

CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture
Organization of the
United Nations



World Health
Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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REPORT OF THE 24TH SESSION OF

THE CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Brisbane, Australia

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SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para(s)
Members CCEXEC77 CAC42	Adoption	Draft Principles and guidelines for the assessment and use of voluntary Third-Party Assurance (vTPA) programmes	N27-2017	5	53 and App. III
CCEXEC77 CAC42 EWG Members CCFICS25	Approval/ Drafting/ Comments	Project document for new work on the consolidation of Codex Guidelines related to equivalence		1,2,3	32 (ii) and (iii) (b)
CCEXEC77	Information	Outcome of the assessment of the experimental approach for Intersessional PWGs (trial) combined with webinar technology			77 - 78
CAC42, CCGP and other Committees		Note the ongoing discussions in CCFICS on the food integrity food authenticity and food fraud			60
EWG/PWG CCFICS25	Drafting Discussion	Proposed Draft Guidelines on recognition and maintenance of equivalence of National Food Control Systems (NFCS)		2/3	32 (i) and (iii) (a)
		Proposed Draft consolidated Codex Guidelines related to equivalence		1,2,3	32 (ii) and (iii) b
		Proposed Draft Guidance on paperless use of electronic certificates (Revision of <i>Guidelines for Design, Production, Issuance and Use of Generic Official Certificates</i>)		2/3	39
		Draft Principles and guidelines for the assessment and use of voluntary Third-Party Assurance (vTPA) programmes		6/7	53 (ii) and App. III
USA, EU, Iran, EWG CCFICS25	Drafting Discussion	Discussion paper on role of CCFICS with respect to tackling food fraud in the context of food safety and fair practices in food trade			57 - 58
Australia/Canada CCFICS25	Drafting Discussion	Review and update Appendix A - the list of emerging global emerging issues			68

LIST OF ABBREVIATIONS

CAC	Codex Alimentarius Commission
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCFICS	Codex Committee on Food Import and Export Inspection and Certification Systems
CCGP	Codex Committee on General Principles
CL	Circular Letter
CRD	Conference Room Document
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
CXG	Codex Guidelines
IPPC	International Plant Protection Convention
NFCS	National Food Control Systems
OIE	International Organisation for Animal Health
PWG	Physical Working Group
vTPA	Voluntary Third-Party Assurance
WCO	World Customs Organization
WHO	World Health Organization
WTO	World Trade Organization
WG	Working Group

INTRODUCTION

1. The Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) convened its twenty-fourth session, in Brisbane, Australia, from 22 to 26 October 2018, at the kind invitation of the Government of Australia. Ms Fran Freeman, First Assistant Secretary, Exports Division, Department of Agriculture and Water Resources, Australia, chaired the Committee, assisted by Mr Tom Black, Director, Exports Division, Department of Agriculture and Water Resources, Australia. Forty-one Member countries, one Member organization and four observer organizations attended the session. A list of participants is contained in Appendix I.

OPENING OF THE SESSION¹

2. A local indigenous man, Mr Douglas James, performed a traditional smoke-signal ceremony to welcome participants to Brisbane.
3. The Chairperson welcomed all participants and the presence of the three Vice-Chairpersons of the Codex Alimentarius Commission, underscoring Australia's commitment to Codex as an inclusive, transparent and consensus-based organization. Commending her predecessor Mr Greg Read's valuable contributions over many years, she acknowledged how honoured she was to assume the responsibilities of chairing CCFICS and highlighted the strategic importance of the Committee's outcomes to consumers, food-traders and governments alike.
4. Vice-Chairperson of the Codex Alimentarius Commission Mr Steve Wearne (United Kingdom) also addressed the Committee, commending its application of innovative technological approaches to expedite work, and underscoring the strategic importance of facilitating broad international participation and developing generally applicable guidance to ensure that Codex remained globally relevant.

Division of competence²

5. The Committee noted the division of competence between the European Union (EU) and its member States, according to paragraph 5, Rule II, of the Rules of Procedure of the Codex Alimentarius Commission.

ADOPTION OF THE AGENDA (Agenda item 1)³

6. The Committee adopted the agenda.

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND ITS SUBSIDIARY BODIES (Agenda item 2)⁴

7. The Committee took due note of the matters referred for information and agreed to consider those referred for action under the relevant agenda items.
8. The representatives of Brazil and Chile welcomed the decision of the Commission to refer the question of the inclusion of examples in Codex texts to the Codex Committee on General Principles (CCGP) for consideration and looked forward to the outcome of that work.

INFORMATION FROM FAO AND WHO AND OTHER INTERNATIONAL ORGANIZATIONS RELEVANT TO THE WORK OF CCFICS (Agenda item 3)⁵

9. The Chairperson drew the attention of the Committee to the reports containing information regarding the activities of the Food and Agriculture Organization of the United Nations (FAO), the International Plant Protection Convention (IPPC), the International Organisation for Animal Health (OIE), the World Customs Organization (WCO) and the World Health Organization (WHO) relevant to the work of CCFICS.

Report of the World Customs Organization

10. The Observer of the WCO highlighted its initiatives relating to paperless certification and digital processing, interoperability and the facilitation of safe and legitimate trade, in particular the WCO Data Model and Single Window Compendium.

¹ Opening remarks (CRD17).

² Division of competence between the European Union and its Member States (CRD1).

³ CX/FICS 18/24/1 Rev.1

⁴ CX/FICS 18/24/2; CX/FICS 18/24/2 Add.1; Comments of India (CRD9).

⁵ CX/FICS 18/24/3; CX/FICS 18/24/3 Add.1; CX/FICS 18/24/3 Add.2.

Report on the activities of the Food and Agriculture Organization of the United Nations

11. The delegation of Japan expressed concern that the formulation of paragraph 20 of CX/FICS 18/24/3 may be inappropriate and misleading, and that the document did not explain the rationale for or background of its development, and requested clarification in this regard.

