conformities, use of sanctions, procedure for appeal).	• Requirements have been specified to the certification bodies.
The vTPA owner shall have requirements for the certification body (accredited/ non-accredited) / independent auditor to have a process for reviewing audit reports, decisions relating to non-conformities, use of sanctions, and appeals.	• Evidence of this requirement is available.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 5b:** 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?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA owner				

4.6 Data Sharing and Information Exchange

The vTPA owner should be aware of national privacy/data protection rules (either in-force or in-draft / development), should have a procedure/process in place for monitoring/tracking changes to national privacy/data protection rules (including any guidance/recommendations from government) and should update the vTPA programme based on these changes.

The CA should assess if the vTPA owner has the necessary permissions and processes/procedures in-place to share information / data regarding FBO certification with the CA in a secure manner.

4.6.1 LIST OF PARTICIPATING FBOS

CXG 93-2021 F13 Criterion 6a:
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?

Table 4.6.1-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.6.1-1 Best practices regarding listing participating FBOs.

Best practice in this area:	How this can be assessed:
The vTPA owner can provide an up-to date list of participating FBOs, including their status	• Records listing current FBOs participants and their status is provided by the vTPA owner.
The list should be available to the public, through a publicly accessible database.	• List is available to the public, preferably on vTPA owner's website.
Procedure/process for updating this list (e.g., timeframe for adding new members, delisting of members that leave the programme, dealing with members that are suspended or withdrawn from the programme)	• Processes / procedures for updating the list of FBO participants is in-place, and includes timeframe for adding new members, delisting of members that leave the programme, dealing with members that are suspended or withdrawn from the programme

Outcome of Assessment of CXG 93-2021 F13 Criterion 6a: 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?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA owner				

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4.6.2 NOTIFICATION OF THE CA WHEN SIGNIFICANT RISK DETECTED

CXG 93-2021 F13 Criterion 6b:
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?

Table 4.6.2-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.6.2-1 Best practice regarding communication of significant risk to public health or consumer deception to the Competent Authority.

Best practice in this area:	How this can be assessed:
The vTPA owner have a robust mechanism in place to ensure that the CA is informed of any 'significant risk to public health' or 'consumer deception' (directly from FBO to CA or indirectly via certification body as appropriate depending on national legislation).	• The vTPA owner has a robust mechanism to ensure the CA is informed of any 'significant risk to public health' or 'consumer deception' (either directly from FBO to CA or indirectly via certification body as appropriate depending on national legislation).
The vTPA owner's definition of 'significant risk to public health' & 'consumer deception', where there is a significant food safety risk, should align with the CA.	• Processes / procedures relating to the mechanism for informing the CA must define what is meant by each type of significant risk to public health and consumer deception and must ensure these align with CA definitions.
Data sharing is subject to privacy and confidence agreements and permission from the involved parties	• Evidence of privacy and confidence agreements and permission from the involved parties is available.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 6b:** 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?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA owner				

4.6.3 PERMISSION TO SHARE FBO INFORMATION / DATA WITH CAS

CXG 93-2021 F13 Criterion 6c:
Does the vTPA owner have permission to share FBO information / data with competent authorities and is this in accordance with national data protection obligations?

Table 4.6.3-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.6.3-1 Permission to share FBO information / data with CAsBest practice regarding permission to share FBO information / data with the Competent Authority.

Best practice in this area:	How this can be assessed:
There shall be a process for acquiring permission from FBOs and the certification bodies / independent auditors to share FBO information / data with competent authorities.	• Evidence of agreements regarding permission from the involved parties is available.
The vTPA owner shall define the types of information to be shared with the CA and how it will be used.	• The scheme documents and/ or the agreement between the vTPA owner and the FBOs and the certification bodies / independent auditors will specify types of information they propose to share with the CA.
Data sharing is subject to privacy and confidence agreements and in accordance with national data protection obligations.	• Evidence of agreements regarding privacy and confidentiality are is available.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 6c** Does the vTPA owner have permission to share FBO information / data with competent authorities and is this in accordance with national data protection obligations?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA owner				

4.6.4 NOTIFICATION OF THE CA OF FBOS THAT CEASE TO PARTICIPATE

CXG 93-2021 F13 Criterion 6d:
Does the vTPA owner inform competent authority of any FBO that ceases to participate either directly or via a web-accessible platform?

Table 4.6.4-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.6.4-1 Best practices for notification of the Competent Authority of FBOs that cease to participate in the programme.

