

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda item 6

CX/FICS 18/24/6 Add.1
October 2018

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

Twenty-fourth Session

Brisbane, Australia, 22 - 26 October 2018

PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE ASSESSMENT AND USE OF VOLUNTARY THIRD-PARTY ASSURANCE PROGRAMME

Comments at Step 3 (Replies to CL 2018/53/OCS-CCFICS)

Comments of Colombia, Ecuador, Egypt, Guyana, Indonesia, Jamaica, Japan, New Zealand, Norway, Philippines, USA and IUFOST

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2017/53/OCS-CCFICS issued in August 2018 with a deadline for submission of comments of 28 September 2018.

Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby attached as **Annex I** and are presented in table format.

E

ANNEX I

COMMENTS ON THE PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE ASSESSMENT AND USE OF VOLUNTARY THIRD-PARTY ASSURANCE PROGRAMME"

Comments at Step 3 (Replies to CL 2018/53-FICS/OCS-FICS)

General Comment)	Member/Observer and Rationale where applicable
<p>Colombia supports advancing the document at Step 3 as presented, considering that the purpose of the guidance is to help competent authorities in decision-making, with information or data supplied by third parties, thus promoting a regulatory surveillance approach to supplement and support the National Food Control System planning.</p> <p>In addition, there is a global trend that consists of generating regulatory changes to take into account such new schemes, providing an alternative standard solution to meet users' needs to obtain certification.</p>	Colombia
<p>Over the last few years, Ecuador has worked with a view to developing a regionally recognized accreditation system and to become a reference point for accreditation and conformity assessment that can be trusted by local authorities, national and international markets and society at large, facilitating trade by means of conformity assessment results global acceptance agreements. In this regard, both the state and the companies that are part of the abovementioned system have made efforts to attain that goal. Therefore, Ecuador supports the initiative presented by the United Kingdom, Canada and Mexico and considers that the document is generally well structured. Ecuador thus agrees with the initiative to develop a proposed draft that defines the principles and guidelines for the evaluation and use of voluntary third-party assurance programmes, and supports advancing the proposed draft to the next step.</p>	Ecuador
<p>PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE ASSESSMENT AND USE OF VOLUNTARY THIRD-PARTY ASSURANCE PROGRAMMES</p>	<p>Egypt Egypt approves the proposed draft principles and guidelines for the assessment and use of voluntary third-party assurance programmes to be submitted (at step 3) with no comments</p>
<p>Guyana agrees with the contents of this document.</p>	Guyana
<p>Indonesia would like to express our appreciation and thanks for great efforts done by the United Kingdom, Canada and Mexico for preparing a Proposed Draft Principles and Guidelines for The Assessment and Use Of Voluntary Third-Party Assurance Programmes</p>	Indonesia
<p>The document went through a series of changes before arriving at this present stage. Jamaica, support the advancement of this proposed draft, however, emphases</p>	Jamaica

the need for work to be done to strengthen the participation and recognition of the Competent Authority in vTPA programmes.	
In order to facilitate better understanding of the document, we propose to develop practical examples on the use of the vTPA form experienced countries as a Codex information document.	Japan
New Zealand supports the development and progress of this work and has welcomed the opportunity to be an active participant if both the electronic and physical working groups lead by the United Kingdom and co-chaired by Canada and Mexico.	New Zealand
The Philippines would like to congratulate the electronic working group chaired by United Kingdom and co-chaired by Canada and Mexico in coming up with the document that will assist countries in formally recognizing vTPA schemes. We acknowledge the importance and supporting role of vTPA in achieving NFCS objectives, thus, we highly support the deliberation of the document through the Codex process. However, we cannot endorse the advancement of the document to Step 5 as it still needs to undergo revisions to ensure clarity and consistency in the document.	Philippines
IUFoST strongly supports this proposed draft. Assuring acceptable food quality and safety of all marketed foods can be greatly aided by interaction between competent authorities and the food industry at all levels. Systems to assure that raw materials and finished products as marketed meet all regulatory requirements are critical to the food industry and to all consumers. In addition to voluntary programs, legislative requirements such as prohibiting false guarantees, as exist in the USA FD&C Act could also be considered as this type of requirement promotes better attention to assuring that all food quality and safety requirements are met.	IUFOST
PREAMBLE	
A: PREAMBLE	New Zealand There is a degree of repetition in the Preamble particularly in paras 3 and 4. New Zealand suggest that the Preamble would benefit from a further edit once the entire text has been reviewed.
1. Food business operators (FBOs) have the primary role and responsibility for managing the food safety of their products and for complying with regulatory requirements relating to those aspects of food under their control. Competent Authorities require FBOs to demonstrate that they have effective controls and procedures in place to protect the health of consumers and ensure fair practices in food trade. As a result, many Many FBOs use quality assurance systems, including voluntary third-party assurance (vTPA) programmes to reduce supply chain risks and confirm help assure food safety outcomes.	New Zealand The last sentence is not a consequence of the preceding sentence. New Zealand therefore suggest that the words 'As a result' are deleted and the word 'confirm' should be replaced with 'help assure'.
2. The Codex Principles and Guidelines for National Food Control Systems (NFCS) (CAC/GL 82-2013) ¹ foresee competent authorities taking into account quality assurance systems in their national food control system. However, before	Norway