Conclusion

12. The Committee thanked FAO, IPPC, OIE, WCO and WHO for the information provided.

PROPOSED DRAFT GUIDANCE ON THE USE OF SYSTEMS EQUIVALENCE (Agenda item 4)⁶

13. New Zealand, as Chair of the EWG, introduced the item and detailed the process followed by the EWG, which had held two intersessional Physical Working Group (PWG) meetings using webinar technology in addition to conventional email-based discussions. He drew the Committee's attention to the recommendations of the EWG and proposed that the Committee first consider the proposed draft guidance document before discussing recommendations for advancing the work on equivalence.
14. The Chairperson informed the Committee that agenda item 4 was closely related to agenda item 10.1, "Discussion paper proposing to consolidate and modernize guidance on the use of equivalence", and that the three EWG Co-Chairs, Chile, New Zealand and the United States of America, had submitted CRD12, containing a proposal for the amendment of the approved project document for the ongoing work on guidance on the use of system equivalence. CRD12 was intended to address the recommendations related to the handling of additional work as stated in the EWG report. She supported the proposal of the EWG Chair to first consider the proposed draft guidance and then CRD12.
15. The Co-Chairs commended New Zealand's leadership, acknowledged the need for further work and supported the Chair's proposed approach to the discussion of the EWG report.

Discussion

Proposed draft guidelines on recognition and maintenance of equivalence of National Food Control Systems (NFCS)

16. The Committee, taking into account comments submitted, reviewed the current draft guidelines paragraph by paragraph, made editorial amendments and agreed to provide general comments to inform the further drafting of the proposed guidelines:

Section 1 — Preamble/Introduction

17. It was clarified that the term "level of protection" applied to the SPS Agreement and not the TBT Agreement, thus "TBT" should be deleted from footnote 3.

Section 3 — Definitions

18. The Committee agreed that the existing CCFICS definitions be used and that new definitions should be concise and exclude principles. There was a need to examine the use of terms for consistency. The Committee recommended that the need for the use of the terms [Equivalence] and [System Equivalence] be further considered, and therefore placed them within square brackets. Other terms such as "assessment of systems equivalence" should be used across the text for consistency in case of "equivalence of systems assessment".

Section 4 — Principles

19. It was clarified that in general, the principles set out under section 4 provided a good road map to the implementation of recognition and maintenance of equivalence of National Food Control Systems (NFCS); and that they should not be in contradiction of the *Principles and Guidelines for National Food Control Systems* (CXG 82-2013); *Principles and guidelines for the exchange of information between importing and exporting countries to support the trade in food* (CXG 89-2016).

⁶ CX/FICS 18/24/4; Comments of: Colombia, Cuba, Ecuador, Egypt, Guatemala, Honduras, Indonesia, Jamaica, Japan, Kenya, Nicaragua, Norway, Paraguay, Philippines, Sri Lanka, Zambia and FAO (CX/FICS 18/24/4 Add.1); Comments of EU, Malaysia and African Union (AU) (CX/FICS 18/24/4 Add.2); El Salvador (CRD6); Papua New Guinea (CRD7); Nigeria (CRD8); and India (CRD9); Amendment to Project Document for New Work on Guidance on the Use of Systems Equivalence (CRD12); and Comments of: Thailand (CRD 13); Ghana (CRD16).

Section 5 – Process Steps

20. One EWG Co-Chair noted the significant overlap between Section 5 and existing Codex texts on equivalence (e.g. *Guidelines for the Development of Equivalence Agreements Regarding Food Imports and Export Inspection and Certification Systems* (CXG 34-1999) and *Guidelines on the Judgement of Equivalence of Sanitary Measures associated with Food Inspection and Certification Systems* (CXG 53-2003).
21. The terms used in the text should be clear and consistent and may need further explanation (e.g. “recognition” as used in the SPS Agreement vs. “determination” as used in *Guidelines on the Judgement of Equivalence of Sanitary Measures associated with Food Inspection and Certification Systems* (CXG 53-2003); “initial discussion” vs. “preliminary consideration”).
22. Which country should take the lead in all relevant steps, including preliminary consideration, should be clarified. Decision criteria should be established in a cooperative manner between the importing and exporting countries. The decision criteria (see Step 2) could consider the FAO/WHO Food Control System Assessment Tool and could be added as a separate questionnaire.
23. The need or otherwise for examples (e.g. possible indicators) in the current draft guidelines was noted, as were concerns raised regarding how examples should be used in CCFICS texts. It was noted that CCGP would address the use of examples in Codex texts and any guidance it may produce should be followed.
24. A delegation noted that the decision-making process should be transparent and take into account the level of development of different countries.
25. The guidelines should not put a heavy burden on the importing country, in particular to provide evidence on how its NFCS met the objectives. Figure 1 should be revised after redrafting to consider the need for additional information in the steps (e.g. reasons for non-equivalence and how to overcome these) and possible simplification, and ensure that it was consistent with the steps in the text.

New project document

26. New Zealand, as Chair of the EWG, explained that the three Co-Chairs were in agreement on working towards merging the current draft standard once finalized with the other two existing Codex guidelines related to equivalence (i.e. *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CXG 34-1999) and the *Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CXG 53-2003)) and making any relevant consequential amendments.
27. There was an exchange of views among delegates regarding the process and the next steps of the complex work related to consolidating Codex guidelines on equivalence, emphasizing the importance that a consolidated document be practical and avoid overlap and duplication. Further clarification was required as to whether the new project document should include the ongoing work on system equivalence or only address the consolidation of the new guidelines with the existing Codex guideline on equivalence.
28. The Codex Secretariat informed the Committee that the project document for the work under way stated that “as a consequence of this new work, modification of existing texts might be necessary”. Consolidation could therefore be considered as covered by the current project document. However, if the Committee wished to revise the current project document or develop a new one to expand the work and clarify the process, then the new work proposal should be submitted to CAC for approval.
29. Several delegations emphasized the need for clarity and transparency, including for those countries not present at CCFICS24, and requested a new project document to address the consolidation part that would take place following the adoption of the current draft guidelines on system equivalence.
30. The Chairperson noted the need for transparency and that erring on the side of caution would mean asking for CAC approval of a new project document.
31. The Committee agreed to establish an in-session working group to prepare a draft project document for new work on consolidating Codex guidelines on equivalence. It was proposed that an EWG would seek to complete the guidelines on system equivalence in parallel with commencing the new work on the consolidation of all equivalence-related guidance, in recognition of the strong linkage between the two. The need to hold a PWG immediately prior to CCFICS25 to progress the ongoing work in line with approved timelines was noted.