Best practice in this area:	How this can be assessed:
There shall be a process for notifying the competent authority of FBO that ceases to participate either directly or via a web-accessible platform.	• The scheme documents and/or the agreement between the vTPA owner and CA shall outline the process for notifying the CA of any FBO that ceases to participate • Evidence of these notifications will be available.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 6d:** Does the vTPA owner inform competent authority of any FBO that ceases to participate either directly or via a web-accessible platform?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA owner				

4.6.5 NOTIFICATION OF THE CA OF ANY CHANGES TO THE PROGRAMME

CXG 93-2021 F13 Criterion 6e:
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?

Table 4.6.5-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.6.5-1 Best practices for notification of the Competent Authority of any changes to the programme.

Best practice in this area:	How this can be assessed:
There shall be a process for notifying 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	• The scheme documents and/or the agreement between the vTPA owner and CA shall outline the process for notifying the CA of any changes. • Evidence of these notifications will be available..

Outcome of Assessment of **CXG 93-2021 F13 Criterion 6e:** 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?					
Fit for Purpose?	Yes		No		
What are the missing elements?					
Additional Information required from vTPA owner					

4.6.6 SHARING INFORMATION WITH THE CA REGARDING CONFORMITY WITH THE STANDARD

CXG 93-2021 F13 Criterion 6f:
Does the vTPA owner share information / data relating to conformity with the standard where the standard aligns with regulatory requirements to inform the NFCS?

Table 4.6.6-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.6.6-1 Best practices for sharing information with the Competent Authority regarding conformity with the standard.

Best practice in this area:	How this can be assessed:
There shall be a process for sharing information / data relating to conformity with the standard where the standard aligns with regulatory requirements to inform the NFCS.	• The scheme documents or the agreement between the vTPA owner and CA shall outline the process for information sharing.
The vTPA owner shall define the types of information to be shared with the CA.	• The scheme documents or the agreement between the vTPA owner and the CA will specify types of information they propose to share with the CA.
There shall be defined timeliness of information sharing	• The scheme documents or the agreement between the vTPA owner and CA shall specify the timelines for information sharing.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 6f:** Does the vTPA owner share information / data relating to conformity with the standard where the standard aligns with regulatory requirements to inform the NFCS?					
Fit for Purpose?	Yes		No		

What are the missing elements?	
Additional Information required from vTPA owner	

4.6.7 DATA SECURITY

CXG 93-2021 F13 Criterion 6g:
If the data available is in electronic form are there adequate arrangements for maintaining the security of the data?

Table 4.6.7-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.6.7-1 Best practices for maintaining security of the data.

Best practice in this area:	How this can be assessed:
Security of electronic data must be ensured using best practice	• Processes / procedures based on industry best practice are in-place to ensure security of electronic data.

Outcome of Assessment of **CXG 93-2021 F13 Criterion 6g:** If the data available is in electronic form are there adequate arrangements for maintaining the security of the data?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA owner				

4.6.8 INFORMATION RETENTION ARRANGEMENTS

CXG 93-2021 F13 Criterion 6h:
Does the vTPA owner have a protocol in place for information / data retention?

Table 4.6.8-1 outlines best practices in this area to consider to determine if the vTPA programme meets this criterion.

Table 4.6.8-1 Best practices regarding information / data retention.

Best practice in this area:	How this can be assessed:
Data retention periods must meet legislative requirements, or where these do not exist, they must be determined by the vTPA programme (e.g., based on shelf-life of the product)	• Processes / procedures for data retention are aligned with national legislative requirements, or where these do not exist, they must be determined by the vTPA programme (e.g., based on shelf-life of the product)

