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

Agenda item 6

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DRAFT REVISION AND UPDATING OF THE *PRINCIPLES FOR TRACEABILITY/PRODUCT TRACING AS A TOOL WITHIN A FOOD INSPECTION AND CERTIFICATION SYSTEM* (CXG 60-2006)

Step 3

(Report prepared by the Electronic Working Group¹ chaired by the United States of America and co-chaired by Australia, Ecuador, Honduras, and the United Kingdom)

Codex Members and Observers wishing to submit comments, at Step 3/4, on this draft (Appendix) should do so as instructed in CL 2024/72-FICS available on the Codex webpage/Circular Letters 2024:
<https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

INTRODUCTION & BACKGROUND

1. In 2006, Codex adopted the *Principles for Traceability/Product Tracing as a Tool Within a Food Inspection and Certification System* (CXG 60-2006). Since the document was adopted in 2006, there has been a growing realization of the importance of traceability and the critical role it plays in supporting national food control systems (NFCS). The 2006 guidance established the design principle of one step forward and one step back, which is now a widely adopted requirement in most regulatory food control systems. However, some industry sectors and governments are responding to the increased risks in food supply chains by harnessing emerging technologies to modernize their traceability systems. When implemented, these enhanced traceability systems enable rapid identification of the source of a problem in a supply chain, which in turn means corrective actions are more proportionate to the extent and severity of the problem.

2. During the 25th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS25) (2021), the Committee considered a paper prepared by the United States and the United Kingdom to revisit the existing principles document on traceability/product tracing to ensure the scope and content are fit for purpose. Although the time available for a discussion during CCFICS25 was very limited, there was general agreement among Members that traceability is an important topic and that it would be useful to have a more in-depth discussion at CCFICS26.

3. CCFICS25 agreed that an electronic working group (EWG), co-chaired by the United States and the United Kingdom, should consider whether the *Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System* (CXG 60-2006) needed to be revised and updated, and for the EWG to report to CCFICS26 with their recommendations. The Committee also acknowledged that it would be helpful to gather information from Food Business Operators (FBOs) about the technology platforms they were using to better understand how the use of emerging technologies can enhance traceability systems. The EWG was tasked with developing a discussion paper on traceability and a possible project document to be presented at CCFICS26.

4. At the 26th Session of the Codex Committee on Food Import and Export Inspection Certification Systems (CCFICS26) (2023), the United States and the United Kingdom provided the input from the EWG. A discussion paper on the review and update of the *Principles for Traceability/Product Tracing as a Tool Within a Food Inspection and Certification System* (CXG 60-2006) was introduced. The discussion paper recommended CCFICS26 consider the merits of undertaking new work to update CXG 60-2006. A draft project

¹ Australia, Argentina, Brazil, Canada, Chile, China, Costa Rica, Dominican Republic, Ecuador, European Union, Guatemala, Honduras, India, Indonesia, Italy, Japan, Kenya, Mexico, Morocco, Norway, Panama, Republic of Korea, Saudi Arabia, Spain, Thailand, United Arab Emirates, United Kingdom, United States, Uruguay, International Chewing Gum Association, and Institute of Food Technologists.

document was also presented. A side event was held to further orient Members ahead of the discussion in plenary.

5. CCFICS26 agreed to forward the project document on the revision and updating of CXG 60-2006 to CAC46 for approval as new work and to establish an EWG, open to all Members and Observers, chaired by the United States of America and co-chaired by Australia, Ecuador, Honduras, and the United Kingdom, working in English and Spanish, subject to approval of the new work, to prepare a proposed draft revision of the *Principles for Traceability/Product Tracing as a Tool Within a Food Inspection and Certification Systems* (CXG 60-2006) for consideration at CCFICS27.

PARTICIPATION AND METHODOLOGY

6. Codex Members and Observers were invited to register (by 10 August 2023) to participate in the EWG. 29 Members and 2 Observers registered for the EWG.