Conclusion

32. The Committee agreed to:
 - (i) return the proposed draft guidelines on recognition and maintenance of equivalence of National Food Control Systems to Step 2 for redrafting to take into account the comments made and/or submitted at CCFICS24, then circulation for comments at Step 3 with the intention to advance the draft guidance to adoption in line with the timeframe in the original project document (REP17/FICS, Appendix III);

- (ii) start new work on updating and consolidating Codex guidelines related to equivalence (Appendix II) and to submit the project document for approval at CAC42; and
- (iii) re-establish the EWG, chaired by New Zealand, co-chaired by Chile and the United States of America and working in English only, with the possibility of convening physical working groups, including immediately prior to CCFICS25, to:
 - a. continue to develop the draft guidelines on recognition and maintenance of equivalence of NFCs for circulation for comments at Step 3 and consideration at CCFICS25; and
 - b. commence the consolidation of all Codex guidance related to equivalence (Appendix II) and subject to approval by CAC 42, prepare a proposal for circulation for comments at Step 3 and for consideration to CCFICS25.

PROPOSED DRAFT GUIDANCE ON PAPERLESS USE OF ELECTRONIC CERTIFICATES (REVISION OF THE GUIDELINES FOR DESIGN, PRODUCTION, ISSUANCE AND USE OF GENERIC OFFICIAL CERTIFICATES – CXG 38-2001) (Agenda item 5)⁷

33. The representative of the Netherlands, as Chair of the EWG, introduced the report, recalling that discussion on paperless certification had been under way since CCFICS21, in 2014, and emphasizing that the draft guidance before the Committee, based on *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* (CXG 38-2001), was not intended to serve as an implementation manual for paperless certificates, but as a tool to help build confidence and enable countries to go paperless. The draft guidelines elaborated in the main text and Annex II were basic, took into account current paper-based models and existing experience in paperless, and reflected the diverse national circumstances among Codex Member countries. He proposed that the Committee first consider proposed draft Annex II, followed by the proposed revision to the main text of CXG 38-2001.
34. The representative of Australia, as Co-chair of the EWG, commended the significant progress made in the EWG and reaffirmed the proposal that the Committee first consider Annex II with a view to clarifying some issues which would in turn inform the revision of the main text of the *Guidelines for design, production, issuance and use of Generic Official Certificates – (CXG 38-2001)*.

Discussion

35. The Committee made extensive editorial and technical comments on the proposed draft Annex II (Requirements, responsibilities and data model for paperless exchange of official certificates) then decided to refocus its discussion on broader aspects so as to provide guidance to the EWG in moving forward with the work effectively and building confidence among developing and developed countries. The Committee noted the following potential focus areas for future work:
- a. While the text was generally acceptable, it should be revised in line with established Codex style to ensure consistency and clarity, and remove repetition. The general guidance should highlight general principles and be written in plain language readily understood by users, avoiding excessive technical detail.
 - b. Provisions to clarify the following aspects: the paper-to-paperless transition; validation of certificate authenticity; data protection, retention and confidentiality; the handling of electronic certificates in situations such as export/import rejection and/or redirection/re-consignment of goods in transit; and the handling of invalid certificates, etc.
 - c. References to relevant WCO work and tools should be added to Annex II.
 - d. In the light of the intersection between competent authorities and the Single Window System, the necessity to address the elements of the different systems used by countries and contain additional detail depending on system so as to provide flexibility to countries.
 - e. Consider definitions consistent with *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* (CXG 38-2001).
 - f. The work should focus on developing guidelines for e-certificates and resolving issues that would facilitate the paperless use of e-certificates.

⁷ CX/FICS 18/24/5 Rev.1; Comments of: Colombia, Cuba, Ecuador, Egypt, Guatemala, Guyana, Honduras, Indonesia, Jamaica, Kenya, New Zealand, Nicaragua, Norway, Paraguay, Philippines, United States of America and WCO (CX/FICS 18/24/5 Add.1); EU and AU (CX/FICS 18/24/5 Add.2); El Salvador (CRD6); Papua New Guinea (CRD7); Nigeria (CRD8); India (CRD9); Australia (CRD11); Canada (CRD15); and Ghana (CRD16).

36. In response to a query regarding the status of references associated with the source of definitions, the Codex Secretariat clarified the references were often included in texts during drafting to indicate the source of a definition but removed once finalized. However, such information could be retained in the final text if so required, for example, as a footnote, with a clear articulation of its relationship to the body text. It was noted that work was under way by the Codex Secretariat on the harmonization of the use of references across Codex committees.
37. The EWG Chair and Co-Chair underscored the high level of participation throughout the drafting process, and clarified that the relevant work the IPPC and OIE had been taken into account. They welcomed further input and reiterated their keen interest in ultimately attaining guidance in this important area that would be useful to the Codex community.
38. The Committee commended the dedicated efforts of the EWG Co-Chairs and, noting the difficulties associated with drafting, proposed that a PWG be held immediately prior to CCFICS25, with a view to reaching Step 5/8 at CCFICS25. That proposal was supported by several delegations from developing countries.

Conclusion

39. The Committee agreed to:
- (i) return the proposed draft guidance on paperless use of electronic certificates (revision of the *Guidelines for design, production, issuance and use of Generic Official Certificates* (CXG 38-2001)) to Step 2 for redrafting taking into account comments received in writing and the discussion at CCFICS24;
 - (ii) re-establish the EWG, chaired by the Netherlands, co-chaired by Australia and working in English only, to continue the drafting of the proposed draft guidance on paperless use of electronic certificates (revision of the *Guidelines for design, production, issuance and use of Generic Official Certificates* (CXG 38-2001)) for circulation for comments at Step 3 and consideration at CCFICS25; and
 - (iii) convene a PWG, chaired by the Netherlands, co-chaired by Australia, working in English, French and Spanish, and meeting immediately prior to CCFICS25 to consider the report of the EWG and any comments thereto and prepare recommendations for the plenary session.
40. The Chairperson encouraged all members and observers to participate in both the EWG and the PWG with a view to expediting the work.

PROPOSED DRAFT GUIDANCE ON REGULATORY APPROACHES TO THIRD PARTY ASSURANCE SCHEMES IN FOOD SAFETY AND FAIR PRACTICES IN THE FOOD TRADE (Agenda item 6)⁸

41. As Chair of the EWG on draft principles and guidelines for the assessment and use of voluntary third-party assurance (vTPA) programmes, the United Kingdom summarized the relevant background of this item. The United Kingdom detailed the work undertaken since CCFICS23 and introduced the draft for the Committee's consideration at Step 3, underscoring that it sought to incorporate sufficient flexibility to reflect the diverse needs, motivations and capabilities among Codex Member countries regarding the use of vTPA to inform and complement their NFCSs but did not compel Competent Authorities to take this approach.
42. The EWG Co-Chairs, Canada and Mexico, further welcomed the broad and active participation of many stakeholders throughout the intersessional work via electronic and physical modalities alike, and looked forward to the plenary's input into the draft guidance.
43. The Committee held a general discussion followed by a preliminary technical discussion on the proposed draft guidance with a view to determining whether to hold an in-session working group.

