

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 4, 5, 6

CRD15

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION
AND CERTIFICATION SYSTEMS
Twenty-fourth Session
Comments of Canada

Agenda Item 4

**AGENDA ITEM 4: PROPOSED DRAFT GUIDANCE ON USE OF SYSTEMS EQUIVALENCE
CX/FICS 18/24/4**

Canada appreciates the opportunity to provide the following comments on the proposed draft guidance on use of systems equivalence.

Section 3 - DEFINITIONS

Proposed definition of “national food control system”:

Canada notes that a “national food control system”, as described in principle 4 of CAC/GL 82/2013 is the sum of activities of various participants (competent authorities, FBOs, academia, consumers), while the recognition of systems equivalence proposed in this draft guidance pertains to the role of competent authorities in the importing and exporting countries. Should the term “national food control system” continue to be used in this document, it should be qualified at the beginning of the document to clarify the above.

Section 4 – PRINCIPLES

Equivalence of Systems

Canada believes it is useful to include a principle that clarifies expectations regarding the exporting country. Canada suggests re-insertion of the following text (previously b2):

“It is the responsibility of the exporting country to objectively demonstrate that its NFCS or the relevant part can achieve the same objective as the importing country’s NFCS with respect to protecting the health of consumers and ensuring fair practices in the food trade.” [Reworked Principle (g) from CAC/GL 53-2003]

Section 4 – PRINCIPLES

Experience, Knowledge and Confidence

Canada proposes the following insertion to improve the text:

“b. Countries should consider existing **relevant** experience, knowledge and confidence and may consider where appropriate relevant assessments by other countries or international organizations.”

Section 5 – PROCESS STEPS

5.1 Step 1: Initial Discussions and Decision to Commence

Preliminary considerations

Canada supports text that does not limit intent for pursuing equivalence recognition. For example, countries may choose to pursue equivalence recognition as a means to enhance risk based prioritization of inspection resources and not as a trade facilitation tool. Canada proposes the following revisions:

“13 The initial discussions should reflect on whether an equivalence of systems recognition is the most appropriate **tool** approach to reduced impediments to trade and duplication of control activities while protecting

~~the health of consumers and ensuring fair practices in the food trade~~, or whether some other mechanism is more appropriate for the circumstances.”

Section 5 – PROCESS STEPS

5.3 Step 3: Description of Importing Country NFCS Objectives

Description and evidence on how the importing country's NFCS meets the objectives

Canada supports deletion of paragraph 30, and believes the concept of reduced information needs based on experience, knowledge and confidence is captured under Step 5 Assessment Process, which indicates that “Experience, knowledge and confidence can assist in reducing the number of elements within the scope that need detailed assessment and therefore reduce the resources required to complete an assessment”.

~~“30— Information should only be required for those areas subject to a more detailed assessment (that is not for those areas covered by existing experiences, knowledge and confidence).”~~

Agenda Item 5

AGENDA ITEM 5: PROPOSED DRAFT GUIDANCE ON PAPERLESS USE OF ELECTRONIC CERTIFICATES CX/FICS 18/24/5

Canada supports the development and progress of the work on the proposed draft guidance on Paperless use of Electronic Certificates. Canada suggests that comments on the draft guidance should be specific to those issues that need to be resolved to provide the necessary guidance that will facilitate the use of electronic certification. Comments on other issues associated with existing guidance set out CAC/GL 38-2001 should be reviewed and prioritized as new work.

In the interest of consistency, Canada suggests that the term “electronic certificates” be used in the document. While the adjective “paperless” provides additional information about the ultimate vision related to electronic certification, it does not provide any additional clarity of the use of electronic certification systems. For example, a party may choose to print a copy of a certificate using the information that was transmitted electronically, either for convenience, or to meet specific importing country requirements.

Finally, the document would be enhanced with additional guidance that would allow importing countries that do not have electronic certificate systems to recognize electronic certificates as being equivalent to a signed paper certificate. The guidance should describe how the competent authorities of the importing and exporting could reach agreement on this principle and identify possible mechanisms to validate the authenticity of an electronic certificate such as the use of a certificate viewer.

Agenda Item 6

AGENDA ITEM 6: PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE ASSESSMENT AND USE OF VOLUNTARY THIRD PARTY ASSURANCES PROGRAMMES CX/FICS 18/24/6

Canada appreciates the opportunity to provide comments on the draft Principles and Guidelines. Canada is of the view that significant progress has been made on the document and further review would be useful to enhance clarity and minimize duplication in the document.

The terminology of “National Food Control System” (NFCS) is often used in the document, when referring to competent authorities' consideration of vTPA programmes to help achieve regulatory objectives. An NFCS is the sum of activities of various participants (competent authorities, FBOs, academia,) as per CAC/GL 82-2013. Since the purpose of this document is to provide guidance to competent authorities should they wish to take into consideration implementation of vTPA programmes by FBOs, it would be more accurate to use the terminology relevant to the role of the competent authority, such as “regulatory oversight”, “regulatory activities”, “regulatory objectives”, “competent authority”, as appropriate to the sentence under consideration, in lieu of “NFCS”. Examples of areas where terminology should be revised include Section A. Preamble, paragraph 10; Section E. paragraphs 12 and 12.b., Section F, paragraph 13; Section G, paragraph 14.