<p>competent authorities can take account of vTPA programmes they should satisfy themselves that any information/data they intend to use is both reliable and fit for purpose.</p>	<p>Regarding the sentence starting "However, before competent authorities...This sentence could be deleted here, as this is taken up under 12b.</p>
<p>3. These guidelines are intended to assist competent authorities in their consideration of vTPA programmes, specifically whether the information/data they generate is reliable and supportive of NFCS objectives. The focus of the guidelines is to assist vTPA programmes that are accredited, and have audit and certification arrangements independent of the programme owner. The guidelines also seek to raise awareness and understanding of the potential value and contribution vTPA programmes can make to NFCS objectives by illustrating the role it plays in helping FBOs demonstrate compliance.</p>	<p>Jamaica <i>EDITORIAL</i></p>
<p>3. These guidelines are intended to assist competent authorities in their consideration of vTPA programmes, specifically whether the information/data they generate is reliable and supportive of NFCS objectives. The focus of the guidelines is vTPA programmes that are accredited, and have audit and certification arrangements independent of criteria for assessing the programme owner. The guidelines also seek to raise awareness integrity and understanding credibility of the potential value governance structures and contribution vTPA the reliability of information/data generated by such programmes can make to support NFCS objectives-objectives. When carrying out such an assessment, competent authorities should be guided by illustrating their intended use of the role it plays in helping FBOs demonstrate compliance. vTPA programme information and should only apply assessment criteria that are relevant to that purpose.</p>	<p>New Zealand There is a degree of repetition in the Preamble particularly in paras 3 and 4, New Zealand also don't consider the last sentence of para 3 is appropriate in a Codex guideline. We suggest a significant rework of both. Para 3 These guidelines are intended to assist competent authorities in the consideration of vTPA programmes and provide a framework and criteria for assessing the integrity and credibility of governance structures and the reliability of information/data generated by such programmes to support NFCS objectives. When carrying out such an assessment, competent authorities should be guided by their intended use of the vTPA programme information and should only apply assessment criteria that are relevant to that purpose.</p>
<p>4. The guidelines provide a framework and criteria for assessing the integrity and credibility focus of governance structures and the reliability of information/data generated by this guideline is vTPA programmes. When carrying out such an assessment, competent authorities should be guided by their intended use of vTPA programmes and should only apply assessment criteria that are proportionate accredited and relevant to their approach. have audit and certification arrangements independent of the programme owner.</p>	<p>New Zealand New Zealand are not entirely convinced that this statement "The focus of this guideline is vTPA programmes that are accredited and have audit and certification arrangements independent of the programme owner" is necessary in the introduction as this is just some of the criteria set out in the guideline. However if it is retained then it should be a separate paragraph 4</p>
<p>6. The document does not constitute any approval, recognition or endorsement of vTPA programmes. It follows that competent authorities may choose approaches other than that described in these guidelines when considering how to take into account vTPA programmes in their risk-based targeting of regulatory controls.</p>	<p>Norway We support the wording of this paragraph, as it reflects that there can be different approaches to vTPAs.</p>
<p>6. The document does not constitute any approval, recognition or endorsement of vTPA programmes. It follows that competent authorities may choose approaches other than</p>	<p>New Zealand New Zealand suggest that this para is actually unnecessary and can be deleted as this point is made by para 8.</p>