Discussion

General considerations

44. The Committee commended the valuable work of the EWG, in particular its piloting of innovative approaches, including web-based virtual-meeting technology at the PWGs, to facilitate broader participation and inclusively expedite work on the draft text in both English and Spanish, in keeping with the Codex Strategic Plan.
45. Delegations emphasized the critical importance of Codex work on vTPA to advise governments on the potential value of the approach and ensure the integrity and competence of such systems should they be adopted. Several delegations, including one Observer organization, noted that vTPA could help countries better focus

⁸ CX/FICS 18/24/6; Comments of: Colombia, Ecuador, Egypt, Guyana, Indonesia, Jamaica, Japan, New Zealand, Norway, Philippines, United States of America and International Union of Food Science and Technology (CX/FICS 18/24/6 Add.1); EU, FAO and AU (CX/FICS 18/24/6 Add.2); Papua New Guinea (CRD7); Nigeria (CRD8); India (CRD9); Nicaragua (CRD10); Australia (CRD11); Thailand (CRD13); Canada (CRD15); and Ghana (CRD16).

their resources on risk-based inspections, deliver acceptable protection to consumer health, and bridge gaps when importing and exporting countries' food-safety assurance requirements and capacities were not aligned.

46. Several delegations, while recognizing that vTPA could enhance risk management, cautioned that it must not replace official government inspections or that its use become obligatory. They noted that the draft guidance could be improved by better articulating specific methods for information management to meet competing demands.
47. In response to comments and queries regarding the generation, ownership and use of data relating to individual food business operators (FBOs), the EWG Chair confirmed that, while such data generated by vTPA programmes belonged to FBOs, experience had demonstrated that the aggregate data subsequently generated by vTPA programme owners could valuably inform NFCSSs.
48. One delegation requested that presentations on the use of vTPA given during the PWGs and the CCFICS24 side event be kept as Codex information documents for the benefit of the Committee.

Specific considerations

49. Following a preliminary discussion on the preamble, scope and principles, the Committee agreed, in order to resolve the substantial editorial and technical comments, to the Chairperson's proposal to convene an in-session working group led by the three EWG Co-Chairs.
50. The plenary considered the proposed draft guidance document as revised by the in-session working group and made further editorial amendments for clarity and consistency, including to the Definitions section.
51. The Committee noted that, most issues having been resolved and a limited number of paragraphs placed in square brackets for further consideration by the Committee, the proposed draft guidance was ready to be advanced in the Codex Step process.
52. The Committee discussed whether to convene a PWG immediately prior to CCFICS25.

Conclusion

53. The Committee agreed to:
 - (i) forward the proposed draft principles and guidelines for the assessment and use of voluntary third-party assurance programmes (see Appendix III) to CAC42 for adoption at Step 5; and
 - (ii) establish an EWG, with the possibility of convening physical working groups, including immediately prior to CCFICS25, chaired by the United Kingdom and co-chaired by Canada and Mexico, working in English and Spanish, to consider comments submitted at Step 6 as well as all outstanding issues, including comments made at CCFICS24.

DISCUSSION PAPER ON FOOD INTEGRITY AND FOOD AUTHENTICITY (Agenda item 7)⁹

54. The representative of the EU, as Co-Chair of the EWG on Food Integrity and Food Authenticity, introduced the discussion paper, which contained definitions of food integrity, food authenticity, food fraud and Economically Motivated Adulteration (EMA); provided an analysis of how different CCFICS texts took into account the issues around food integrity and authenticity; noted a number of areas where further work may be justified; and presented recommendations for the Committee's consideration based on inputs from the EWG.
55. The Committee thanked the Islamic Republic of Iran for leading the EWG.

Discussion

56. The Committee agreed on the important cross-cutting nature of issues relating to food integrity and food authenticity and held a wide-ranging discussion in which many delegations engaged. There was recognition that CCFICS may have a role to play in this area. The Committee noted the following views:
 - The need for horizontal guidance should be carefully considered since several existing Codex texts already addressed relevant issues.
 - Any future CCFICS work in this area should be refined to avoid duplication with existing texts and well defined within the CCFICS mandate, taking into account the discussion held in 2008 on the prevention of intentional contamination of food.

⁹ CX/FICS 18/24/7; Comments of: Cuba, EU, Philippines, Thailand, AU, the e International Food Authenticity Assurance Organization and WCO (CRD2); El Salvador (CRD6); Papua New Guinea (CRD7); Nigeria (CRD8); and India (CRD9).

- Further consideration of relevant definitions may be needed and CCFICS could consider seeking advice from the Commission in that regard, including on which Codex body or bodies had the expertise. Some delegations considered that this could be done following initial consideration by the EWG.
- Other Codex committees were awaiting the outcome of the discussion in CCFICS on food integrity and food authenticity.
- CCFICS could elaborate a range of guidance, including: what types of risks competent authorities should consider when designing control programmes; exchange of information and cooperation between different authorities at the national and international levels; communication with stakeholders and the general public on food fraud incidents; and measures targeting food fraud.

Conclusion

57. The Committee agreed to establish an EWG, chaired by the United States of America and co-chaired by the EU and the Islamic Republic of Iran, working in English only, to:
- (i) further consider the role of CCFICS with respect to tackling the challenge of food fraud in the context of food safety and fair practices in the food trade; and
 - (ii) conduct a comprehensive analysis of existing relevant Codex texts within and outside of CCFICS to avoid overlapping or intrusion onto the mandate of other Codex general subject or commodity committees, noting that a number of related Codex texts existed within and outside of CCFICS.
58. Should the EWG identify gaps in existing CCFICS texts, it may: propose new work, within the scope and mandate of CCFICS, for consideration at CCFICS25; consider what definitions need to be developed; and propose definitions that may be needed in any future project document, consistent with existing Codex texts, scope and mandate for use in prospective project documents as appropriate.
59. The results of the discussion and any proposals for new work in CCFICS would not preclude other Codex Committees from initiating new work that may complement the work of CCFICS falling within the scope and mandate of their respective Committees.
60. The Committee also agreed to inform CCEXEC, the Commission and its subsidiary bodies, including CCGP, of its ongoing discussions on this subject.

