

Food Traceability Rule Overview: A Guide for Florida Food Industry¹

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This EDIS publication provides information to the food industry on the FDA's final Traceability Rule.

Introduction

In 2011, the Food Safety Modernization Act (FSMA) was signed as a science-based mitigation strategy in response to the continued prevalence of foodborne illnesses in the United States (FDA 2023a). This legislation grants the Food and Drug Administration (FDA) permission to implement comprehensive regulations and measures to revolutionize and protect the nation's food supply (FDA 2023a). As part of the FSMA, the FDA has finalized nine essential rules: 1) Agricultural Water, 2) Accredited Third-Party Certification, 3) Food Traceability, 4) Foreign Supplier Verification Programs (FSVP), 5) Laboratory Accreditation for Analyses of Foods (LAAF), 6) Mitigation Strategies to Protect Food Against Intentional Adulteration, 7) Preventive Controls for Human and Animal Food, 8) Produce Safety, and 9) Sanitary Transportation of Human and Animal Food (FDA 2023a). The act also established the Voluntary Qualified Importer Program (VQIP) (FDA 2023a).

The FSMA's Traceability Rule, finalized in 2022, aims to establish a comprehensive system for tracking specific foods along the value chain from farm to fork, to prevent and respond to foodborne illnesses more effectively. The industry should implement the rule by 2026. This revision is

part of the FDA's New Era of Smarter Food Safety blueprint and implements Section 204(d) of the FDA Food Safety Modernization Act (FSMA). The FDA's final Traceability Rule initially focuses on specific food categories identified as higher risk for contamination and foodborne illnesses. These categories are referred to as the "Food Traceability List" (FTL). In this EDIS publication, we have provided to the food industry background information and an overview of the rule's key components and the foods covered by it. Additionally, available resources have been compiled in a table to help the industry understand the rule better and find more information about it.

Six Components of the Traceability Rule

1. Framework of Critical Traceability Events (CTEs) and Key Data Elements (KDEs)

Traceability is a primary aspect of the food supply chain as it minimizes the spread of foodborne diseases through key levers, like swift recall actions (Kennedy, Stitzinger, and Burke 2020). However, establishing a comprehensive traceability system is a significant challenge due to the intricacies of global food systems. To effectively implement traceability throughout the food chain, the FDA creates a robust system model that identifies CTEs and records KDEs for each

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event (FDA n.d., 2023c). CTEs refer to the specific points within a supply chain where data capture is necessary to track the movement of products, including transportation, transformation during processing, and depletion events (Zhang & Bhatt, 2014). KDEs are required to be recorded for each CTE, and these data elements include information such as product identification, lot number, dates, location, etc. (FDA n.d., 2023c). This CTEs/KDEs framework provides details of food products regarding “what, when, and where” as they travel through the supply chain (FDA n.d., 2023c).

2. Standard Language

Implementing the Food Traceability Rule presents a comprehensive approach to traceability throughout the entire supply chain, encompassing both domestic and foreign entities (Zhang and Bhatt 2014). One of the primary hurdles in achieving comprehensive traceability across this diverse system lies in establishing interoperability (i.e., to gather information effectively anywhere across systems). Hence, food systems must speak a uniform traceability language to enable consistent communication, efficient data sharing, and rapid response during foodborne outbreaks. Acknowledging this necessity, the FDA has standardized the language and common terminology within the supply chain to facilitate the efficient exchange of information among stakeholders and to foster greater transparency from growers to retailers and restaurants (FDA 2022). Harmonized information allows the FDA to establish linkages along the supply chain more quickly.

3. Linking Information by Lot Code

The FDA defines the Traceability Lot Code (TLC) as an alphanumeric descriptor that serves to uniquely identify a traceability lot within the records of the firm responsible for assigning the code (FDA 2023d). While traditional lot codes identify lots within an organization, the TLC must uniquely identify lots within the entire food system. As a vital KDE mandated by the rule (FDA n.d.), the TLC plays a critical role in linking a food product to each event occurring in its supply chain (FDA 2023d). Key components of the TLC requirements include the limited circumstances under which TLCs can be assigned and the ongoing association with the TLC Source, which is the entity responsible for assigning the TLC (FDA 2023c). Extensive research has been dedicated to developing techniques for automated identification and the creation of traceability relations (Zhang and Bhatt 2014). However, even with these emerging techniques, linking various supply chain stages during a foodborne outbreak still heavily relies on manual inputs. Hence, the FDA’s new rule on traceability

incorporates the integration of automated traceability to enable prompt identification, thus significantly enhancing process efficiency.

4. Electronic or Paper Records

Traceability Rule does not prescribe specific technologies for maintaining records; the FDA accommodates the use of either electronic or paper records to achieve comprehensive traceability while considering the diverse needs and capabilities of the food industry stakeholders (FDA 2023c). These records must be retained for a minimum of two years from their creation or acquisition (FDA 2023c). The FDA encourages all food industry stakeholders to maintain their traceability records electronically whenever possible as these have the added advantage of including valid, working electronic links to the information mandated by the final rule in addition to their higher efficiency for traceability purposes.