that described in these guidelines when considering how to take into account vTPA programmes in their risk-based targeting of regulatory controls.	
SCOPE	
10. The guidelines are not intended to apply to private standards that are the subject of contractual arrangements between buyers and sellers, and does not apply to components of vTPA programmes that are outside the scope or requirements of the NFCS.	New Zealand Para 10 seems a little confusing - are not all private standards subject to contractual arrangement? In which case is this statement then not indicating that schemes that have standards are excluded from these guidelines.
DEFINITIONS	
C: DEFINITIONS³	Indonesia We propose to add definition of “voluntary third-party assurance” to be included in the draft guidelines.
C:	New Zealand New Zealand suggest that a definition for ‘Certification’ that is specific to this guideline is included. This is because certification is defined in other Codex text but it is being used in this guideline in a slightly different context. This will provide clarity and remove potential future confusion or misunderstanding.
Assurance: Positive declaration intended to give confidence. (Source: Oxford English dictionary).	Indonesia Indonesia would like to clarify the definition of assurance whether the positive declaration needs to be proved by certificate of analysis or other documents
Attestation: issue of a statement, based on a decision following review that fulfilment of specified requirements planned objectives has been demonstrated. (Source: modified ISO/IEC 17000:2004)	Indonesia to be consistent with the definition of audit which explained in CAC/GL 20-1995 that objectives should be fulfilled. Attestation and Audit should have consistence explanation
Conformity assessment: demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. (Source: ISO/IEC 17000:2004)	Indonesia In line with the above comments, Indonesia would like to clarify the term “specified requirements” in the definition of conformity assessment and suggest it to be aligned with the term “planned objectives” in the definition of audit.
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 conflicts of interests. [new]	Indonesia to make it clear and consistent with the roles and responsibilities of competent authorities on section E
Integrity (dictionary): The quality of being honest and having strong moral having clearly articulated principles. (Source: Oxford English dictionary)	USA Recommend defining the concept of integrity to having principles that are clearly articulated. This is more relevant and easier to evaluate.

<p>Review: verification of the suitability, adequacy and effectiveness of selection and determination activities, and the results of these activities, with regard to fulfilment of specified requirements. (Source:ISO/IEC 17000:2004)</p>	<p>Indonesia Indonesia would like to clarify the term “specified requirements” in the definition of review to be aligned with the term “planned objectives” in the definition of audit</p>
<p>Standard: specified requirements contained in the vTPA programme. (Source: new)</p>	<p>Indonesia We propose that the definition of standard refers to the CCFICS documents or texts</p>
<p>Standard: specified requirements contained in the vTPA programme. (Source: new)</p>	<p>Philippines We would like to suggest for the inclusion of a definition for ‘Standard’. ‘Standard – is document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context’ Reference :ISO/IEC Guide 2:2004 Standardization and related activities -- General vocabulary</p>
<p>Voluntary Third-Party Assurance Programme:A non-governmental or autonomous scheme comprising of the ownership of that owns a standard that utilises covering national/international requirements, requirements relating to food safety or food trade; the scheme shall include; a governance structure for certification and enforcement, that provides for periodic on-site audits for FBO’s operations for compliance with the standard;and in which FBO participation is voluntary. [Source: new]</p>	<p>USA The proposed definition is clearer and ties the standard more directly to the scope of the Guidance.It adds a requirement for periodic on-site audits to ensure compliance with the standards.</p>
<p>Voluntary Third-Party Assurance Programme:A non-governmental or autonomous scheme comprising of the ownership of a standard that utilises national/international requirements; a governance structure for certification and enforcement, and in which FBO participation is voluntary. [Source: new]</p>	<p>Indonesia Indonesia would like to ask for clarification about the term “the ownership of a standard” and the term “national/international requirements” in the definition of voluntary third-party assurance programs</p>
<p>Voluntary Third-Party Assurance Programme:A non-governmental or autonomous scheme comprising of the ownership of a standard that utilises national/international requirements; a governance structure for certification certification, inspection and enforcement, and in which FBO participation is voluntary. [Source: new]</p>	<p>New Zealand The governance structure should also apply to 'inspection' and New Zealand suggest that this term is included in the definition</p>
<p>PRINCIPLES</p>	
<p>PRINCIPLES</p>	<p>Indonesia Indonesia propose the brackets are opened in all principles</p>
<p>When considering the potential role of vTPA programmes and the potential contribution they may make to FBO compliance with regulatory requirements and broader NFCS objectives, competent authorities should be guided by the following principles:</p>	<p>Norway In our view, the drafted principles are a mixture of principles, guidance and steps, we would therefore suggest some amendments to the principles.</p>
<p>Principle 1 [Decision making and planning]</p>	<p>Jamaica If the Competent Authority is participating in a programme that is developed base on risk profiling then why should the Comptent Authority consider whether or not to use the information/data received or gain.There should be an establish</p>