DISCUSSION PAPER ON CONSIDERATION OF EMERGING ISSUES AND FUTURE DIRECTIONS FOR THE WORK OF CCFICS (Agenda item 8)¹⁰

61. Australia introduced the discussion paper prepared in collaboration with Canada, recalling the topic had been under consideration since CCFICS 20 (2013), with the objectives of facilitating forward-looking strategic discussion on emerging global issues, and conducting a regular horizon-scanning exercise to identify potential future issues, challenges and advances. The intent was to ensure the Committee was well positioned to consider new work or revise Codex standards, and members well prepared to contribute to such discussions. It was envisaged for this to be a standing item on the CCFICS agenda to identify and prioritize its long-term work strategy.
62. The Committee thanked Australia for having led the work and consolidated its various aspects in the document before the Committee.

Discussion

63. The Committee exchanged views on the approach presented in the discussion paper and noted the following proposals:
- a. CCFICS should consider examining wider issues e.g. the use of CCFICS texts by countries in line with the Codex Strategic Plan; how CCFICS could contribute to relevant Sustainable Development Goals; how CCFICS work is related to other relevant FAO/WHO work.
 - b. The prioritization criteria needed further clarification. The need to update the information used needed to be taken into account.
 - c. Appendix A (Emerging global issues), should be kept up-to-date and should indicate the version when it was prepared. Appendices B (Framework for the preliminary assessment and priority areas) and C (Outline for New work proposals) needed further clarification and consideration. In case of Appendix B, the scoring system was not clear especially the distinction between low, medium and high in situations

¹⁰ CX/FICS 18/24/8; Comments of: Papua New Guinea (CRD7); and Nigeria (CRD6).

when multiple proposals had been received. Appendices B and C should to be piloted in the first instance.

64. It was clarified that Appendix B and C were intended to assist in prioritization only and their use was not compulsory; and that they could be used where there were multiple proposals.
65. A delegation proposed that CCFICS should consider establishing a mechanism like that in CCFH for receiving and evaluating proposals. Such a mechanism would involve the Codex Secretariat issuing a Circular Letter (CL) requesting for Proposal for new work; and that each session, CCFICS would evaluate and rank the proposals in order of priority.
66. It was further clarified that Appendix A contained the list of emerging global issues that could be analysed to inform the future work of CCFICS.
67. Regarding the request from CCEXEC75 on the need for guidance similar to that under development by CCFH on the management of (micro)biological foodborne crises/outbreaks, the Committee noted that the existing *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CXG 19-1995) and the *Principles and Guidelines on National Food Control Systems* (CXG 82) could be used to prepare for and manage such situation, and agreed to inform CCEXEC that CCFICS will await the results of the discussion at CCFH on this matter, before having further discussion on this topic.

Conclusion

68. The Committee agreed to:
 - (i) consider Appendix A (Emerging global issues) as a standing document under the agenda on “emerging issues and future direction of CCFICS”, noting the need for analysis and periodic update;
 - (ii) rotate the custodianship of Appendix A commencing at CCFICS25 through members on a meeting-by-meeting basis;
 - (iii) review the list included in Appendix A at CCFICS25 (2020);
 - (iv) pilot the application of the prioritization tool (Appendix B), and the tool assisting members drafting a proposal for new work for consideration by CCFICS (Appendix C), on a trial basis, and revisit these Appendices at CCFICS25; and
 - (v) await the outcome of CCFH50 (2018) discussion on guidance on the management of (micro)biological foodborne crises/outbreaks before embarking upon a discussion on this topic within CCFICS.

ASSESSMENT OF THE EXPERIMENTAL APPROACH FOR INTERSESSIONAL PWGS (Agenda item 9)¹¹

69. Australia introduced the paper, recalling that two PWGs had been held, in Santiago, Chile, and Edinburgh, United Kingdom, and had incorporated the experimental approach of using webinar technology to provide for face-to-face interaction, facilitate the participation of countries, and promote inclusiveness. The approach generated valuable experience and lessons learned, and should be supported.
70. Chile, as Co-Chair of the PWG, commended Australia, the United Kingdom and the professional team involved in setting up the systems used by the PWG; noted that fewer countries than expected had remotely participated and that a number of issues (e.g. the number of countries/people that managed to connect; duration of connection, reasons for not connecting/participation) required further examination through data and information collection; and highlighted some of the technical challenges experienced i.e. occasional breakages in the Spanish channel.
71. The United Kingdom, as Co-Chair of the PWG, noted that the valuable lessons learned from the Chilean experience had greatly contributed to the success of the Edinburgh PWG.

Discussion

72. Several delegations welcomed the initiative of integrating webinar technology into PWGs as an innovative process that had generally increased participation, and could serve as a useful tool for future meetings. Webinars enhanced access, inclusiveness and participation by providing an opportunity for countries to participate remotely, with significant cost savings in terms of travel, thereby remaining fully up-to-date on the progress of discussions to inform national preparations for the subsequent plenary session.
73. Some delegations noted that the document (CX/FICS 18/24/9) may not have clearly reflected all challenges encountered during the trial to allow for better assessment of participation and effectiveness. It was also noted that experience had varied among countries. Challenges encountered in the use of the technology included:

¹¹ CX/FICS 18/24/9; Comments of: AU (CRD4); Nigeria (CRD8).

some technical issues; the social dimension (remote participants missing out on informal discussions during breaks); situational awareness (lack of clear identification of participants in the room, lack of clarity on when to intervene); global time-zone differences; and excessive length of sessions/computer fatigue.

74. It was unclear why more countries had not participated in the PWG webinar pilot. Analysis could be conducted on why countries were not able to connect/or participate in the webinars, and time management during meetings could be improved.
75. One delegation raised the separate issue that developing countries, especially in the CCAFRICA region, faced challenges in using the Codex Online Commenting System (OCS), noting that it seemed rather complicated to use.
76. The Codex Secretariat drew attention to its significant capacity-building initiatives to support participation in Codex work via online tools, recalling the four recently conducted regional training workshops on the use of Codex online tools, including the OCS, Online Registration System and the EWG platform, and noting that further such workshops would be held soon. Besides in-person workshops, the Codex Secretariat also offered remote-online training on the use of Codex webtools, via webinar or skype. Members were encouraged to request additional online training on such tools.