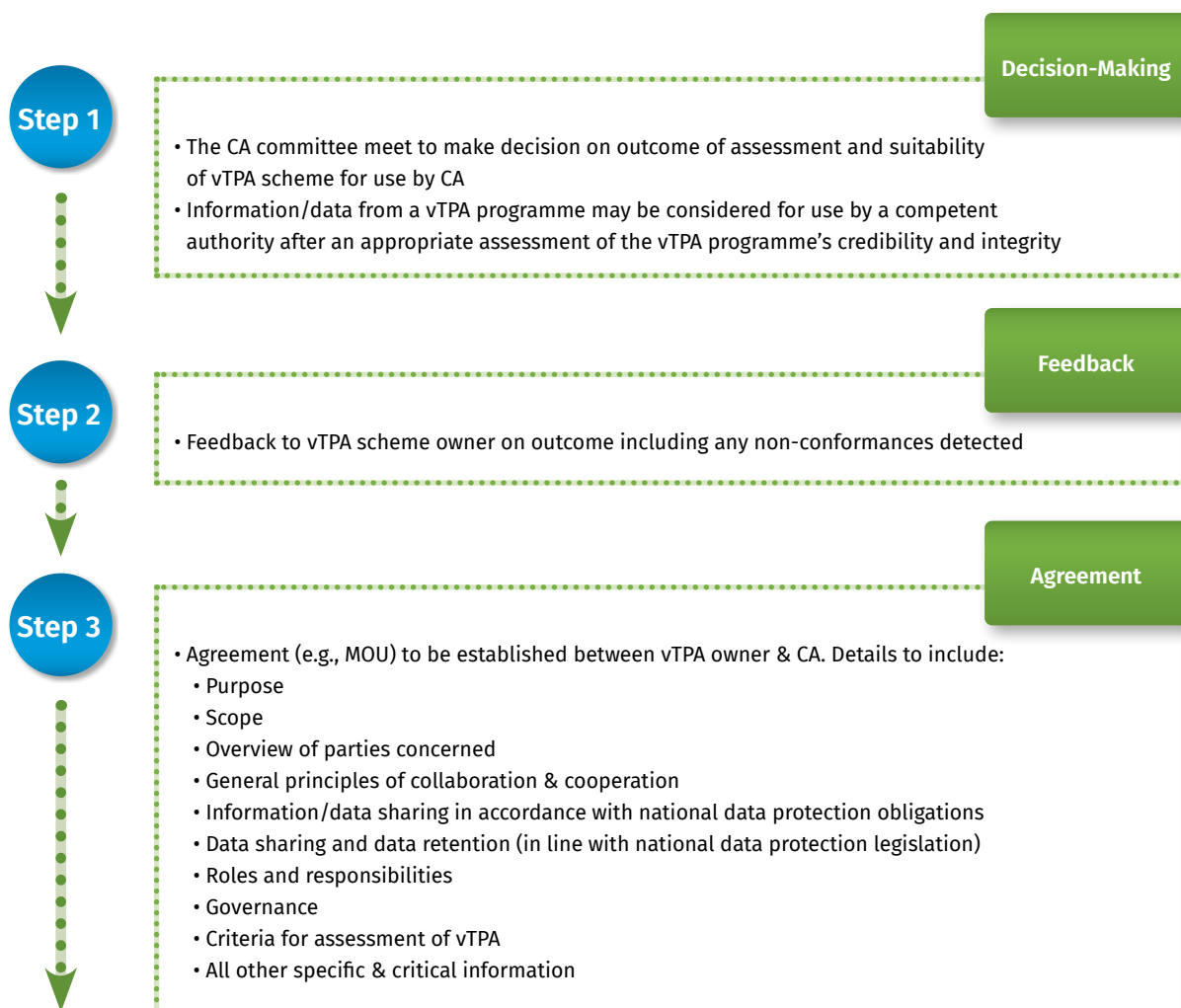| Outcome of Assessment of **CXG 93-2021 F13 Criterion 6h:** Does the vTPA owner have a protocol in place for information / data retention?				
Fit for Purpose?	Yes		No	
What are the missing elements?				
Additional Information required from vTPA owner				

4.7 Assessment conclusion

The findings of the assessment are compiled and presented to the CA committee to decide the outcome of the evaluation as outlined in Section 5.1. The vTPA owner will be given an opportunity to address any of the missing elements identified and if both parties are happy to proceed an agreement is prepared.

5. Regulatory Approaches Post Assessment

5.1 Post Assessment

Figure 5.1-1 outlines the process for process and policy considerations for developing an agreement between the CA and the vTPA owner and for the on-going monitoring of this agreement.

Figure 5.1-1 Policy considerations for developing an agreement between the CA and the vTPA owner.