<ul style="list-style-type: none"> Competent authorities retain discretion whether or not to consider information/data from vTPA programmes in their regulatory oversight, inspection and control framework, planning and decision-making process. 	<p>mechanism or criteria to use vTPA programme information. Removing the discretionary claws will help to align principle 1 with principle 3, Discretion is subjective and does not speak to the mandate of transparency, hence should not be an item under the principles.</p>
<ul style="list-style-type: none"> Competent authorities retain discretion whether or not to consider information/data from vTPA programmes in their regulatory oversight, inspection and control framework, planning and decision-making process. 	<p>Philippines To mention that decision-making process in choosing whether or not to consider vTPA programs/schemes is based on set criteria and established framework.</p>
<p>Principle 2 [Role and responsibilities]</p> <p>Competent authorities remain responsible for maintaining appropriate oversight of the implementation of regulatory requirements and controls including enforcement actions regardless of actions. The competent authorities are also responsible for establishing the participation mechanism for the assessment and recognition of FBOs in vTPA programmes programs that will be tapped to support the NFCS objectives.</p>	<p>Philippines The principle should be revised to mention the role of competent authorities in considering, assessing or choosing probable vTPA programs. The principle should always be correlated with the chapeau statement of Section D: Principles.</p>
<p>Principle 3 [Process and policies]</p>	<p>Norway In our view this is not a principle, rather a guidance on a process step.</p>
<p>Principle 3 [Process and policies]</p>	<p>Indonesia Indonesia would like to clarify what is meant by “owner” in the term “vTPA owner”, whether it means an organization or person who owns the TPA</p>
<p>Principle 3 [Process and policies]</p> <ul style="list-style-type: none"> Where the competent authority has assessed vTPA arrangements and identified information/data that aligns and indicates compliance with relevant regulatory requirements and NFCS objectives, the competent authority should establish a process for information/data sharing and handling of non-compliances with the vTPA owner to alert the competent authority of any significant public health risk or consumer deception. 	<p>New Zealand To cover full mandate of Codex</p>
<ul style="list-style-type: none"> Where the competent authority has assessed vTPA arrangements and identified information/data that aligns and indicates compliance with relevant regulatory requirements and NFCS objectives, the competent authority should establish a process for information/data sharing and handling of non-compliances with the vTPA owner to alert the competent authority of any significant public health risk. 	<p>Philippines Under this principle, there should be a formal agreement between the competent authority and the vTPA program owner prior to sharing of any information or handling of non-compliances.</p>
<p>Principle 4 [Regulatory framework]</p> <ul style="list-style-type: none"> The vTPA standard, its audit and inspection does not replace regulatory requirements or controls carried out by the competent authority. <p><u>The Competent Authority must have in place legal framework to allow oversight and enforcement of compliance should there be the need to suspend, revoke, and reinstate vTPA programme/owner in the event of non-compliance</u></p>	<p>Jamaica The Competent Authority must have in place legal framework to allow oversight and enforcement of compliance should there be the need to suspend, revoke, and reinstate vTPA programme/owner in the event of non-compliance</p>

<ul style="list-style-type: none"> The vTPA standard, its audit and inspection does not replace regulatory requirements or controls carried out by the competent authority. 	<p>Philippines Although the vTPA program does not replace regulatory requirements and other controls implemented by the competent authority, it has to be acknowledged that the vTPA complements the official controls.</p>
<p>Principle 5 [Proportionality]</p> <ul style="list-style-type: none"> The actions of the competent authority to make use of vTPA information/data should not directly or indirectly mandate additional requirements, costs or restrictions on FBOs over and above regulatory <u>requirements nor does it mean automatic compliance to regulatory requirements.</u> 	<p>Philippines</p>
<p>Principle 6 [Transparency]</p> <ul style="list-style-type: none"> Competent authorities should make their approach to the use of vTPA programmes, including the assessment process <u>process, results, and criteria</u> publicly available in line with Principle 3 of CAC/GL 82-2013⁴. 	<p>Philippines</p>
<p>ROLES, RESPONSIBILITIES AND RELEVANT ACTIVITIES:</p>	
<p>12.The roles and responsibilities of all actors <u>participants</u> along the food chain should not change as a result of any decision by a competent authority to take account of vTPA information/data in their NFCS relating to consumer protection and ensuring fair trade practices.</p>	<p>USA “Actors” would be better worded as “participants”</p>
<p>The roles and responsibilities of all actors <u>participants</u> along the food chain should not change as a result of any decision by a competent authority to take account of vTPA information/data in their NFCS relating to consumer protection protecting the health of consumers and ensuring fair trade practices <u>practices in food trade.</u></p>	<p>New Zealand Use of Codex language.New Zealand is also uncertain that the statement in this paragraph “that the will be not change as a result of any decision by the competent authority” is actually correct.There will be some change in responsibly if the Competent authority and the Scheme owner enter into an agreement because the CA will be undertaking some level of checks to ensure the scheme is able to deliver the required level of confidence.New Zealand also suggests that placement of this section after dealing with reaching an agreement relating to the vTPA programme may be more useful.</p>
<p><u>COMPETENT AUTHORITIES</u></p>	
<p><u>ROLES AND RESPONSIBILITIES COMPETENT AUTHORITIES</u></p>	<p>Jamaica</p>
<p><u>COMPETENT AUTHORITIES</u></p>	<p>New Zealand Points d to g seem to be repeating some of the Principles and then separating aspects that would be better stated together.</p>
<p>a. Have statutory responsibilities for regulatory requirements set down in the NFCS, as recommended in CAC/GL 82-2013 and authorised by relevant national legislation.</p>	<p>New Zealand The point would also address conflict of interest as it relates to the competent authority</p>