Conclusion

77. The Committee agreed to inform CCEXEC that:
- (i) webinar technology had the potential to enhance participation in and the inclusiveness of Codex meetings and that challenges and/or lessons learned from this pilot exercise should be taken into account when considering its deployment in Codex committee work; and
 - (ii) analysis was required to better understand the barriers for participation and how to overcome them.
78. The Committee recommended that Codex continue to explore the challenges and advance the possible use of webinar technology in its work.

OTHER BUSINESS (Agenda item 10)

Discussion Paper Proposing to Consolidate and Modernize Guidance on the Use of Equivalence (Agenda item 10.1)¹²

79. The Chairperson recalled that the Committee had considered this matter under item 4.

DATE AND PLACE OF THE NEXT SESSION (Agenda item 11)

80. The Chairperson informed the Committee that its twenty-fifth session was tentatively scheduled to be held in Australia from 27 April to 1 May 2020, with final arrangements subject to confirmation by the Host Government in consultation with the Codex Secretariat.

¹² CX/FICS 18/24/10; Comments of: the Philippines and AU (CRD5); El Salvador (CRD6).

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Appendix II

**PROJECT DOCUMENT FOR NEW WORK ON
THE CONSOLIDATION OF CODEX GUIDELINES RELATED TO EQUIVALENCE****1. Purpose and scope of the proposed new work**

The purpose of the work is to consolidate all equivalence guidelines to provide clear, consistent and useful guidance to countries considering the use of any form of equivalence. The scope of the consolidated guidelines will cover equivalence with respect to the protection of the health of consumers and ensuring fair practices in the food trade. They will include the process to be followed for considerations of equivalence for a specifically identified measure or set of measures as well as the National Food Control Systems (NFCS) in whole or the relevant part. It would also include guidance on how any such recognition of equivalence may be formalized in an agreement or arrangement. This work builds upon the Committee's ongoing work developing guidelines on the use of system equivalence, which will continue through to adoption, noting the Committee was also tasked to consider consequential modifications of existing work that may be necessary.

2. Relevance and timeliness

Consolidation of all guidelines related to equivalence (*Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CXG 34-1999) , *Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CXG 53-2003) and the results of the ongoing (job number N25-2017) work on guidance on the use of system equivalence) will improve the clarity of the guidance for countries considering the use of any or all forms of equivalence and ensure there is appropriate consistency as to which process to follow in different situations. This will be a more productive use of the time of the Committee than just considering minor consequential amendments to the existing guidance as previously proposed.

3. The main aspects to be covered

The proposed new work will consolidate all guidelines related to equivalence (CXG 34-1999, CXG 53-2003 and the results of the ongoing work on the guideline on the use of systems equivalence) into a single cohesive guide that provides clear guidance as to which process may be appropriate in different situations. Minor amendments to other Codex guidance documents that mention equivalence may also be considered if appropriate.

4. An assessment against the Criteria for the Establishment of Work Priorities

The proposal is consistent with the criteria as follows:

General Criterion: Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

The proposed new work will further facilitate the trade of safe food while freeing up resources to allow better targeting of greater risk scenarios, thus meeting the general criterion of consumer protection.

Criteria Applicable to General Subjects:

a) Diversification of national legislations and apparent resultant or potential impediments to international trade:

Countries are increasingly prescribing not only standards for end products but also detailed production and processing requirements, resulting in increased requests for information, audit visits and product inspections. Recognition of equivalence, where competent regulatory systems are already in place, could reduce the burden on resources and unnecessary restrictions on trade caused by such processes.

b) Scope of work and establishment of priorities between the various sections of work:

Refer to Scope above.

c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies):

The WTO/SPS Committee's decision (G/SPS/19) provides for some further clarification on how WTO members should make use of the "equivalence" provisions of the SPS Agreement i.e. Article 4. This decision, published in 2001 encouraged CODEX to complete its work developing guidelines on equivalence as expeditiously as possible. To that end, CCFICS has developed a number of standards that provide for the use of equivalence including the work currently progressing to develop specific guidance on a process for the potential recognition of the equivalence of whole or parts of NFCSs Consolidating all of the guidance on equivalence would further facilitate and enable better use of existing Codex guidelines and the results of the Committee's ongoing work

on the use of system equivalence. The Committee will take into account any relevant international work in this area that is identified during the course of the work.

d) Amenability of the subject of the proposal to standardisation:

The Committee believes that consolidation of all three guidelines will further assist standardisation and improve clarity.

e) Consideration of the global magnitude of the problem or issue:

The Committee has assessed that there is currently a significant burden imposed on importing and exporting countries due to the lack of recognition of the equivalence of existing food control measures or the whole or parts of NFCSs and that further practical international guidance in a consolidated form in this area will help reduce that burden. The scarcity of notified equivalence agreements to the WTO/SPS Committee in accordance with G/SPS/7/Rev.2/Add.1 is further evidence that greater clarity of guidelines in this area is both timely and relevant.

5. Relevance to Codex strategic objectives

The proposed work is directly related to the purpose of the Codex Alimentarius Commission, according to its statutes, to protect the health of the consumers and ensure fair practices in the food trade, as well as to the first Strategic Goal of the Codex Alimentarius Commission's Strategic Plan 2014-2019 "establish international food standards that address current and emerging food issues", and is consistent with Objective 1.2 "proactively identify emerging issues and member country needs and, where appropriate, develop relevant food standards". Further, it contributes to Activity 1.2.2 "develop and revise international and regional standards as needed, in response to needs identified by Members and in response to factors that affect food safety, nutrition and fair practices in the food trade". It is also consistent with Objective 1.3 "strengthen coordination and cooperation with other international standards-setting organizations seeking to avoid duplication of efforts and optimize opportunities".

6. Information on the relation between the proposal and other existing Codex documents

The proposed work will take into consideration the results of the ongoing work being progressed by the Committee on the use of system equivalence; the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CXG 34-1999); the *Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems* (CXG 53-2003); and the relevant parts of *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CXG 26-1997).

The proposed work will also take into account aspects of the recently promulgated *Guidelines for National Food Control Systems* (CXG 82-2013); the *Guidelines for Food Import Control Systems* (CXG 47-2003); and the *Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food* (CXG 89-2016).