The draft principles and guidelines appear to be built on the premise that the vTPA owner is the principal provider of information to the competent authorities on FBOs, which would allow for risk-profiling of FBOs or

sectors. This is stated in a number of areas in the document, including paragraph 5 of the Preamble, Principle 3, and Section G.14.e. It is expected that a vTPA owner would be aware of the membership of an FBO to its programme and the overall conformity or non-conformity of an FBO, but detailed information on FBOs would generally lie with certification bodies and FBOs. Canada would appreciate clarifications from vTPA programme owners whether they would have sufficient data to share, to enable risk profiling and targeting of individual FBOs. This would help to clarify the draft document.

A: Preamble

Canada suggests including a paragraph to explain what vTPA programmes are in the preamble of the document, after paragraph 1. The following addition is proposed:

"vTPA programmes in the context of these guidelines are non-governmental assurance programmes which include specific requirements and have governance structure for certification and conformity assessment. The requirements contained in vTPA programmes may or may not reflect national or international standards. Participation of FBOs in these programmes is typically on a voluntary basis or on the basis of buyer-seller contractual agreements."

There would also be benefit in briefly identifying the various participants in vTPA programmes and their function, in the preamble of the document. These are:

- The vTPA programme owner, which develops and reviews the program;
- The FBO which decides to be a member of a vTPA programme;
- The certification bodies which audit FBOs against the vTPA programme requirements for conformity or non-conformity.
- The accreditation bodies which accredit the certification bodies.

A: Preamble

Paragraph 1

Canada proposes to revise the sentence as follows:

~~"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, m~~**Many FBOs opt to use quality assurance systems, including voluntary third-party assurance (vTPA) programmes to reduce supply chain risks and confirm food safety outcomes, or as a condition of buyer-seller contractual arrangements. FBOs' adoption of vTPA programmes may help them manage their operations and help them demonstrate that they have effective controls and procedures in place to manage the safety and quality of their products."**

Rationale: The sentence, as originally written, implies that FBOs adopt quality assurances systems, including vTPA, as a consequence of the obligation to demonstrate to competent authorities that they have effective controls in place. The revision clarifies the intent of the sentence, which is to indicate that FBOs' adoption of vTPA programmes is a voluntary business decision that may help FBOs achieve multiple objectives, including demonstration of compliance with regulatory requirements or if they are required by their buyers to adopts such programmes.

A: Preamble

Paragraph 3

Canada proposes revision of the last part of the sentence as follows, to clarify the intent of the document:

~~"...by illustrating the role it **they** could plays in helping FBOs demonstrate compliance~~ **with regulatory requirements."**

A: Preamble

Paragraph 4

Canada proposes replacing "approach" at the end of the sentence with "**objectives**".

Rationale: The objective of the competent authority should guide the approach that would be used in the assessment, including criteria and depth of the assessment.

B: Scope
Paragraph 7

Canada suggests revising the first sentence as follows:

“7. These guidelines are intended to assist competent authorities ~~within their national boundaries~~ in the effective assessment and transparent use of reliable vTPA programme information/data in support of their NFCS objectives.”

Rationale: These guidelines are intended to provide guidance to competent authorities to adjust regulatory oversight, which would apply to both domestic and imported products, hence, it is suggested to delete “within their national boundaries”, since this could be interpreted as applying only at the domestic level and not for products in trade.

B: Scope
Paragraph 8

Canada suggests revising this paragraph as follows:

“The guidelines do not ~~compel~~ **require or mandate** competent authorities to take account of vTPA programme outcomes nor ~~does it~~ **do they** recommend or mandate the use of vTPA information/data **by Competent Authorities or the use of vTPA Programmes** by FBOs. “

Rationale: The first revision is facilitate readability since the term “compel” is not commonly used; the second revision is editorial; and the 3rd revision is to clarify the intent of the sentence.

B: Scope
Paragraph 10

Canada suggests revising this paragraph as follows:

“The guidelines are not intended to apply to private standards that are **specific and unique to** ~~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 **Competent Authority.**”

Rationale: The purpose of the revision is to clarify the sentence, and to enhance accuracy (please see general comment on “NFCS” vs “competent authority”).