<p>b. May consider <u>Establish criteria that will establish confidence in taking account of information/data generated by vTPA programmes to support the objectives of their NFCS and inform the design, implementation, monitoring and review activities to verify FBO compliance levels.</u></p>	<p>Jamaica Removing the discretionary position of Competent Authority in the use of vTPA information</p>
<p>b. May consider taking account of access information/data generated by vTPA programmes to support the objectives of their NFCS and inform the design, implementation, monitoring and review activities to verify FBO compliance levels.</p>	<p>Indonesia we are of the view that there are authorities to have access directly to information/data from vTPA owner.</p>
<p>c. Have <u>Shall</u> ultimate responsibility for the delivery and frequency/intensity of regulatory controls and enforcement action for all FBOs regardless of whether a FBO participates in a vTPA programme.</p>	<p>Indonesia we are of the view that there are authorities to have access directly to information/data from vTPA owner.</p>
<p>d. Need to clearly describe the use of a vTPA programme <u>information/data</u> within their NFCS <u>NFCS and restrict its use when information provided is false or otherwise lacks credibility.</u></p>	<p>USA Expanding clause d to -- uses of and restrictions on information or data -- will support removing clause h below.</p>
<p>d. Need to clearly describe the use of a vTPA programme within their NFCS. Should have defined and transparent processes to: <u>1) identify, assess and verify the integrity and credibility of the TPA programme and the information/ data to be used to support the NFCS</u> <u>2) maintain appropriate confidentiality of data in alignment with their national legislation.</u></p>	<p>New Zealand Suggested more logical combination of points</p>
<p>e. Should ensure any arrangements to use vTPA information/data is fully transparent.</p>	<p>New Zealand covered by previous suggested text</p>
<p>f. Have <u>Shall</u> to protect against potential conflicts of interest.</p>	<p>Indonesia To emphasize the sentence and it is responsibility belong to competent authorities.</p>
<p>f. Have to protect against potential conflicts of interest.</p>	<p>New Zealand In relation to the Governance of vTPA programmes conflict of interest is addressed in section F, 13 2)</p>
<p>g. Have <u>Shall</u> to maintain appropriate confidentiality of data.</p>	<p>Indonesia To emphasize the sentence and it is responsibility belong to competent authorities.</p>
<p>g. Have to maintain appropriate confidentiality of data.</p>	<p>New Zealand covered by new suggested text</p>
<p>h. Should be able to impose sanctions where false information/data is given to them by the vTPA owner.</p>	<p>Norway Would suggest "measures" not "sanctions".</p>

h. Should be able to impose sanctions where false information/data is given to them by the vTPA owner.	<p>Jamaica We recommend that provisions be establish for suspend, revoke and reinstate vTPA in the event of non-compliance.</p> <p>This is recommendation was place under principles 4</p> <p>A new section should be devoted to providing guidance for the different types of non-compliance and procedures for each, to include re-instating a vTPA</p>
h. Should be able to impose sanctions where false information/data is given to them by the vTPA owner.	<p>USA Most competent authorities don't have this authority, so the clause could overly restrict the uses of vTPAs. The corrective action that a competent authority would have (in most cases) would be to stop using the data, which is captured above in the revision.</p>
h. Should be able to impose sanctions where false information/data is given to them by the vTPA owner.	<p>Philippines Is there a responsibility for vTPA owner to provide competent authority with the necessary information? The imposition of sanctions can only be implemented if there is a formal agreement between the two parties.</p>
<u>FOOD BUSINESS OPERATORS (FBOs)</u>	
<u>ROLES AND RESPONSIBILITIES OF FOOD BUSINESS OPERATORS (FBOs)</u>	Jamaica
<u>FOOD BUSINESS OPERATORS (FBOs)</u>	<p>Philippines The Philippines proposes the inclusion of the following texts as:</p> <p>e. Both FBOs (if participating in vTPA) and vTPA owners enter and comply with arrangement/agreement on matter relating to confidentiality, exchange of information, and compliance with the requirement of vTPA programme.</p>
a. Have the Establish and implement primary role-roles and responsibility responsibilities for managing the food safety of their products and for complying with regulatory requirements relating to those aspects of food under their control.	Jamaica
d. Owns the information/data generated by the vTPA programme_ e. to demonstrate there are no conflicts of interest	Jamaica New proposal
d. Owns the information/data generated by the vTPA programme.	New Zealand Point d) seems to be contradicted by point c) below
<u>VOLUNTARY THIRD-PARTY ASSURANCE OWNERS</u>	
<u>VOLUNTARY THIRD-PARTY ASSURANCE OWNERS</u>	<p>Guatemala It is important to further develop these 2 points for clarification purposes. Although it is true that it is the consumer that must be provided with confidence about food safety, the vTPA must first provide assurance to the competent authorities, which will verify third-party assurance. As to point b, programme owners must be</p>