Minor amendments to other Codex guidelines that mention equivalence may also be considered, if appropriate.

7. Identification of any requirement for and availability of expert scientific advice

Not required.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for:

Not required at this time.

9. Proposed timeline for completion of the new work and other conditions

Subject to the approval of the Codex Alimentarius Commission at its 42nd session in 2019, it is expected that the new work can be completed within three or four sessions of CCFICS, should it continue to meet as currently scheduled i.e. every 18 months.

Appendix III

DRAFT PRINCIPLES AND GUIDELINES FOR THE ASSESSMENT AND USE OF VOLUNTARY THIRD-PARTY ASSURANCE**(for adoption at Step 5)****A: PREAMBLE**

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. Many FBOs use quality assurance systems, including voluntary third-party assurance (vTPA) programmes to reduce supply chain risks and confirm food safety outcomes.
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. 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, they should satisfy themselves that any information/data they intend to use is both reliable and fit for purpose.
3. These 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 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.
4. Reliable vTPA information/data may be used in general to better risk-profile sectors, and in some circumstances individual 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.

B: SCOPE

5. 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.
6. Its focus is the structure, governance and components of vTPA programmes that align and support NFCS objectives relating to protecting consumer health and ensuring fair practices in food trade.
7. The guidelines do not oblige competent authorities to use vTPA programme outcomes nor do they mandate the use of vTPA information/data from FBOs i.e. emphasising that the decision to use vTPA information/data by the competent authority is voluntary.
8. The guidelines 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*² that certify to a regulatory standard for which compliance is mandatory.
9. The guidelines are not intended to apply to private standards [that are the subject of commercial contractual arrangements between buyers and sellers, and does not apply to components of vTPA programmes] that are outside the scope or requirements of the competent authority.
10. These guidelines do not constitute 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.

¹ CAC GL 82-2013: Principles and Guidelines for National Food Control Systems paragraph 54: *Where quality assurance systems are used by food business operators, the national food control system should take them into account where such systems relate to protecting consumer health and ensuring fair practices in the food trade.*

² CAC/GL 20-1995: **Officially recognized inspection systems and officially recognized certification systems** are systems which have been formally approved or recognized by a government agency having jurisdiction.

C: DEFINITIONS³

Assessment: A process of determining the presence or absence of a certain condition or component, or the degree to which a condition is fulfilled. (Source: CAC/GL 91-2017)

Accreditation: third party **attestation** related to a **conformity assessment** body conveying formal demonstration of its competence to carry out specific tasks. (Source: ISO/IEC 17000:2004)

Accreditation body: authoritative body that performs accreditation (Source: ISO/IEC 17000:2004)

Assurance: Positive declaration intended to give confidence. (Source: Oxford English dictionary).

Attestation: issue of a statement, based on a decision following **review** that fulfilment of **specified requirements** has been demonstrated. (Source: ISO/IEC 17000:2004)

Audit: is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives. (Source: CAC/GL 20-1995)

Certification body: A provider of certification services, accredited by a nationally recognised **accreditation** body. (Source: ISO/IEC 17000:2004)

Conformity assessment: demonstration that **specified requirements** relating to a product, process, system, person or body are fulfilled. (Source: ISO/IEC 17000:2004)

Credibility (dictionary): The quality of being trusted and believed in. (Source: Oxford English dictionary)

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.[new]

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 (Source: CAC/GL 20-1995).

Integrity: The quality of being accurate and reliable. (new)

Procedure: specified way to carry out an activity or a process. (Source: ISO/IEC 17000:2004)

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)

Specified requirement: need or expectation that is stated. (Source: ISO/IEC 17000:2004)

vTPA Standard: specified requirements contained in the vTPA programme. (Source: new)

Voluntary Third-Party Assurance Programme: An autonomous scheme 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 for FBO operations for compliance with the standard, and in which FBO participation is voluntary. [Source: new]

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

D: PRINCIPLES

11. 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:

Principle 1 Planning and decision making

- Competent authorities retain discretion whether and how to consider information/data from vTPA programmes in their regulatory oversight, inspection and control framework, planning and decision-making process.

³ Based (in part) on EN ISO/IEC 17000 “Conformity assessment – Vocabulary and general principles”.

Principle 2 Role and responsibilities

- Competent authorities 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 3 [Process and policies]

- ~~[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 may establish a mechanism / process with the vTPA owner for information/data sharing and handling of non-compliance where failure to alert the competent authority of any significant public health risk or consumer deception is identified.]~~

Principle 4 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 5 [Proportionality]

- 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 requirements.

Principle 6 Transparency

The assessment criteria should be transparent. Competent authorities should make their approach to the use of vTPA programmes, including the assessment process and criteria publicly available in line with Principle 3 of CAC/GL 82-2013⁴.

Principle 7 Assessment

- The depth and extent of any assessment of the vTPA programme should be commensurate with the intended use of the vTPA information/data.

E: ROLES, RESPONSIBILITIES AND RELEVANT ACTIVITIES:

12. The roles and responsibilities of all participants 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 protecting the health of consumers and ensuring fair practices in the food trade.

COMPETENT AUTHORITIES

- 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.
- b. May consider using information/data generated by vTPA programmes to support the objectives of their NFCS.
- c. Have 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.
- d. Need to clearly describe the use of a vTPA programme information / data within their NFCS and restrict its use when information provided is false or otherwise lacks credibility.
- e. Should ensure any arrangements to use vTPA information/data is fully transparent.
- f. Have to protect against potential conflicts of interest.
- g. Have to maintain appropriate confidentiality of data [In accordance with the corresponding legal framework in each country.]

⁴ All aspects of a national food control system should be transparent and open to scrutiny by all stakeholders, while respecting legal requirements to protect confidential information as appropriate. Transparency considerations apply to all participants in the food chain and this can be achieved through clear documentation and communication.

FOOD BUSINESS OPERATORS (FBOs)

- a. 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.
- b. Need to demonstrate that they have effective controls and procedures in place to protect the health of consumers and ensure fair practices in food trade.
- c. May elect to participate in vTPA programmes to meet business needs, demonstrate compliance with relevant food safety standards, and provide independent assurance of the integrity of their products or production systems to buyers.
- d. Owns the information/data generated by the vTPA programme.
- e. [Is able to demonstrate that it has no conflicts of interest with the operation of the vTPA.]

