03/09/2024

EU reply to CL 2024/72-FICS

Request for comments, at Step 3, on the Draft revision and updating of the Principles for Traceability/Product Tracing as a Tool Within a Food Inspection and Certification System (CXG 60-2006)

Mixed Competence
European Union Vote

The European Union and its Member States (EUMS) would like to thank the United States of America, Australia, Ecuador, Honduras, and the United Kingdom for leading this work on traceability.

The EUMS have the following comments on the proposed draft guidelines as presented in Appendix I of document CX/FICS 24/27/6:

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.

   The sentence in brackets could be re-worded, changing the whole paragraph as follows:

   Past food incidents have demonstrated that being able to trace food and feed, within a National Food Control System (NFCS) throughout the food chain all the way to consumer can 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.

   No need to provide a definition since 'traceability is defined later in the text. It would be relevant to mention, instead, the importance of traceability.

   A sentence could be introduced here to indicate that in this document, when referring to 'traceability' it should be read 'traceability/ product tracing'. That way there would be no need to repeat 'product tracing' throughout the text.

   The preamble should lay down the purpose of this guidance. Is it supposed to focus purely on food safety - as an effective tool to manage food incidents/crises? However, traceability is also meant to address fraud and to facilitate trade (purposes other than food safety).

   Furthermore, going back to the previous CCFICS, the scope of the project document for this paper involved:

   - The work will foster harmonization and help manage food safety risk, ensuring fair practice in food trade.
   - Promote the use of traceability/product tracing in the context of the whole and/or parts of a National Food Control System (NFCS), as appropriate.

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~~ other operators** in the food supply chain **and avoiding unnecessary trade disruptions**.

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. **It can also ensure the reliability of information supplied to consumers in terms of substantiating claims made by Food Business Operators.**

This is also another aspect of the traceability requirement in general.

5. Traceability/product tracing can help increase transparency and confidence in the safety, quality**, integrity (including authenticity),** and provenance of food by importing countries, thus facilitating trade and potentially adding value for buyers and sellers.

Traceability is also used for fraud prevention; thus, integrity and authenticity are relevant concepts to be captured.

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 WOAH, 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 tracing[1]: the ability to follow the movement of a food or food ingredient through specified step(s) of production[2], processing, and distribution[3].

The footnote 3 on 'distribution', refers to 'customers' indicating business operators that receive food products upon payment. However, distribution also covers the activities of a food bank/redistribution centre which receive food products free of charge. The EUMS therefore propose an alternative wording on footnote 3.

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

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.

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[1] Original definition from the Codex Procedural Manual. Footnotes added for additional explanation/reference.

[2] 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)

[3] Distribution includes distribution to the customer level, **as well as to other receivers free of charge (such as food banks) and up to the consumer level. It c**an include, among others, handling, storage, and transportation.

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.**~~

Traceability requirements being proportionate to risk of a food is an idea that needs further reflexion:

Without prejudice to sector-specific rules, proportionality does not apply to traceability itself. The proportionality applies to the action taken once a problem has been identified and traceability is a tool to contain a crisis and take proportional action. Traceability does not itself make food safe. It is a way of assisting in containing a food safety problem.

The following alternative text could be suggested:

Traceability/product tracing should be designed to identify and contain food safety problems: Robust traceability/product tracing can ensure effective and rapid tracing along the supply chain, targeted withdrawals/recalls of unsafe products in a speedy and cost-efficient manner, ***taking into account the risk involved*** *and maintaining consumer trust in food safety.*

Whilst the EUMS recognise that proportionality and a risk-based approach is to be applied for traceability measures in some instances, it is not appropriate to bring it up into this document. The standard is meant to establish and overarching guiding principle that does not go into the granularity of how much information or for how long it has got to be kept. This standard focuses on the one step back/one step forward principle, which must be put in place regardless of the risk.

Proportionality is also an ambiguous term to be introduced in the standard. How is it defined or how far-reaching is it? Would it mean that zero traceability could be acceptable if no risk was perceived?

