

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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World Health
Organization

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Agenda item 6

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ORIGINAL LANGUAGE

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

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PROPOSED DRAFT GUIDANCE ON REGULATORY APPROACHES TO THIRD PARTY ASSURANCE SCHEMES IN FOOD SAFETY AND FAIR PRACTICES IN FOOD TRADE

(Comments from EU, FAO and African Union)

EUROPEAN UNION

Mixed Competence
European Union Vote

The European Union and its Member States (EUMS) would like to thank the United Kingdom, Canada and Mexico for leading the work on third party assurance programmes. The EUMS would like make the following comments on the draft text.

General comments

While Codex Principles and Guidelines for National Food Control Systems (NFCS) (CAC/GL 82-2013) foresee that competent authorities should take into account quality assurance systems in their national food control system it is left for Codex members to decide how to do this. This flexibility should be retained in the draft guidance on third party assurance programmes. It could be clarified that the guidance apply to a situation where competent authorities choose to have an arrangement with a vTPA programme owner to use the data/information generated by the vTPA programme to support their regulatory controls.

Specific comments

Paragraph 2 should be modified as follows:

“The Codex Principles and Guidelines for National Food Control Systems (NFCS) (CAC/GL 82-2013) foresee competent authorities taking into account quality assurance systems in their national food control system. **Competent authorities may choose to do this by establishing an arrangement with a vTPA programme owner to use the data/information generated by vTPA programme to support their regulatory controls. In any case,** ~~However, before competent authorities can take account of vTPA programmes they should satisfy themselves that any information/data they intend to use is both reliable and fit for purpose.”~~

Rationale: Competent authorities may take into account data/information generated by vTPA programmes by establishing an arrangement and assessing these data or by considering them as a part of a food business operator’s internal control system in which case there is no need to establish any arrangement with a vTPA programme owner and to assess the reliability of vTPA programmes.

Paragraph 6 would better fit under the scope as paragraph 10bis.

Paragraph 8 should be modified as follows:

“The guidelines do not compel competent authorities to use ~~take account of~~ vTPA programme outcomes nor does it mandate the use of vTPA information/data by FBOs, **i.e. emphasising that the decision to use vTPA information data by the competent authority is voluntary.**”

Rationale: According to CAC/GL 82-2013 competent authorities should take into account quality assurance systems (i.e. vTPA programme outcomes) but there is no obligation to use them. The same approach should be kept in this specific guidance.

Principle 1 (paragraph 11) should be modified as follows:

“Competent authorities retain discretion whether ~~or not~~ **and how** to consider information/data from vTPA programmes...”

Rationale: The proposed wording gives flexibility for CA on how to consider information/data from vTPA programmes.

Principle 3 (paragraph 11) should be modified as follows:

“...the competent authority ~~should~~ **may** establish a process for information/data sharing...”

Rationale: The establishment of a process for information sharing should be optional.

Indent b of paragraph 12 should be modified as follows:

“May consider **using** ~~taking account of~~ information/data generated by vTPA programmes to support the objectives of their NFCS...”

Rationale: The guidance should focus on a situation where competent authorities actually use the data generated by vTPA programmes and not just take it into account.

Indent c of paragraph 12 should be modified as follows:

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

Rationale: The qualifier “ultimate” makes the responsibility of competent authorities somewhat ambiguous.

The first sentence of paragraph 13 should be modified as follows:

“Competent authorities that choose to **use** ~~take account of~~ vTPA programmes in their NFCS should satisfy themselves that the private information/data can be trusted and is fit for purpose.”

Rationale: Only if competent authorities actually use the data generated by vTPA programmes they should assess the reliability of vTPA programmes. If vTPA programmes are just taken into account a part of a food business operator’s internal control system there is no need to assess them.

Paragraph 13, indent 5 under sub-heading “Governance arrangements” should be amended to read:

“If the accreditation arrangement does not adhere to IAF or ILAC, does the vTPA programme owner ensure that ~~accreditation~~ **certification** bodies have the capacity and competency to perform effectively?”

Rationale: the vTPA has no oversight on accreditation bodies. Performance of activities for vTPA is carried out by certifying bodies.

Paragraph 13, indent 1 under sub-heading “Conformity assessment” should be amended to read:

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

Rationale: the vTPA has no oversight on accreditation bodies. A vTPA does not define policies for accreditation bodies. It is not its role.”

Paragraph 14 should be modified as follows:

“This section provides examples of ~~necessary~~ considerations and the practical uses...”

Rationale: The considerations in paragraph 39 are optional and thus not necessary.