VOLUNTARY THIRD-PARTY ASSURANCE OWNERS

- a. Are responsible for implementing the governance arrangements of a vTPA programme, which may include utilising national/international standards and independent accredited audit and certification.
- b. [Are accountable to FBOs that participate in vTPA programmes]
- c. Sharing information/data generated by the vTPA programme owners for use by the competent authority, according to the process established by the vTPA programme owners and the competent authority.
- d. Have policies and processes when sharing vTPA information such as notification to the FBO and protections for proprietary information.
- e. Have policies to ensure a vTPA alerts the competent authority of any significant [public health risks associated with] non-compliances by the regulated industry.
- f. 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.

F: CRITERIA TO ASSESS THE CREDIBILITY AND INTEGRITY OF vTPA PROGRAMMES

13. Competent authorities that choose to use vTPA programmes in their NFCS should satisfy themselves that the vTPA 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 vTPA 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 as a start point for this assessment.

Governance Arrangements

- 1) Are the governance arrangements and responsibilities within the vTPA programme clearly defined and documented?
- 2) Are the oversight arrangements structured to avoid potential conflicts of interest?
- 3) Does the vTPA programme have management controls to ensure consistent and effective implementation and maintenance?
- 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) or another accreditation body that has similar recognition, international standing and credibility?
- 5) If the accreditation arrangement does not adhere to IAF or ILAC, does the vTPA programme owner ensure that [certification/accreditation] bodies have the capacity and competency to perform effectively?

Accreditation of Certification Bodies

- 1) Does the vTPA programme have an independent process to ensure the use of appropriately accredited certification bodies?
- 2) Is the accreditation of certification bodies subject to a periodic review and renewal?
- 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?

- 4) Is the certifying body accredited for the vTPA programme according to the relevant accreditation standard?

Standard Setting Process

- 1) Do the vTPA programme owners set their own standards or utilise national or international standards for assurance?
- 2) Do the vTPA standards contain specified requirements to protect consumers in relation to food safety and fair practices in food trade?
- 3) Have the vTPA standards been developed through a transparent consultative process with relevant experts reflecting the range of business processes within the target sector?
- 4) Are the vTPA standards open, transparent in governance and subject to continuous improvement by regular review to keep them up to date?
- 5) To what extent are the vTPA standards consistent with Codex or other relevant international standards and/or applicable national regulatory requirements?
- 6) Are the vTPA standards written in a way that they can be assessed for conformance?

Conformity Assessment

- 1) Does the vTPA programme have written policies on frequency, methodology, announced and unannounced audits and competency requirements for certification bodies?
- 2) 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?
- 3) Does the vTPA programme have procedures in place to ensure that auditors have and maintain the required auditor competence?
- 4) Does the vTPA programme have a transparent system to identify FBOs that conform to the standard (e.g. certification)?

Responses to Non-Conformance

- 1) Do the vTPA programme arrangements include clearly defined procedures for dealing with non-conformities against the standards, failures to rectify non-conformities, and other situations where sanctions might be required?
- 2) Do the arrangements include a system for review of audit reports, decisions on interpretation and sanctions, and a procedure for appeal?

Data Sharing and Information Exchange

- 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?
- 2) Subject to national privacy legislation, will the vTPA programme owner inform the competent authority immediately when they become aware of a significant risk to public health or consumer deception?
- 3) Will the vTPA programme owner notify the competent authority of any FBO that ceases to participate?
- 4) Will the vTPA programme owner agree to notify the competent authority of any changes made to the vTPA programme, including but not limited to: the standard, governance, certification and accreditation arrangements?
- 5) Will the vTPA programme owner share information/data relating to compliance with the standard where the standard aligns with regulatory requirements to inform the NFCS?
- 6) If the data available is electronic form are there adequate arrangements for maintaining the security of the data?
- 7) Does the vTPA owner have permission to share FBO data with competent authorities and is this in accordance with national data protection obligations?
- 8) Does the vTPA owner have a protocol for data retention?

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

14. This section provides examples of necessary considerations and the practical uses that can be made by competent authorities of vTPA information/data to support their NFCS objectives.
15. [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 may establish a mechanism / process with the vTPA owner for information/data sharing and handling of non-compliance where failure to alert the competent authority of any significant public health risk or consumer deception is identified.]

Process considerations

- a. A vTPA programme may be considered for use by a competent authority after an appropriate assessment of its credibility and integrity informed by the criteria in this guidance.
- b. Competent authorities need only apply relevant assessment criteria commensurate with their intended use of vTPA information/data.
- c. Where there is a positive assessment outcome the competent authority may choose to enter into an arrangement with the vTPA owner by mutual consent.
- d. Competent authorities may need to establish transparent procedures to verify the reliability of the vTPA information/data that it intends using.
- e. Competent authorities may choose to set up regular meetings, or other communication channels, with the vTPA owner in order to analyse the information/data shared to look for trends and the competent authority may consider the need for any intervention needed.
- f. Competent authorities may compare comparable regulatory audit data with that generated by the vTPA audits to verify consistency and reliability.
- g. In addition to specific and critical information detailed in an agreement 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.
- h. Where competent authorities choose not to enter into an agreement with the vTPA owner they may access the information/data directly from the FBO.
- i. 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).

Policy options

- 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.
- 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 information/data.
- 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.
- 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 ensuring fair practices in food trade.
- e. Audit information/data generated by the vTPA programme, and FBO certification status may be used to inform NFCS planning leading to reduced intensity or frequency of regulatory inspection for participating FBOs.
- f. Competent authorities may reduce levels of official inspection where there is verification through their official data that participation in a vTPA programme is achieving higher levels of compliance with relevant regulatory requirements.
- g. The suitability and extent to which competent authorities use vTPA information/data will be determined by the depth of any assessment of the integrity and credibility of the vTPA programme.

- h. vTPA information/data indicating a trend could be used to target specific interventions such as focused inspections or national training/information programs where the vTPA information/data helps identify a systemic issue.
- i. The competent authority may determine that FBOs participating in a vTPA programme that meet the relevant assessment criteria in these guidelines pose a lower food safety risk and so subject them to less frequent regulatory oversight.
- j. Competent authorities may use the additional information/data from vTPA audits to help prioritise regulatory resources to higher risk areas to better protect consumers in relation to food safety and fair practices in food trade.