C: DEFINITIONS
Integrity

Canada proposes a definition of integrity that better reflects the intent of using the term "integrity" in the Draft principles and guidelines:

“**Integrity (dictionary): The condition of being unified or sound in construction. (Source: Oxford dictionary)**”

C: DEFINITIONS
Voluntary Third-Party Assurance Programme

Canada suggests revising the definition as follows:

“**Voluntary Third-Party Assurance Programme:** A non-governmental ~~or autonomous scheme~~ **programme** ~~comprising of the ownership of a standard that utilises national/international~~ which includes **quality and/or safety** requirements [standards]; a governance structure for certification ~~—~~ **conformity assessment** and ~~enforcement~~, and in which FBO participation is voluntary. [Source: new]”.

Rationale: A vTPA programme may or may not include standards that are similar to national or international standards. Only those programmes that include vTPA standards which are similar to or reflect national/international standards would be of interest to competent authorities. This would be a criterion that

competent authorities would use for the evaluation of vTPA programmes with respect to their benefit to regulatory oversight. This criterion is already captured in Section F, Standard Setting Process, point 4). Further, the term "enforcement" is generally used in the regulatory context. In the context of vTPA, it would be more appropriate to use conformity assessment.

D: PRINCIPLES

Principle 5

Principle 5 is unclear as currently written and seems to contradict the text in Section G, Process Considerations, Paragraph e. It is suggested that the 24th session of the CCFICS further discuss the intent of this principle or to delete it.

D: PRINCIPLES

Principle 6

Canada suggests revising the principle as follows:

"Competent authorities should make their approach to the use of **information/data from** vTPA programmes, including the assessment process and criteria publicly available in line with Principle 3 of CAC/GL 82-2013".

Rationale: Canada is of the view that competent authorities do not "use" vTPA programmes. FBOs choose to use vTPA programmes as a business decision. The competent authority could consider information/data from assessed vTPA programmes.

E. ROLES AND RESPONSIBILITIES

Competent Authorities

Paragraph d.

Canada suggests revising paragraph d. as follows:

"d. Need to clearly describe **how they take into consideration the implementation** the use of a vTPA programme ~~within their NFCS~~ **by FBOs in their regulatory oversight activities.**"

Rationale: Competent authorities do not "use" vTPA programmes. FBOs choose to use vTPA programmes as a business decision or based on buyer seller contractual agreements. Further, a "NFCS" is broader than the role of the competent authority, as indicated in Canada's general comments. Hence, the proposed revision more accurately reflects how competent authorities would take into consideration vTPA programmes.

E. ROLES AND RESPONSIBILITIES

Food Business Operators (FBOs)

Paragraph d.

Canada suggests to delete this point ("d. Owns the information/data generated by the vTPA programme") or to move it under Section F, Criteria.

Rationale: The bullet, as written, seems to dictate ownership of the data and is not about roles and responsibilities of FBO. Ownership of the data is a matter between third parties: the FBO, the certification body and the vTPA scheme owner. If ownership of the data is a criterion for consideration by regulators when they determine whether to take into account a FBO's vTPA programme in their regulatory activities, then this point should be moved to Section F, and its relevance should be explained.

E. ROLES AND RESPONSIBILITIES

Voluntary Third Party Assurance Owners

Canada questions whether it is appropriate for this Codex document to specify the roles and responsibilities of vTPA owners. In Canada's view, this sub-section on the roles and responsibilities of vTPA owners should be deleted, and the elements in this sub-section should be integrated in section F, which lists the criteria to be considered by competent authorities in determining whether to take into consideration a certain vTPA programme.

G: REGULATORY APPROACHES FOR THE USE OF vTPA INFORMATION/DATA

Process Considerations

Paragraph e.

Canada suggests revising paragraph e. by splitting this paragraph into two ideas:

“e. Competent authorities may choose to set up regular meetings, or other communication channels, with the vTPA owner in order to analyse or seek clarifications on the information/data shared to look for trends;

e(bis): The Competent Authority may consider the need for interventions based on its analysis of data shared by vTPA owners.”

Rationale: It would be important to keep a clear distinction between the role of the competent authority the role of vTPA owners. There are 2 concepts in this sentence:

1) analysis or clarification of the data; and, 2) consider the need for and type of intervention based on the data. While the first idea could be done in conjunction with vTPA owners in order to ensure clarity in interpretation of the data and avoidance of misunderstandings, the second concept would be addressed separately by the competent authority or the vTPA owner and not in close collaboration in order to avoid conflicts of interest. The competent authority could consider regulatory or policy actions based on the data analysis. The vTPA owner could consider adjustments to its vTPA programme. The intervention of a competent authority is strictly limited to the regulatory space (i.e. informing regulatory oversight), and not mandating changes to the vTPA programme or its requirements. Further, should a competent authority consider the need for an intervention based on information/data received, it is not expected that it would do it with the vTPA owner.

G: REGULATORY APPROACHES FOR THE USE OF vTPA INFORMATION/DATA

Policy Options

Canada is of the view that a number of points in this section (points b, e, f, g, i, j) are redundant and reiterate concepts captured in earlier parts of the document. Other points are better placed elsewhere in the document; in particular, points a. and d. are principles and should be moved to Section D, Principles, while point c. should be moved to section F.