CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



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Agenda item 4

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Twenty-fifth Session

Virtual, 31 May – 8 June 2021

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

REPORT/RECORD OF THE CCFICS VTPA WEBINAR HELD ON 25 MARCH 2021

(Prepared by Canada, Mexico and the United Kingdom)

1. <u>Welcome & Introduction</u>

The objective of this informal webinar was to update Codex Members and Observers on the progress that has been made on the Draft Principles and Guidelines for the Assessment and Use of Voluntary Third-Party Assurance Programmes (vTPA) since the committee last met in October 2018. The webinar was structured to remind participants of the background to the work, provide an update on the current status, and outline key issues to emerge from the electronic working group (EWG) consultation. Participants were then invited to comment and ask questions. The webinar focused on the main discussion points highlighted by the co-chairs, UK, Canada, and Mexico, and which were based on the analysis of comments provided by Members and Observers in CX/FICS 20/25/4 Add.1 and CX/FICS 20/25/4 Add.2, and discussed by the electronic working which had been reactivated following the postponement of CCFICS25.

The CCFICS Chair opened the meeting, noted the continued broad support for the work and urged participants to use the available time at the upcoming session efficiently by not reopening discussion on topics that had been agreed upon previously. The Chair further noted that much has happened since CCFICS24, not least the impacts of the pandemic which meant there would be a packed agenda at CCFICS25.

2. Background

The Codex Vice-chair noted that the work is firmly rooted in regulatory modernisation. The vTPA journey began in 2016 at CCFICS22 when Canada and the UK were tasked with co-authoring a discussion paper. A new work proposal was appended to the discussion paper and this was approved at CCFICS23 in Mexico City in 2017. The EWG was set up soon after with the UK as chair and Canada and Mexico as co-chairs.

The text of the draft guidelines had been developed using the full suite of available Codex tools. This included piloting virtual participation at two physical working groups (PWGs), one in Santiago and the other in Edinburgh. Noting that the vTPA approach was new to many members the co-chairs had invited relevant experts to present at each of the PWG meetings and at a side event at CCFICS24. Interest in the topic continues to grow, where the World Trade Organization's (WTO) Standards and Trade Development Facility (STDF) is funding two pilot projects in the Latin American and Caribbean and African regions and the WTO Sanitary and Phytosanitary (SPS) Committee recently held a thematic session on third-party assurance programmes.

The scope of the guidelines was settled quite early in the development of the text. The guidelines are intended to support competent authorities that use information/data derived from vTPA programmes within their national boundaries. The approach does not in any way change the roles and responsibilities of the competent authority, food business owners, or vTPA owners. The approach supports regulatory oversight. Finally, the guidelines are not an endorsement of vTPA programmes and do not require competent authorities to use vTPA programme information/data in their regulatory oversight.

3. Progress of Work

The EWG Chair began by noting that a Circular Letter (CL) had not been issued requesting comments ahead of CCFICS25. Advice from the Secretariat was that the text had already been the subject of two CLs following CCFICS24 (CL 2019/93/OCS-FICS and CL 2020/26/OCS-FICS) so another was not necessary. This does not

however preclude members and observers from submitting comments ahead of the plenary session of CCFICS25.

Following the postponement of CCFICS25 in 2020, the EWG tasked with further developing the guidelines was re-activated to help maintain momentum.

Analysis has been completed on all of the comments from the two CLs. The task was complicated due to the CLs inviting comments on two different versions of the text. The co-chairs were able to synthesise and pull out the key issues into a more manageable format for consideration by the reactivated EWG. There continues to be broad support for the work and the co-chairs were able to take on board many of the comments, including many largely editorial comments that improve the clarity of the text, and a number that helped streamline the guidelines by removing some redundancies. The analysis supporting these changes can be found in Appendix 4 of the reactivated EWG report, found in CX/FICS 21/25/4.

There are, however, a number of issues that the co-chairs felt merited further discussion and consideration at CCFICS25 given the views expressed by EWG participants. These issues were presented during the webinar, providing an opportunity for webinar participants to provide feedback and ask questions. The issues and feedback are summarized in the subsequent section.

4. EWG Analysis and Conclusions / Feedback and Questions

Principle 8 - Rights & Obligations

Discussion on whether to retain or delete the following text:

In developing an appropriate approach to make use of vTPA programme conformity information/data, competent authorities should ensure that their approach is consistent with applicable international rights and obligations

This text was originally found in section G of the guidelines and was moved, following a member's comment, to the Principles section.

Some members have suggested deletion of the principle as international rights and obligations are not unique to these guidelines. Conversely other participants found it served as a useful reminder to countries in the context of the guidelines.

Many participants commented that there isn't a precedent in other Codex texts for including a reminder on international rights and obligations. One participant asked, "if this one then why not every other Codex text?"

In addition, as the scope makes clear that the guidelines are intended to assist competent authorities within their national boundaries this text looks redundant.