5. Records Provided to FDS within 24 Hours

The FDA’s Traceability Rule mandates the provision of records within 24 hours upon request to facilitate effective traceability and regulatory processes (FDA 2023c). Receiving facilities or restaurants are responsible for ensuring the availability of records outlined in §1.1345, whether maintained by themselves or another entity (FDA 2023c). Individual franchise locations of restaurants must comply with the rule due to their involvement in “holding” Food Traceability Lot (FTL) foods, as stated in §1.1310 (FDA 2023c). However, exemptions apply to individual retail food establishments (RFEs) and restaurants with average annual food sales below \$250,000 (FDA 2023c). Franchisees have the option to delegate record maintenance to another entity while still ensuring record availability within 24 hours upon FDA request, as defined in §1.1455(b) (FDA 2023c).

6. Faster Product Identification and Removal

The key to a successful traceability system is the ability to expedite the identification and removal of potentially contaminated food products from the market to minimize foodborne outbreaks. As previously mentioned, establishing, and utilizing KDEs, such as product identifiers, lot codes, and critical tracking events, allow rapid product identification throughout the supply chain (FDA n.d., 2023d). The sharing of KDEs among stakeholders enables the rapid tracing of product flow and facilitates the precise identification of potential sources of contamination or quality issues (Bhatt et al. 2013). Furthermore, using

TLCs to identify specific batches or lots of food products facilitates precise tracking and targeted removal when necessary (FDA 2023c, 2023d). Additionally, the FDA encourages the development and implementation of traceability plans (FDA n.d.), which outline the procedures and processes for capturing and sharing traceability data. By fostering a collective approach, stakeholders can actively exchange information, enabling seamless communication and data sharing throughout the supply chain (Bhatt et al 2013; Zhang and Bhatt 2014). This collaborative endeavor promotes transparency, facilitates the traceability of food products, and enhances the overall effectiveness of the traceability system.

Food Categories Covered and Exempt by the Food Traceability Rule

The following food categories on the FTL will be covered by the rule (FDA 2023b). You can find more information by following the link provided in Table 1.

1. Cheese (except for cottage cheese, ricotta, and hard cheese aged over 60 days)
2. Shell eggs
3. Finfish, including smoked or raw tuna, and shellfish (e.g., oysters, mussels, clams)
4. Fresh-cut fruits and vegetables
5. Leafy greens (e.g., lettuce, spinach, kale)
6. Herbs (e.g., cilantro, parsley)
7. Tomatoes
8. Melons
9. Cucumbers
10. Sprout

The following are exempt from compliance with the rule (FDA 2023c):

- Fishing vessels
- Entities that handle food from a fishing vessel, if the fishing vessel owner still owns the food
- Raw bivalve molluscan shellfish

- Dry seafood
- The kill step
- Changing a food to a form not on the TFL (e.g., processing fresh finfish into dry fish)
- Commingled seafood from different farms or different landing vessels after the vessels have landed
- Preparing electronic sortable spreadsheets if the preparer is a smaller entity with specific monetary value

The FDA has developed a tool that can be used to identify whether your facility and products are exempt from compliance. See Table 1 for a link to this tool, along with some other available tools and resources.

Conclusion

Implementing the Food Traceability Rule represents a critical step toward achieving a comprehensive and efficient traceability system in the food supply chain. Businesses can request modified requirements or exemptions based on their unique circumstances as they work toward compliance. While the road to compliance is still a long haul, the industry stakeholders should start preparing for compliance now to help achieve the goal of end-to-end traceability.

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Table 1. Resources relevant to Food Traceability final rule.

FSMA	Food Safety Modernization Act (FSMA)	https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma
	FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods	https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods
	FSMA Traceability Rule – Frequently Asked Questions	https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma-food-traceability-rule
	FSMA Technical Assistance Network	https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan
Food Traceability Rule	Food Traceability Proposed Rule Overview	Slides: https://www.fda.gov/media/145723/download
	Food Traceability List (FTL)	https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list
	FDA Webinar on the Food Traceability Final Rule	Recording: https://www.youtube.com/watch?v=flUW3cE0dAw Slides: https://www.fda.gov/media/163838/download
	Exemptions to the Food Traceability Rule	https://collaboration.fda.gov/tefcv13/
	Critical Tracking Events (CTEs) and Key Data Elements (KDEs)	https://www.fda.gov/media/163132/download
	Requirements for Additional Traceability Records for Certain Foods	https://www.federalregister.gov/documents/2022/11/21/2022-24417/requirements-for-additional-traceability-records-for-certain-foods
	FL Sea Grant Seafood Academy Webinar on Traceability	Recording: https://www.youtube.com/watch?v=LcWtKNggMoY
	<i>New Era of Smarter Food Safety</i> Blueprint	https://www.fda.gov/food/new-era-smarter-food-safety/new-era-smarter-food-safety-blueprint
	Retail Food Establishments (RFEs) and Restaurants Records	https://www.fda.gov/media/163014/download
Supply Chain	Seafood Supply Chain Example	Recording: https://www.youtube.com/watch?v=RCT86_Nhwmc Transcript: https://www.fda.gov/media/163058/download Slides: https://www.fda.gov/media/163055/download