7. A draft proposed guidance and questions for the EWG were prepared by the chair and co-chairs and circulated, in English and Spanish, to the EWG in December 2023. Questions posed to the EWG included:

- a. Whether “production, processing, and distribution” cover the whole food chain.
- b. Whether it is preferable to define “interoperability” in a narrow way to refer to digital information exchange, or more broadly to refer to any information exchange.
- c. Whether there are other definitions that would be useful to include in the document.
- d. Whether there are other responsibilities of competent authorities and FBOs to include.
- e. Whether it is helpful to include factors to consider related to risk in the document.
- f. Whether there are other elements to communication specific to traceability/product tracing that should be covered in the document.

8. There was broad agreement that production, processing and distribution are sufficiently broad. The EWG provided feedback that a broader definition of interoperability was preferable. EWG members suggested adding a definition of food supply chain to the document. There was general agreement but not consensus to include the factors to consider related to risk in the document. There was broad agreement that the communication section was complete.

9. In addition to responding to the questions, the EWG members provided numerous helpful comments on the text that were used to create a revised draft.

10. A second draft guidance based on the written comments was prepared and circulated to the EWG, in English and Spanish, in June 2024. The second draft requested focused feedback from the EWG members on 10 questions that had emerged from the analysis of the comments provided during the first consultation round. The questions included:

- a. Whether reference to other Codex, IPPC, and WOH documents should be included.
- b. Whether the scope should include reference to feed, primary products, and food packaging.
- c. Whether two additional principles should be added.
- d. Whether the responsibilities of the FBOs should include a responsibility to the buyers.
- e. Whether reference should be made to assistance to other countries.
- f. Whether information to characterize a traceability/product tracing system should be included.
- g. Whether additional examples of system design would be useful.
- h. Whether additional information protection material should be included.
- i. Whether it is useful to include additional text related to communication and cooperation.
- j. Whether it is helpful to include a list of existing definitions that are pertinent to the traceability/product tracing guidance as an appendix.

11. There was broad agreement on some of the questions posed, including that the guideline should not reference a responsibility to buyers, the additional principles were useful, no additional material was needed related to assistance to other countries, additional information related to characterization of a traceability/product tracing system and additional information on information protection were not needed, and that the material on communication and cooperation should be retained. There was slight preference expressed for retaining a reference to other Codex, IPPC, and WOH texts, and for the removal of the

additional scoping language. There was no consensus on the inclusion of the appendix with references to definitions from other Codex texts or on the use of examples related to system design.

SUMMARY OF DISCUSSION

12. The co-chairs proposed to revise the title to include guidelines in addition to principles and to reflect the relevance of traceability/product tracing within a National Food Control System (NFCS).

13. The guidance drew significantly from the existing principles document and sought to provide additional guidance for competent authorities considering how best to incorporate traceability/product tracing into their NFCS.

14. Substantial agreement was reached on the Definitions and Responsibilities sections. Broad agreement was reached on the Principles and Legal Requirements sections; however, further discussion will be necessary on the title of the Legal Requirements section.

15. There are some divergent views on the Scope with a handful of Members expressing a preference for the inclusion of animal feed for food for animals and food packaging while others prefer to focus on food. There have also been differences of opinion on the breadth of the content contained in the Good Practices section, with some Members preferring to limit the material presented to traceability/product tracing systems and requirements while others prefer to include the broader use of traceability/product tracing as is currently presented in the text.

RECOMMENDATIONS

16. The Committee is invited to:

- a. note the extensive work undertaken to date and the continued support for the work to revise and update CXG 60-2006
- b. consider the proposed draft revised text presented at Step 3 in Appendix 1
- c. consider whether to recommend to CAC47 advancement of the revised text to Step 5.

APPENDIX I**DRAFT PRINCIPLES AND GUIDELINES ON TRACEABILITY/PRODUCT TRACING WITHIN A NATIONAL FOOD CONTROL SYSTEM****(Step 3)****PREAMBLE**