	accountable to the FBOs and also to the competent authorities, which will verify the actions performed by the vTPA. Currently, some FBOs already use vTPA very often; this proposed draft discusses delegating some official inspections. Therefore, these points should be defined or further developed, so that they can be more effectively implemented.
<u>VOLUNTARY THIRD-PARTY ASSURANCE OWNERS</u>	<p>Philippines The Philippines also proposes the inclusion of the same texts under vTPA as:</p> <p>e. Both FBOs (if participating in vTPA) and vTPA owners enter and comply with arrangement/agreement on matter relating to confidentiality, exchange of information, and compliance with the requirement of vTPA programme.</p> <p>Further, we recommend the following texts under vTPA:</p> <p>g. Publish public information on vTPA's</p> <p>h. process of granting, refusing, maintaining, renewing, suspending, restoring or withdrawing certification or expanding or reducing the scope of certification</p> <p>i. The certification body shall provide by any means it chooses certification documents to the certified client.</p> <p>j. Processes for handling requests for information, complaints and appeals</p>
a. Are responsible for implementing the governance arrangements of a vTPA programme, which will include utilising national/international standards and independent accredited audit and certification.	<p>New Zealand Does specifying requirements for 'accredited' audit and a 'certification' component limit the schemes that can be acceptable.Suggest these factors may be better captured under Section F below.Also there will be an accountability change if the Owners enter into an agreement with a competent authority.</p>
c. May choose to establish mechanism to share information/data generated by the vTPA programme for use by the competent authority.this include the maintenance of records (include third party audit reports) that may be required by the Competent Authority.	Jamaica
c. May choose to share information/data generated by the vTPA programme for use by the competent authority. C. bis Have policies to ensure a vTPA alerts the competent authority of any significant public health risks associated with non-compliance by regulated industry	<p>USA Added C BIS This clause will help ensure that information is exchanged when needed to protect public health and that policies address this.</p>
c.May choose .Have clear rules of engagement on requesting access to share information/data generated by the vTPA programme for use by information, such as notification to the competent authority,food business operator, and protections for proprietary information	<p>USA The value of a vTPA is in the sharing of information with the foreign government.The US has proposed additional text to articulate standards for information sharing between third party schemes and governments that provide exchanges when needed to protect public health, while also protecting confidential business information and/or proprietary information from inappropriate disclosure.</p>

c. May choose to share information/data generated by the vTPA programme for use by the competent authority.	Indonesia
c. May choose to with the agree of scheme participants share information/data generated by the vTPA programme for use by the competent authority.	New Zealand Is point c) in contradiction to point d) above - is some extra text is needed here about the Programme Owner having agreement of scheme participants to share data with the CA
c. May choose to share information/data generated by the vTPA programme for use by the competent authority.	Philippines We would like to seek clarification on the intent of the sentence. We were of the impression that information/data is to be shared once the vTPA owners sign an agreement with the competent authority
d. Will have appropriate systems in place to protect against potential conflicts of interest between TPA owners, auditors and FBOs, and be able to demonstrate adherence to data protection obligations.	Norway Might need to be clear on who are the auditors mentioned in this paragraph. This in connection with paragraph a) and certification bodies.
d. Will Shall have appropriate systems in place to protect against potential conflicts of interest between TPA owners, auditors and FBOs, and be able to demonstrate adherence to data protection obligations.	Indonesia Rationale: because its mandatory for the TPA organization to manage the impartiality based on ISO/IEC 17065 clause 4.2.2 The certification body shall be responsible for the impartiality of its certification activities and shall not allow, commercial, financial or other pressures to compromise impartiality.
CRITERIA TO ASSESS THE CREDIBILITY AND INTEGRITY OF vTPA PROGRAMMES	
<p><u>New Proposal: New Section -</u></p> <p><u>Criteria for vTPA programmes</u></p> <p><u>The Competent Authority should ensure that the vTPA meets the following criteria:</u></p> <ul style="list-style-type: none"> <u>- has legal status to operate in the country and enter into formal third party programmes with FBOs</u> <u>- it has sufficient resources (financial and human), including the expertise, equipment and infrastructure required, to undertake the service to FBOs</u> <u>- has formal accreditation in order to be recognized for providing information/data to competent authority.</u> <u>- Conformity to systems and processes are in place. this involves demonstrating the programme will include having systems approach to quality management, documentation, standard operating procedures, quality and food safety manuals</u> <u>- declaration of any conflict of interest and how the company tends to deal with such issues while undertaking the vTPA</u> 	<p>Jamaica</p> <p>New Proposal: Criteria for establishment of vTPA Programmes New Proposal to help establish framework on which to assess vTPA see proposal just above section F:</p>