Step 1 — Decision-Making
- The CA committee meet to make decision on outcome of assessment and suitability of vTPA scheme for use by CA
- 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

Step 2 — Feedback
- Feedback to vTPA scheme owner on outcome including any non-conformances detected

Step 3 — Agreement
- Agreement (e.g., MOU) to be established between vTPA owner & CA. Details to include:
  - Purpose
  - Scope
  - Overview of parties concerned
  - General principles of collaboration & cooperation
  - Information/data sharing in accordance with national data protection obligations
  - Data sharing and data retention (in line with national data protection legislation)
  - Roles and responsibilities
  - Governance
  - Criteria for assessment of vTPA
  - All other specific & critical information

Step 4

- 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.
  - Sharing of relevant information / data
  - Timeliness of data transfer
  - Mechanism of transfer
  - Data types / File formats
  - Security and storage
  - Data protection / confidentiality
  - Handling non-conformities
  - Criteria for notification of non-conformities
  - Timeliness of information sharing
  - Key personnel to be informed
  - Process for handling findings

Step 5

- Competent authorities should have transparent procedures to verify the reliability of the vTPA programme information/data that they intend to use. Data to be verified include:
  - Audits
  - Inspections
  - Comparison with regulatory audit data
  - Analysis of routine information/data
- 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.

Step 6

- Competent authorities may choose to set up regular meetings, or other communication channels, with the vTPA owner in order to analyze the information/data shared to look for trends. The competent authority may consider the need for any intervention. This may include
  - Trend analysis
  - Quantitative / qualitative analysis
  - Intervention to be taken when trend 'approaches unsatisfactory'
  - Types of intervention (focused inspections, targeted sampling and testing, or national training/ information programs where the vTPA programme information/data helps identify a systemic issue)
  - Approach for documentation in relevant policy & legislative documents (to ensure legal basis)
- Competent authorities may compare relevant regulatory audit data with that generated by the vTPA audits to verify consistency and reliability.
- 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.
- Where competent authorities choose not to enter into an arrangement with the vTPA owner they may access the information/data directly from the FBO.
- 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. These include:
  - Identification of relevant data to support data driven prioritization of official controls

5.2 Process Steps to be Considered Post Assessment

Assuming a favourable outcome from the assessment process outlined in Section 4, the CA needs to consider the following process considerations and develop processes and procedures in these areas.

1. The CA now needs to identify the relevant information / data it would like to receive from the vTPA owner.

The CA has established the credibility and integrity of the vTPA programme information / data through the assessment process **(CXG 93-2021 G14 Process Consideration 1a).** This assessment focuses on the criteria commensurate with their intended use of vTPA programme information / data **(CXG 93-2021 G14 Process Consideration 1b). 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 (CXG 93-2021 G14 Process Consideration 1j).**

2. The CA establishes an agreement between the CA and the vTPA owner, such as a Memorandum of Understanding (MoU); other agreement mechanism may also be considered, such as Letter of Agreement (LoU), Implementation Letter (IL).

This arrangement with the vTPA owner is by mutual consent (CXG 93-2021 G14 Process Consideration 1c). Where competent authorities choose not to enter into an arrangement with the vTPA owner they may access the information / data directly from the FBO (CXG 93-2021 G14 Process Consideration 1i).

3. Mechanisms are established to allow for data sharing, and for handling findings of non-conformities, including alerting the competent authority of any significant public health risk or consumer deception (CXG 93-2021 G14 Process Consideration 1d) subject to national privacy legislation.

4. The CA will develop transparent procedures to verify the reliability of the vTPA programme information / data that they intend to use. (CXG 93-2021 G14 Process Consideration 1e).

5. The CA will carry out analysis of the data and compare to regulatory audit data from the NFCS to verify consistency and reliability (CXG 93-2021 G14 Process Consideration 1g).

6. The CA has communication mechanisms with the vTPA owner to discuss any trends identified through analysis of the data, and to consider any interventions needed (CXG 93-2021 G14 Process Consideration 1f). There will be a mechanism for sharing routine information that demonstrates the vTPA programme is operating in-line with its agreed governance (CXG 93-2021 G14 Process Consideration 1h).

5.3 Policy Options to be Considered for Regulatory Programming

This section outlines examples of some of the policy considerations the CA can consider when designing a vTPA assessment process. The approach the CA chooses to take should be documented and checked against relevant policy and legislative documents to ensure legal basis for the process.

5.3.1 WHEN DESIGNING THE ASSESSMENT PROCESS

1. The CA may consider comparing the vTPA standards with relevant international standards and/or national regulatory requirements in relation to food safety and fair practices in food trade ((CXG 93-2021 G14 Policy Option 2a).

2. Some vTPA standards will go beyond regulatory requirements, the assessment by the CA needs to focus on the relevant regulatory requirements that protect the health of consumers in relation to food safety and ensuring fair practices in food trade (CXG 93-2021 G14 Policy Option 2b). The competent authority should identify the information / data from the vTPA programme audits that are of most value to support its NFCS objectives (CXG93-2021 G14 Process Consideration 1j) and the assessment process will then focus on credibility and integrity of these requirements.