1. [Traceability/product tracing consists of acquiring information about food products, which can be retrieved along the supply chain all the way to the consumer.] Traceability/product tracing may be applied, when and as appropriate, within a National Food Control System (NFCS) to contribute to the protection of consumers against foodborne hazards and fraudulent or deceptive practices, and to facilitate trade, such as on the basis of accurate product description.
 2. These guidelines are intended to promote good practice, not mandate a single way to conduct traceability/product tracing.
 3. In the case of a foodborne illness outbreak or contamination event, efficient traceability/product tracing enables competent authorities and food business operators (FBOs) to rapidly find the source of the contamination event, identify where it may have occurred, and determine the scope and extent of the implicated product distribution. This results in faster, targeted removal of the affected product from the marketplace, thereby reducing incidences of foodborne illnesses. Effective traceability/product tracing helps reduce the scale of removal, thereby mitigating food waste and minimizing costs to producers and others in the food supply chain.
 4. Robust traceability/product tracing can also act as a deterrent to fraudulent practices and incidents in food supply chains, and as a source of evidence to support investigations when food fraud is suspected or has taken place.
 5. Traceability/product tracing can help increase transparency and confidence in the safety, quality, and provenance of food by importing countries, thus facilitating trade and potentially adding value for buyers and sellers.
 6. Traceability/product tracing can facilitate identification of risks related to food production; however, an NFCS requires appropriate measures to improve food safety and fair trade outcomes.
 7. The availability and application of new technology, such as digital tools, may facilitate traceability/product tracing by enabling faster access to food supply chain information. Digital tools can improve communication across food supply chains and play an essential part in enhancing traceability to effectively manage and respond to risks. For this to work, the digital technologies rely on guidelines and standards so that the data exchanged are interoperable and are enable communication across the food supply chain.
- 7bis. This guideline should be read in conjunction with all relevant Codex texts as well as those adopted by IPPC and WOA, as appropriate.

SCOPE

8. This document provides guidance to assist competent authorities on establishing traceability/product tracing as part of their NFCS. It also provides guidance to food business operators (FBOs) on implementation of traceability/product tracing within their food operations and throughout the food supply chain.

DEFINITIONS

9. Where words in this document have been defined in previous Codex texts, those definitions apply in this document (see Appendix 1). Otherwise, the following definitions apply:

Traceability/product tracing²: the ability to follow the movement of a food or food ingredient through specified step(s) of production³, processing, and distribution⁴.

Traceability/product tracing system: the mechanism established to collect, process, visualize, and analyze traceability data and information.

² Original definition from the Codex Procedural Manual. Footnotes added for additional explanation/reference.

³ Production can include a primary production which is those steps in the food chain up to and including storage and, where appropriate, transport of outputs of farming. This would include growing crops, raising fish and animals, and the harvesting of plants, animals or animal products from a farm or their natural habitat. (CXC 1-1969)

⁴ Distribution includes distribution to the customer level. Can include, among others, handling, storage, and transportation.

Interoperability: the ability to exchange data/information between different data management systems.

Food supply chain: the range of activities required to take a product from its initial production, through the intermediate phases of production, to delivery to final consumers.

PRINCIPLES

10. These principles cover the context, rationale, design, and application of traceability/product tracing within an NFCS.

- a. Traceability/product tracing should be designed to support NFCS objectives

Robust traceability/product tracing that can identify and extract reliable data/information about the sourcing or movement of a food and/or any of its ingredients and packaging, as well as associated process steps, is an important part of a well-functioning NFCS.

- b. Traceability/product tracing requirements should be proportionate to risk

Competent authorities and FBOs should consider the risk posed by and to food products and the capabilities and resources of competent authorities and FBOs to manage those risks. At a minimum, traceability/product tracing should be one step forward and one step back.

- c. Traceability/product tracing should facilitate the exchange of data/information along the food supply chain, including between FBOs and competent authorities.

Competent authorities should consider the entire food supply chain when designing and implementing traceability/product tracing within an NFCS. The application of traceability/product tracing should be practical⁵, be technically feasible, be economically viable for a FBO and within an NFCS, and avoid unnecessary burdens.

Traceability/product tracing should improve communication among the involved parties; improve the standardization, appropriate use, and reliability of data/information; and improve effectiveness and productivity of the organization.

- d. Traceability/product tracing should support the exchange of data/information throughout the food supply chain (interoperability)

Interoperability between systems can support competent authorities of exporting and importing countries and FBOs to exchange data/information across different systems without the need for all entities to be on a single operational, proprietary, or technology platform.