F: CRITERIA TO ASSESS THE CREDIBILITY AND INTEGRITY OF vTPA PROGRAMMES	
F: CRITERIA TO ASSESS THE CREDIBILITY AND INTEGRITY OF vTPA PROGRAMMES	USA The use of a checklist may oversimplify the process for assessing the credibility and utility of these programs. While it is important to receive yes responses to these sorts of questions a yes/no response would not substantiate the capability of the vTPA to carry out its activities and prove stability and reliability to a competent authority. This checklist may be a good starting point for a competent authority but it is important that governments understand they will need more in depth knowledge of vTPAs.
13. Competent authorities that choose to take account of vTPA programmes in their NFCS should satisfy themselves that the private the information/data can be trusted and is fit for purpose. In order to do this they may carry out a full or partial assessment of the credibility and integrity of the vTPA programme, commensurate with their intended use of the private information/data. When carrying out such an assessment, competent authorities should select the criteria below that are appropriate to the extent of their intended use of the vTPA programme.	USA Use of word private is inappropriate see comment above
Governance Arrangements	
4) Does the vTPA programme have an accreditation arrangement that adheres to the International Accreditation Forum's (IAF) Multilateral Recognition Arrangement or the International Laboratory Accreditation Co-operation (ILAC)?	Norway Please explain the relevance of ILAC, in our view the reference should be deleted as it is not relevant here.
4) Does the vTPA programme have an accreditation arrangement that adheres to the International Accreditation Forum's (IAF) Multilateral Recognition Arrangement or Arrangement the International Laboratory Accreditation Co-operation (ILAC)(ILAC) or another accreditation body that has a similar recognition, international standing and credibility?	USA Allows for consideration of bodies other than those listed by name.
Accreditation of Certification Bodies	
3) Does the Accreditation Body assess the certifying body using the relevant standards including for example ISO/IEC 17020, ISO/IEC 17065 or ISO/IEC 17021-1 supplemented with ISO/TS 22003?	New Zealand so as to reduce prescription, give some flexibility of what is acceptable and to future proof
Standard Setting Process	
1) Do the vTPA standards contain specified requirements to protect the health of consumers in relation to food safety and and/or fair practices in food trade?	Japan The vTPA standards does not necessarily include fair practices.

<p>1) Do the vTPA standards contain specified requirements to protect the health of consumers in relation to food safety and fair practices in food trade?</p>	<p>New Zealand In this context fair practices are about deception and not all aspects of deception have a health effect.</p>
<p>3) Are the vTPA standards subject to a regular review to keep them up to date?</p>	<p>USA Edits to capture additional concepts on governance.</p>
<p>3) Are the vTPA standards <u>open, transparent in governance and subject to a continuous improvement by regular review-reviews</u> to keep them up to date?</p>	<p>USA Edits to capture additional concepts on governance.</p>
<p>4) To what extent are the vTPA standards consistent with Codex or other relevant international <u>standards</u>? <u>Do the standards and/or reflect applicable national regulatory requirements??(MOVE TO TOP OF LIST)</u></p>	<p>New Zealand there are two points here one of which - alignment with national regulatory requirements is a core issue and should come first in this list and be stated separately from relevant international standards</p>
<p>Data Sharing and Information Exchange</p>	
<p>1) Is there an up-to-date list of participating FBOs (including their status) that are certified or verified as conforming to the vTPA standard, and is this information available to the competent authority?Is the information available in the public domain?</p>	<p>USA Deletion of the final sentence suggested as not essential.</p>
<p>2)Subject to national privacy legislation, will the vTPA programme owner inform the competent authority immediately or when they become aware of a significant risk to public health or fraud?</p>	<p>New Zealand The reference to national legislation are a little puzzling New Zealand would consider these to be more of a yes / no question. That is will they advise the CA immediately they become aware of a significant risk – because if not then they are not an appropriate scheme of the CA to consider.</p>
<p>7) Does the vTPA owner have permission to share <u>relevant FBO data</u> and is this in accordance with national data protection obligations <u>the competent authority</u>?</p>	<p>New Zealand Similar to point 2) above. The reference to national legislation are a little puzzling New Zealand would consider these to be more of a yes / no question. Does the scheme owner have permission to share relevant data – if not then it is not a suitable scheme.</p>
<p>G: REGULATORY APPROACHES FOR THE USE OF vTPA INFORMATION/DATA</p>	
<p>REGULATORY APPROACHES FOR THE USE OF vTPA INFORMATION/DATA</p>	<p>Philippines 1. To reflect the principles under Section G throughout the document. It is important to emphasize in the document the procedure or approaches in considering whether or not to use, or when to use vTPA information or data. 2. If the means to recognize the legitimacy of vTPA data, which will be used by the competent authority, is through accreditation, then this should be clearly and consistently reflected throughout the document.</p>
<p>Process considerations</p>	