3. The suitability and extent to which CAs use vTPA programme information / date will be determined by the depth of the assessment carried out (CXG 93-2021 G14 Policy Option 2e).

5.3.2 WHEN ESTABLISHING DATA SHARING ARRANGEMENTS WITH VTPA OWNERS

1. The CA may compare conformity data with the vTPA programme with their official compliance information / data to verify reliability of the information / data (CXG 93-2021 G14 Policy Option 2c).

5.3.3 WHEN USING VTPA DATA TO SUPPORT OFFICIAL CONTROLS

1. The CA may compare conformity data with the vTPA programme with their official compliance information / data to verify reliability of the information / data (CXG 93-2021 G14 Policy Option 2c).

2. 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 (CXG 93-2021 G14 Policy Option 2d).

3. The suitability and extent to which CAs use vTPA programme information / data will be determined by the depth of the assessment carried out (CXG 93-2021 G14 Policy Option 2e).

4. Participation in a vTPA programme can be taken into consideration when risk profiling the business. Information / data generated by the vTPA programme and FBO certification status may be used by the CA to determine the food safety or consumer deception risks associated with the participating FBOs. This can then be used to inform NCFS planning, to adjust frequency or intensity of regulatory oversight, and hence, help prioritise resources to higher risk areas (CXG 93-2021 G14 Policy Option 2f).

5. 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 programmes where the vTPA programme information / data helps identify a systemic issue (CXG 93-2021 G14 Policy Option 2g).

6. Appendices

6.1 Template: Email to vTPA Owner

Dear vTPA Owner,

As the representative of the vTPA assessment committee for <insert name of Regulatory authority>, I am contacting you regarding the vTPA programme <insert name of programme>. We propose to conduct an assessment of this programme to determine if compliance with this programme achieves some or all of the Regulatory requirements as per <insert legislation>.

If the programme is deemed suitable, we can enter into an agreement with you to receive information which will allow the competent authority to take account of participation in this quality assurance programme in determining the necessary official controls that need to be carried out as part of the national food control system.

This assessment involves the following stages:
> Stage 1- document review
> Stage 2 verification via interview and questions onsite or virtually.

Can you confirm that you are happy for this assessment to proceed?

Also, can you advise us if you have already been assessed by any other regulatory authorities in another jurisdiction for this programme?

Please respond to this email address <insert email address> within 28 days if you are happy to proceed or if you require further information.

Regards,
<insert signature>
Representative of the vTPA Assessment Committee

6.2 Template: Initial Agreement

Initial Agreement

This Initial Agreement (the "Agreement") is entered into by and between: -

_____ (vTPA Owner)

Herein referred to as 'The Disclosing Party' and

_____

Competent Authority, herein after referred to as 'The Receiving Party'. The Receiving Party shall treat the details and contents of all received documents as private and confidential.

The Agreement has been prepared for the purpose of preventing the unauthorized disclosure of Confidential and Sensitive Information as defined below.

The parties agree to enter into a confidential relationship with respect to the disclosure of certain proprietary and confidential information that will be shared with the Receiving Party (herein referred to as "Confidential Information").

Definition and Control of Confidential Information:

For purposes of this Agreement, "Confidential Information" shall include all information or material that has or could have confidential, technical, and commercial value or other utility in the business in which Disclosing Party is engaged.

> a) Where the Confidential Information is in written form, including sketches drawings, reports, specifications, digital and paper information, illustrations etc....
>
> b) Any Confidential Information that is transmitted orally by the Disclosing Party or any other party shall be treated confidentially and controlled as other written confidential communication.
>
> c) Where any Confidential Information is communicated via electronic means the Recipient will transfer such information to a 'safe storage' facility, and shall remove, by means of electronic shredding, the confidential information held on intermediate storage devices. (i.e., laptops computers hard drives etc)

Exclusions from Confidential Information.
The Receiving Party's obligations under this Agreement do not extend to information that is:
> a) Publicly known at the time of disclosure or subsequently becomes publicly known through no fault of the Receiving Party;
> b) Discovered or created by the Receiving Party before disclosure by Disclosing Party;
> c) Learned by the Receiving Party through legitimate means other than from the Disclosing Party or the Disclosing Party's representatives; or
> d) Is disclosed by Receiving Party with Disclosing Party's prior written approval.