- e. The implementation of traceability/product tracing within an NFCS should not be more trade restrictive than necessary.

- f. Different traceability/product tracing systems may achieve the same objectives and outcomes.

It should not be mandatory for an exporting country to replicate (i.e., establish the same) the traceability/product tracing requirements or system as used by the importing country, when applicable.

Responsibilities

11. Competent authorities have the following responsibilities:

- a. Establish and implement appropriate legal requirements for traceability/product tracing based on risk.
- b. Develop and maintain appropriate infrastructure to access, manage, and assess traceability/product tracing data/information.
- c. Establish and maintain controls to ensure the confidentiality, as appropriate, of business-sensitive traceability/product tracing data/information when it is shared by an FBO.
- d. Communicate with stakeholders, including to provide guidance to assist FBOs to implement traceability requirements, as appropriate.

12. FBOs have the following responsibilities:

- a. Establish and maintain traceability/product tracing systems, consistent with national requirements and, when exporting products, those requirements of importing countries.
- b. Share relevant data/information with other FBOs in their food supply chain, in accordance with NFCS requirements, as appropriate to enable traceability/product tracing.

⁵ For example, for raw agricultural commodities that may be comingled during collection.

- c. Provide traceability/product tracing data/information in accordance with NFCS requirements to a competent authority when requested and within established timeframes.
- d. Test their traceability/product tracing system to ensure it operates as intended.
- e. Implement the traceability/product tracing system adapted to their organization, their sector, their supplier profile, customer requirements (contractual requirements) and legal requirements. Based on these, evaluate the internal and external needs. Identify the data/information that needs to be traced and define the parameters of traceability.
- f. Identify how continuity and confidentiality of data/information will be guaranteed throughout the process steps of the traceability/product tracing system.

Legal requirements

- 13. Traceability/product tracing should at a minimum be able to identify at any specified stage of the food chain from where the food came (one step back) and to where the food went (one step forward), as appropriate to support the NFCS objectives.
- 14. Key considerations for competent authorities when designing legal requirements for the use of traceability/product tracing within their NFCS include:
 - a. the assessed food safety risks and/or the characteristics of the potential fraudulent practices being addressed.
 - b. the purpose of the traceability/product tracing data/information within their NFCS and establishing data/information requirements commensurate with their NFCS needs.
 - c. whether the appropriate legal framework exists or needs to be established to implement traceability/product tracing.
 - d. whether additional data/information protection requirements are needed within the context of national legislation to ensure protection of commercially sensitive data/information.
- 15. When establishing traceability/product tracing requirements that take account of risk for specific products or sectors, competent authorities and FBOs may want to consider:
 - a. the known risks of a particular food from a food safety and a food fraud perspective.
 - b. the likelihood that a particular food has a high potential risk for contamination or food fraud due to the nature of the food or the processes used to produce such food.
 - c. the step in the manufacturing or distribution process of the food where contamination or food fraud is most likely to occur.
 - d. the likelihood of contamination or food fraud and steps taken during the manufacturing or distribution process to reduce the possibility.
 - e. the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food.
 - f. the likely or known severity, including health and economic impacts, of a foodborne illness or food fraud attributed to a particular food.

Good practice

- 16. Traceability/product tracing should support the objectives of the NFCS and the scope, purpose, objectives and specifications of traceability/product tracing should be clearly described.
- 17. The application of traceability/product tracing should consider the capabilities of developing countries.
- 18. The objectives, scope and related procedures for traceability/product tracing in an NFCS should be transparent and made available to competent authorities of the exporting country upon request.
- 19. If, as related to traceability/product tracing, an importing country has objectives or outcomes of their NFCS which cannot be met by an exporting country, the importing country should consider the provision of assistance to the exporting country, and especially in the case of a developing country. Assistance may include longer time frames for implementation, flexibility of design, and technical assistance, so that the objectives or outcomes of the NFCS of the importing country can be met.