The measures in relation to traceability e.g. the number of checks, may be associated to proportionality, but that is different to the requirement of traceability, in general terms, being linked to proportionality.

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. **For food safety purposes,** ~~**At a minimum,**~~ traceability/product tracing should be one step forward and one step back, **at a minimum**.

As per the comment above, the EU does not agree with the first sentence: When it comes to food safety, traceability itself is not proportionate to risk.

Rationale for the changes suggested in the second sentence:

Traceability, for purposes other than food safety, e.g. food labelling/origin labelling, goes beyond one step back and one step forward.

It could be added that **business operators do not have to identify the immediate customers when they are final consumers.**

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**,** **including business operators redistributing surplus foods,** when designing and implementing traceability/product tracing within an NFCS. The application of traceability/product tracing should be practical[4], be technically feasible, be economically viable for a FBO and within an NFCS and avoid**/minimize** unnecessary burdens.

It is important to flag that the food chain also includes redistribution organisations such as food banks.

[4] For example, for raw agricultural commodities that may be comingled during collection.

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.

As per the comments above, it may be that proportionality is relevant for traceability for purposes **other than food safety.**

As per point 14(b) below, the designing of the traceability requirement depends on the purpose behind it. If the purpose is food safety, proportionality to risk should not apply - as any food could be potentially unsafe.

If the purpose is something other than food safety, then a proportionality consideration or appreciation of a risk (e.g. risk in terms of potential food fraud) could be relevant.

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, **including traceability information records,** consistent with national requirements and, when exporting products, those requirements of importing countries.

b. Collect from and share relevant data/information with other FBOs in their food supply chain, in accordance with NFCS requirements, as appropriate to enable traceability/product tracing. **This includes collection of information from other FBOS – one step back/one step forward.**

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**/receiver** 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.

The addition of 'receiver' is suggested to address food banks that receive foods for free for further distribution.

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, **for purposes other than food safety**, 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 **(and potential food safety concerns)**.

    This paragraph targets food fraud primarily. However, here one may need also to consider potential links with food safety (e.g. food fraud with substances that are harmful to health. With that in mind, the EU suggests the rewording on point 15(a) so that food safety reference come after food fraud.

    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**~~ **probability**.

    The 'possibility' will still be there. 'Probability' might be a more suitable word.

    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 **or the circumstances around the distribution of food**.

    The circumstances concerning the food distribution could also be an element that may need to be taken into account (freezing during transportation etc.).

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:

    a. 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**/withdrawal**, or to identify food fraud.

    b. The minimum data/information necessary to establish traceability/product tracing sufficient to manage specific risks.

    Paragraph 21 (b) should be reworded to make sure that for food safety purposes proportionality is not a consideration. For other purposes, this could be a consideration.

    c. 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.

    d. 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)?

    Due to the different role of FBOs, the burden will be different. However, it might be worth explaining that the requirement will be the same e.g. one step back and one step forward.

    e. 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.

    f. 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:

    a. What data requirements and conventions should be in place to ensure useability and reliability of the data/information (interoperability)?

    b. Whether records should be maintained in paper or electronic format?

    c. How and in what format will the FBOs submit data/information to the competent authority, when requested?

    d. 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 standards[5] as a benchmark for their traceability/product tracing.~~

No need to keep this paragraph.

The text should be worded in terms of the goal and/or intended result, rather than in terms of prescribing how that result may be achieved. A more general approach allows a greater flexibility in the implementation of the requirement and is thus likely to reduce compliance costs. However, it requires both food businesses and the control authorities to take an active role in ensuring effective implementation.

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.

Under paragraph 26, it might be worth including that for reasons of public interest, information about certain products may need to be communicated to the public.

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.

27bis. To safeguard personal data and business-sensitive information, the exchange of traceability/product tracing data and information between competent authorities should be restricted only to what is necessary.

This is intended to ensure that only necessary information shall be shared between competed authorities. This aligns with the principles outlined in CAC/GL 19-1995, which emphasize the careful and necessary exchange of information.

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**.]**

The sentence in brackets may be kept.

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

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)