Section E, sub-section 12., 1) Roles and Responsibilities of Competent Authorities, paragraph f. Conflict of Interest

This section is related to the responsibilities of competent authorities regarding conflict of interest. Comments from the CLs resulted in a refinement of wording with 2 options for alternative text:

Option 1: Should protect against potential conflicts of interest

Option 2: Should recognize potential conflicts of interest and their impact on the reliability of the information/data of the vTPA programme.

Option 2 is designed to add more clarity to the provision and make note of the potential impact on the reliability of the data.

One participant commented that there needs to be a stronger position on "conflict of interest", that option 2 needs reformulating so it doesn't just guide on recognising conflicts of interest but includes a need to demonstrate that the competent authority is taking action to protect against conflicts of interest.

The co-chairs noted the comment for further reflection as the current formulation of option 2 focussed on recognising potential conflicts of interest and likely impact on trust.

Section E, sub-section 12., 1) Roles and Responsibilities of Competent Authorities, paragraph g. Confidentiality of data

Two options for the text were discussed:

Option 1: Should ensure and maintain the confidentiality of data shared by the vTPA owner

Option 2: Should maintain the appropriate confidentiality of information/data shared by the vTPA owner, according to the legislative framework of the country

EWG participants were divided; some thought the additional text "appropriate" and "according to the legislative framework of the country" is not needed as it is implicit in option 1. Other participants maintain the view that addition of this text adds clarity.

The co-chairs noted that the additional text doesn't actually change the meaning and in the eyes of some, adds clarity.

Section E, sub-section 12., 3) Roles and Responsibilities of vTPA owners paragraph h, Alerting competent authorities

There has been discussion since the first physical working group on vTPA programmes alerting competent authorities of any significant public health risks. Much effort has been taken to find the appropriate text which takes into account the different views of member countries:

Have policies and processes to alert the competent authority of any significant public health risks or consumer deception associated with non-conformities by the FBO(s).

Some countries with practical experience of the vTPA approach have similar text included in their arrangements with vTPA owners. The EWG report (CX/FICS 21/25/4) includes additional background on the value of such text, to act as both a filter and safety net. A filter so that the competent authority does not spend time following up on non-conformities that will be fixed as part of the vTPA governance arrangements, and a safety net due to the potential reduction in official visits. It was also noted that the expectation, and practical experience, was that such alerts were exceptional and not routine.

One participant commented that they supported retaining "significant public health risk" and felt it did not need to be defined. Another participant agreeing with the sentiments suggested alternative text to tighten it up with the addition of "imminent and serious".

One participant suggested that "risk profile" might fit better as it was a broader description of the food safety problem and its context. (Reference: FAO and WHO, 2019 - Codex Alimentarius Procedural Manual). The current text may cause confusion for readers. They noted that, to their knowledge, the term "significant public health risks" does not have a definition with international consensus and could be subject to interpretation by members.

Two participants reflected on the confidentiality agreements between vTPA programmes and FBOs and that work was needed to ensure that these guidelines are possible in conjunction with those agreements.

One participant suggested looking at the language in the general food hygiene principles which used the term "significant hazards". However, they were in agreement with others that it was not necessary to define "significant" at this stage.

A couple of participants commented that there needed to be flexibility for countries to define what constitutes "significant" in their national context.

The EWG chair concluded that all comments had been noted and would be used to prepare for CCFICS25 so that time could be used efficiently.

International Organisation for Standards (ISO) definitions

This issue had attracted comments throughout the development of the text. Whilst Codex texts sometimes refer to other standards, in practice this should be minimised. The definitions section in the guidelines have been discussed and commented on throughout the development of the text. In particular, the reference to and use of ISO standards as the foundation of some definitions, bearing in mind that these standards may change over time. As a result of discussions and members' comments the definitions were adapted for the purpose of the guidelines, and references placed in footnotes.

One EWG participant pointed out that in the definitions section a definition is provided for "certification body" when the ISO standard actually refers to a "conformity assessment body". The co-chairs clarified that for the purposes of the guidelines, these terms mean the same thing as both are used interchangeably in the vTPA eco-system. They also reminded attendees that official certification is out of scope of these guidelines. While the term "certification" was used in the title in the early version of the guidelines, it was subsequently removed from the title to help avoid confusion.

One participant commented that some terms are already well understood so could be deleted from the definitions section to avoid confusion. The co-chairs invited the participant to provide more detail in an email so that the points could be considered in full.

Comments from Spanish-speaking Members

Background was provided on how comments made by Spanish speaking countries were considered and taken into account. Some comments focused on the form, the way the text was drafted, and the words used whilst other comments were about the form and substance and potentially changed the meaning of the text.

Changes were made where the comment on the text didn't change the meaning of the paragraph, remaining faithful to the original English text. Where comments led to a change of meaning a resolution was found by using a broader term.

The co-chairs wanted to reassure the Spanish speaking countries that their comments were being noted and reflected in the updated text to maintain consistency with the English version. It was further noted that this would help with similar issues in other Codex languages.

5. Next Steps & Closing Remarks

Participants were invited to consider the EWG report (CX/FICS 21/25/4) including the updated text, ahead of CCFICS25 and consider whether to recommend to CAC44 adoption of the text at Step 8.