Traceability/product tracing system design

20. A traceability/product tracing system consists of two main aspects: (1) the data/information to be maintained and collected; and (2) the means of collection, storage, and presentation of the data/information, such as in digital or paper form.
21. When determining the traceability/product tracing data/information to be maintained and collected, competent authorities may want to consider:
- Defining situations when FBOs will be requested to provide data/information to the competent authority, such as during an investigation of a foodborne outbreak, to identify products subject to recall, or to identify food fraud.
 - The minimum data/information necessary to establish traceability/product tracing sufficient to manage specific risks.
 - Establishing requirements for common data/information to be shared between FBOs to facilitate traceability/product tracing. Competent authorities may want to consider establishing data/information requirements that allow for linking between products as they move through the food supply chain, such as production, batch, or lot codes.

A FBO should not be required to submit confidentially sensitive data/information to other FBOs within their food supply chain.
 - Whether the activities performed by the FBO will impact on the traceability/product tracing data/information they are required to maintain. For example, will the requirements for traceability/product tracing data/information be different for an FBO that manufactures a new food product and an FBO that only distributes finished food products (without additional processing)?
 - How data elements should be linked (at a minimum, one step forward, one step back) within an FBO's records and across the food supply chain, based on the FBO's role.
 - The time frame for retention of records by the FBOs.
22. When establishing requirements related to the presentation of the traceability/product tracing data/information, competent authorities may want to consider:
- What data requirements and conventions should be in place to ensure useability and reliability of the data/information (interoperability)?
 - Whether records should be maintained in paper or electronic format?
 - How and in what format will the FBOs submit data/information to the competent authority, when requested?
 - What data/information security requirements should be in place to protect sensitive data/information?
23. A traceability/product tracing system should be technology neutral, to support use by FBOs, regardless of their resource availability or constraints. A technology neutral system will also allow for adaptability as technological advances are made.
24. [To encourage interoperability, standardization of syntax (formats) and semantics (meanings) of data/information that are shared wholly or partly by different systems may be useful. This sharing can be internal (among different business processes of an organization) or external (between different organizations).] Competent authorities may want to consider utilizing international data standards⁶ as a benchmark for their traceability/product tracing.
25. In developing their traceability/product tracing approach, competent authorities may consider how FBO traceability/product data/information can be shared within their own NFCS and with the NFCS of importing countries. Competent authorities may want to look to other areas where they have established electronic data/information sharing, such as e-certification, when establishing their traceability/product tracing system.

Information protection

26. Competent authorities must establish appropriate security measures to ensure the confidentiality and protection of data/information provided from FBOs and other stakeholders. Competent authorities may want to consider whether their national legislation includes sufficient information protection provisions.

⁶ [An example of a body that has developed data standards is GS1].

27. Data/information sharing agreements may be needed between competent authorities to provide a robust governance mechanism that enables data/information to be shared across a food supply chain by providing the necessary assurances on data protection and security.

Communication and Cooperation

28. Competent authorities may look to existing guidance in establishing communication related to traceability/product tracing between competent authorities; for example, CXG 89-2016, Principles and Guidelines for the Exchange of Information Between Importing and Exporting Countries to Support the Trade in Food; and CXG 82-2013, Principles and Guidelines for National Food Control Systems.
29. Competent authorities may require data/information from FBOs within a specified timeframe and may request relevant traceability/product tracing data/information from other competent authorities to assist in their investigations; for example, during a food safety incident, to identify impacted food products and address any public health risks or food fraud.
30. Competent authorities should respond in a timely manner to requests from other competent authorities for traceability/product tracing data/information, consistent with their national legislation and relevant data/information protection requirements. **【When requests for traceability/product tracing data/information is related to a food safety incident or emergency to identify impacted food products and address any public health risks, they might want to refer to CXG 19: 1995, Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations.】**

Annex 1: Definitions

Definitions from other Codex texts applicable here:

Food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances used only as drugs (Codex Procedural Manual)

Food business operator (FBO): The entity responsible for operating a business at any step in the food chain. (CXC-1-1969)

Food safety: Assurance that food will not cause adverse health effects to the consumer when it is prepared and/or eaten according to its intended use. (CXC 1-1969)

Primary production: Those steps in the food chain up to and including storage and, where appropriate, transport of outputs of farming. This would include growing crops, raising fish and animals, and the harvesting of plants, animals or animal products from a farm or their natural habitat. (CXC 1-1969)