Indent g under Process considerations in paragraph 14 should be modified as follows:

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

Rationale: To bring the wording in line with other paragraphs as these considerations are optional.

The first sentence of indent i under “Process considerations” in paragraph 14 should be modified as follows:

The competent authority ~~may should~~ **may** 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.

Rationale: To bring the wording in line with other paragraphs as these considerations are optional.

FAO

FAO would like to thank the United Kingdom, Chair, supported by Canada and Mexico, for guiding the work of the Electronic and Physical working groups towards the preparation of document CX/FICS 18/24/6.

FAO would like to offer the following comments:

General comment

Access to data collected by reliable voluntary third party assurance programmes (vTPA) can be an opportunity for Competent Authorities (CAs) to improve targeting of priorities for the national food control system. The document currently refers to the use of this data essentially to influence on the frequency of official inspections, which is certainly one possible use, but not the only one. FAO would like to propose that the document refers more explicitly to other possible uses, such as collecting data that could be used to support a better knowledge of the risks through contribution to the data sets of the monitoring and surveillance programmes, informing risk profiles etc. This would however also require a possibility to access more specific data than only the audit reports conclusion, or being informed on the listing/delisting of a Food Business Operator (FBO) from the vTPA programme. FAO would therefore propose to spell out more explicitly in the document the right of CAs to define what type of data that should be subject communicated to them.

In more general terms, FAO understands that opting for this approach of considering vTPA data in regulatory programmes would be at the discretion of CAs and that it would not constitute for FBOs an obligation to enter into a vTPA programme. However we also know that vTPA programmes come at a high cost for medium and small scale food business operators, especially in developing countries. We also know that access to data is an issue for CAs in a number of countries, especially developing. As this text could be interpreted as a strong encouragement to FBOs to consider entering into such programmes, FAO is of the opinion that this text should provide unambiguous support to CAs in their negotiations with vTPA to access the data that is of strategic interest to them.

Specific comments

- Paragraph 7: the scope seems to be restricted to national boundaries. However, this approach could be equally used with respect to national FBOs belonging to the importers category, therefore *de facto* expanding onto FBOs located in other countries. So is the mention of restriction to national boundaries not misleading?
- Paragraph 13 - "Data sharing and Information exchange-5": based on our introductory comment, we wonder if the current formulation ("information/data relating to compliance with the standard") couldn't be interpreted in a very restrictive and limited manner (i.e. yes/no), regarding the type of information/data that could be sought by CAs. FAO proposes to include a more explicit reference to "data as defined by the CA that could contribute to improve the risk base of the national food control system" (i.e. could include own-control analytical results etc.).
- Paragraph 14.
 - There are some overlaps between the section on "Process consideration" and the section on "Policy options" (for example "Process consideration/f" and "Policy option/b", which seem repetitive).
 - We also note that the sub-paragraph "Process consideration/i" refers to the identification of the information/data from the vTPA audits of most value to the food control system. We interpret this as a sign of openness with regard to the type of data that can be requested by CAs to vTPA. However, the text further refers to "paragraph 13 - data sharing and Information exchange-5" mentioned in our previous comment, which could be interpreted in a very restrictive manner. So this would reinforce the need for our proposal to align the formulation of access to the type of data as needed by the CAs to strengthen the risk base of the national food control system.
 - Sub-paragraph "Policy options" could mention in more specific terms other possible uses of this information/data to support an improved risk basis for the national food control system. This would support the understanding that in some cases, CAs may need to access specific data/information coming from vTPA. In bullet e, only the frequency of inspections are mentioned; bullet h mentions "targeted national training/information programmes" and bullet j refers in very broad terms to the "prioritization of regulatory resources to higher risk areas". Examples of other possible uses could be: contributions to data sets contributing to monitoring and surveillance programmes; information supporting the development of risk profiles.

AFRICAN UNION**Issue**

Competent authorities in various countries are increasingly considering and using third-party assurance schemes to better inform their risk profiling of food businesses so as to more effectively target resources within their National Food Control System (NFCS).

The proposed guidelines are intended to assist competent authorities within their national boundaries in the effective assessment and transparent use of reliable voluntary third party assurance, information/data in support of their NFCS objectives. Its focus is the structure, governance and components of Voluntary Third Party Assurance (vTPA) programmes that align and support NFCS objectives relating to protecting consumer health and ensuring fair practices in food trade.

Position

African Union supports the proposed draft of Principles and guidelines for the assessment and use of voluntary third-party assurance programmes as contained in appendix 1 of document, and its advancement to the next step.

Rationale

These guidelines and provisions will support and strengthen National Food Control Systems as private information/data can be used for risk profiling and supplement official information.