<p>k. In addition to specific and critical information detailed in any voluntary agreement <u>an agreement between the competent authority and the vTPA owner</u>, there should be routine information exchanged to demonstrate that the vTPA programme continues to operate in line with its agreed governance.</p>	<p>New Zealand Rational - 'voluntary' should be deleted as it could imply that adhering to the agreement is voluntary. Specify that the agreement is between the CA and vTPA owner for clarity</p>
<p>l. Where competent authorities choose not to enter into an agreement with the vTPA owner they may access the information/data directly from the FBO.</p>	<p>New Zealand It is unclear why h) is needed in this guideline - it is stating the obvious</p>
<p>m. The competent authority should identify the information/data from the vTPA audits that is of most value to its NFCS objectives and agree the access arrangements for those elements. Key elements are identified in para 38 ("Data Sharing and Information Exchange" above).</p>	<p>New Zealand The cross reference to para 38 needs to be corrected - there is no para 38</p>
<p><u>Policy options</u></p>	<p>New Zealand Points e), f) & i) all seem to say the same thing - they should be rationalised</p>
<p>a. In developing an appropriate approach to leverage the vTPA compliance information/data, competent authorities should ensure that the approach is consistent with international rights and obligations.</p>	<p>New Zealand recommend be deleted because these guidelines are about national food control systems therefore international rights and obligation are not relevant</p>
<p>b. Competent authorities may choose to verify the reliability of vTPA information/data through for example a comparison of the compliance data from the vTPA with their official inspection information/data.</p>	<p>New Zealand Point b) seems to be a duplication of f) in the previous section - is it needed?</p>
<p>c. In order to validate the suitability of an assurance system, including a review of the vTPA requirements and its operation the competent authority may consider the value of comparing the vTPA requirements with relevant international standards and/or relevant national regulatory requirements <u>requirements and/or relevant international standards</u>.</p>	<p>New Zealand This should be re-ordered to emphasis compliance with national standards is of most importance within its own territory</p>
<p>d. As many vTPA standards include requirements that go beyond food safety and consumer protection into supplier preferences, the competent authority should focus on the regulatory requirements that protect the health of consumers in relation to food safety and <u>ensuring fair practices in food trade</u>.</p>	<p>New Zealand Codex language</p>
<p>n. Competent authorities may use the additional information/data <u>Competent authorities may use the additional information/data from vTPA audits to help priorities regulatory resources to higher risk areas to better protect the health of consumers in relation to food safety and fair practices in food trade.</u></p> <p><u>New proposed section below J</u></p> <p><u>Non-Compliance</u></p> <p><u>The Competent Authority should establish procedures for handling non-conformity that have been identified in the vTPA programme. Actions towards addressing these issues</u></p>	<p>Jamaica The document speak about imposing sanctions under responsibilities of Competent Authority and also speak about the vTPA establishing procedures for handling Non-Conformity, However, there should be strong procedures are in place for Competent Authority handle Non-Compliance and the various types.</p>

may include suspension, and revoking. Procedures should also be in place to address reinstating any party to the vTPA programme.

Suspension - temporary removal from vTPA audits programmes due to help prioritise regulatory resources non-compliance issues identified during audit process.

Revocation - removal from vTPA programmes due to higher risk areas to better protect major non-compliance issues identified during audit process

Re-reinstatement - parties that have been suspended or expelled from the health of consumers in relation programme may re-apply to food safety-rejoined the programme and fair practices in food trade demonstrate system conformity to the Competent Authority before recognition can be given.