Obligations of Receiving Party.
Under the provision of this Agreement the Receiving Party shall be required and shall agree to hold and maintain the Confidential Information in strictest confidence for the sole and exclusive benefit of the Disclosing Party.

The Receiving Party shall carefully restrict access to Confidential Information to employees, contractors and third parties as is reasonably required and shall require those persons to sign nondisclosure restrictions at least as protective as those in this Agreement.

The Receiving Party shall not, without prior written approval of Disclosing Party, use for Receiving Party's own benefit, publish, copy, or otherwise disclose to others, or permit the use by others for their benefit or to the detriment of Disclosing Party, any Confidential Information.

The Receiving Party shall return to Disclosing Party any and all records, notes, and other written, printed, or tangi-

ble materials in its possession pertaining to Confidential Information immediately if Disclosing Party requests it in writing.

The Receiving Party shall agree and indemnify the Disclosing Party against any damages due to direct or indirect communication and approach to the Disclosing Party's clients / owners of the projects. The Receiving Party shall guarantee to refrain all communication to/ through the Disclosing Party only.

Time Periods.
The non-disclosure provisions and conditions incorporated into this Agreement shall survive the termination of this Agreement and Receiving Party's duty to hold Confidential Information in confidence shall remain in effect until the Confidential Information no longer qualifies as a trade secret or until Disclosing Party sends Receiving Party written notice releasing Receiving Party from this Agreement, whichever occurs first.

Severability.
If a court finds any provision of this Agreement invalid or unenforceable, the remainder of this Agreement shall be interpreted to the best effect of the intent of the parties.

Litigation and Dispute Resolution
The content and guidelines of this initial agreement shall be subject to the laws of <insert country of jurisdiction>. Any litigation or dispute resolution shall follow the procedures of the local courts in <insert country of jurisdiction>.

Integration.
This Agreement expresses the complete understanding of the parties with respect to the subject matter and supersedes all prior proposals, agreements, representations, and understandings.
This Agreement may not be amended except in a writing signed by both parties.

Waiver.
The failure to exercise any right provided in this Agreement shall not be a waiver of prior or subsequent rights.
This Agreement and each party's obligations shall be binding on the representatives, assigns and successors of such party.

Each party has signed this Agreement through its duly authorized representative.

Disclosing Party

_____ (Signature)

_____ (Typed or Printed Name)

Date: _____

Receiving Party

_____ (Signature)

_____ (Typed or Printed Name)

Date: _____

6.3 Template: Feasibility Study Report

INITIAL vTPA PROGRAMME FEASIBILITY STUDY REPORT

Name: <Insert name of vTPA Owner>

An initial agreement was signed with <insert name of vTPA owner> on <insert date> to share documents regarding the programme. The purpose of the initial agreement is to enable the vTPA assessment committee to conduct a feasibility study of the programme <insert name of programme> to determine if compliance with this programme achieves some or all of the Regulatory requirements as per <insert legislation>.

This assessment involved the following stages:
•   Stage 1 - document review
•   Stage 2 - verification via interview and questions onsite or virtually

After the document review, we identified the following non-conformances and discrepancies:

_____

_____

_____

_____

_____

We contacted the <insert name of vTPA owner> for clarifications regarding the above non-conformances and discrepancies via interview questions onsite and virtually.

The vTPA assessment committee is satisfied with the explanations given/corrections made/corrective actions raised and will conduct an in-depth assessment as per the vTPA Assessment Tool.

Signed

_____ (Signature)

_____ (Typed or Printed Name)

Date: _____

6.4 Template: Feedback Email to vTPA Owner

Dear vTPA Owner,

As the representative of the vTPA assessment committee for <insert name of Regulatory authority>, we contacted you regarding the vTPA programme <insert name of programme>. We proposed to conduct an feasibility study on this programme to determine if compliance with this programme achieves some or all of the Regulatory requirements as per <insert legislation>.

The programme has been deemed suitable for assessment; we would therefore like to enter into an agreement with you to receive information which will allow the competent authority to take account of participation to determine the necessary official controls that need to be carried out as part of the national food control system.

Can you confirm that you are happy for us to proceed?

The vTPA committee will conduct an in-depth assessment per our Assessment Tool and we will revert with the outcome of the assessment.

Please respond to this email address <insert email address> within 28 days if you are happy to proceed or if you require further information.

Regards,

<insert signature>

Representative of the vTPA Assessment Committee

UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION