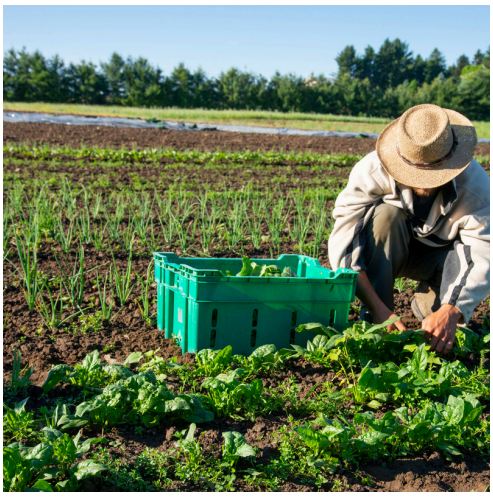
Industry Roundtable Series on the FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods

Top-Line Learnings Summary



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REAGAN-UDALL FOUNDATION FOR THE FDA

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Overview

The FDA final rule on the Food Safety Modernization Act's Requirements for Additional Traceability Records for Certain Foods (Food Traceability Rule) establishes traceability recordkeeping requirements, beyond those in existing regulations, for persons who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL). The compliance date for the final rule is January 20, 2026.

At the core of the Food Traceability Rule is a requirement that persons who manufacture, process, pack, or hold foods on the FTL maintain records containing Key Data Elements associated with specific Critical Tracking Events provide that information to the FDA within 24 hours (or within some reasonable time to which the FDA has agreed). The rule affects domestic and foreign firms producing food for U.S. consumption along the entire food supply chain in the farm-to-table continuum. And, while the final rule aligns with current industry best practices, it will likely require, at varying levels, firms to seek and invest in new systems and new processes. (These industry best practices have not been scaled throughout the entire supply chain and are only routinely utilized in certain segments of the industry.) Although the final rule does not require electronic recordkeeping, some firms may employ new technology to comply with the rule. As the industry prepares to implement the Food Traceability Rule, questions and challenges naturally arise.

In Spring 2024, the Reagan-Udall Foundation for the FDA (Foundation) conducted a brief series of interviews to gain industry perspectives on implementing the Food Traceability Rule and identify challenges facing specific sectors along the entire food supply chain. The Foundation then convened three invitational roundtable discussions that included entities covered under the rule. The discussions aspired to facilitate cross-sector dialogue, document and prioritize concerns, share learnings from those actively engaged in implementation, and discuss strategies for successful implementation by the January 20, 2026, deadline. Following are the themes and highlights discussed across the roundtables. This summary also includes links to FDA resources to assist with implementation of the final traceability rule.

Awareness

Participants described low awareness of the rule and its specific requirements across the food system, especially among certain industry sectors, small and medium-sized suppliers, foreign suppliers, non-chain restaurants, and companies not connected to a trade association. The new requirements may be the first instance some supply chain participants (such as very small restaurants) have been asked to provide information to the FDA and may not routinely maintain or share data at the level the rule requires. While regulatory compliance may be the primary goal, industry, as a whole, may not be aware that the scope of the rule will change, in some cases substantially, the way companies conduct business.

Concerns also were raised about multiple interpretations of the final rule, which may lead companies to mistakenly believe their current operations are sufficient for compliance. Participants noted more education and prescriptive direction on implementation requirements (such as an example of tracking key data elements throughout the supply chain) would improve general awareness and accurate understanding of the specific requirements of the rule.

In addition, participants expressed interest in ensuring that potentially involved regulators (such as state regulators) are aware of their role in enforcement, which requires education about, and understanding of, the rule. (In a related observation, participants sought clarity on the role of local and state public health agencies in implementing the final rule.)

Traceability Lot Code & Labeling

The traceability final rule requires the use and sharing of Traceability Lot Codes (TLCs) to identify a food product as it moves through the supply chain. Firms shipping FTL foods are required to provide the recipient with the TLC for each lot of FTL food, as well as information on the TLC source (the physical location where the TLC for the food was assigned) or a TLC source reference (which provides an alternative method to give FDA access to information on the TLC source).

Several concerns were raised about the new TLC requirements, including discussion of the level of labeling and tracing activity necessary to generate the required information. For example, some participants believe that labeling and tracking at the case-level is essential to generate the required information, although case-level labeling and tracking is not explicitly required in the Rule. In addition, the lack of standardization for TLCs that must be read and tracked through the supply chain was highlighted. One specific concern centered on implementing new labeling standards (which requires aligning and implementing global data standards) and reliance on label availability. Damaged, unreadable, improperly encoded, or lost labels can lead to unreliable reporting of codes, which could compromise the use of the TLC information in investigations of food-borne illness outbreaks. Key TLC themes emerged around defining, capturing, and sharing the TLCs, assuring accuracy and allowing flexibility, and storage of TLCs in case of an investigation. Participants expressed a need to better define

what information is needed in the TLCs, the intersection of lot-level and case-level tracking, and best practices for capturing and storing accurate details.

Warehouse Management System Capability

A significant operational challenge of the final rule occurs within food warehouse management. Distributors closer to the end of the supply chain may carry thousands of different FTL items, which creates significant complexity and requires their warehouse management to be flexible to accommodate the variability of products distributed. Currently, the capabilities of warehouse management systems are highly variable, and most are likely not capable of capturing all KDE data points without significant upgrades or overall system replacement. These are complicated conversions that can require years to implement. For example, existing warehouse management systems are able to capture a single TLC at the pallet level (often as a single lot code per pallet structure). However, some pallets may contain mixed lots of the same product, mixed products, or products provided by more than one grower or manufacturer, and WMS would have to be re-configured to manage this complexity. The rule requires both the TLC and the TLC Source be shared with recipients of the food product and provided to FDA in an electronic sortable spreadsheet that could be produced within 24 hours (or a reasonable time to which FDA has agreed) upon request during an outbreak or recall.

Participants expressed that much of the industry interprets this requirement to mean that every case of food must be labeled and scanned to produce the data FDA may request of downstream entities to trace a lot through the supply chain. This interpretation could potentially require significant increases in labor, equipment, and space, with significant associated costs. Participants discussed various approaches to warehouse management tracking, including offering "most likely" lot codes or use of probability calculations (versus explicit scanning of every product).[1] Using probability calculations would reduce the resources needed to comply with the rule while providing information on the TLCs likely to be present in the shipment. This approach, in aggregate, could provide FDA visibility to common suppliers and TLC information upon review. Such an approach may reduce the risk of error if rigorous scanning practices are not likely to be implemented in existing technology and human capital systems. Some participants supported the concept of providing a reasonable number of TLCs versus exact TLCs. Discussion also explored the complexity of the probability calculation process, as well as the risk of unintentional and inaccurate implication of growers or suppliers in an initial FDA investigation. Lengthy lead times for operational and technology changes and missing labels were also of concern when tracking key data elements. Participants expressed a need to better understand the FDA investigation process; particularly how investigations will be handled when multiple lot codes are submitted.

[1] Representatives of the International Fresh Produce Association presented a probability lot code approach for discussion.

Technology

Various technology systems (such as master data management systems, warehouse management systems, enterprise resource planning systems, third party traceability systems) may support compliance with the rule, but industry must evaluate multiple aspects, ranging from functionality to storage capacity to connectivity with internal and external systems. Participants noted that changes to the master data management process are needed for compliance, as are enhanced integration of systems used to capture data. Questions remain around realistic metrics, opportunities for data/technology standardization, navigating various levels of technical sophistication (from pen and paper to block chain), and what a successful system and output looks like.

FDA staff supplied a sample Electronic Sortable Spreadsheet with roundtable participants. Use of this specific spreadsheet is not required but offers a template for submitting requested information. While the group found the template helpful, concerns were expressed about a low awareness for *when* the spreadsheet needs to be completed and whether smaller companies will have the capacity to gather and report required information in the time frame allotted. (While acknowledging that below a certain threshold, smaller firms are exempt from the requirement to provide the spreadsheet.) Participants suggested making the instructional portion of the spreadsheet template more accessible and providing a sample "completed template" to demonstrate expectations for each sector of the supply chain. Participants also requested the spreadsheet be tested with real-world or simulated data, through the supply chain from farm to restaurant or retailer, to identify any adjustments that might improve its adoption and usability.

Pilots (Concept-Testing)

Since release of the final rule in November 2022, multiple pilot programs have been conducted by industry to test current systems and identify necessary changes. Most of these pilots have been conducted independently and have focused on only one food product or category.

Roundtable participants discussed the value of additional pilots citing the need to invest significant time and energy in preparing for compliance. While pilots should not delay implementation, some agreed that integrated pilots scaled beyond a solitary product or facility could be helpful as well as those that test the new regulatory requirements down the full supply chain from grower/manufacturer to retailer/restaurant and to FDA to assess the usability of the information in investigations of food-borne illness. Such pilots could build from the most widely adopted industry practices and help test the prevalence of those practices. Suggestions also called for creating pilot templates, identifying spaces to actively share pilot learnings, and tailoring pilots to small, intermediate, and larger businesses.

Public/Private Partnership

Participants highlighted the value of the roundtable discussions and expressed interest in not only additional conversation but also exploration of a public-private partnership (PPP) with cross-sector companies of all sizes. A well-organized PPP, which might include state regulators and public health agencies, could facilitate collaboration to support implementation, and could help build consistency on data structure, requirements, timing, and standards. In addition, a PPP could provide a platform to compare pilot learnings and to aggregate implementation challenges to share with FDA.

Structure of a PPP was seen as critical. Roundtable participants voiced that such a partnership should be built around clear goals and expectations and avoid a "pay-to-play approach" that could exclude smaller companies.

Implementation Schedule

Because the Food Traceability Final Rule requires information sharing throughout the supply chain, FDA determined the most effective and efficient way to implement the rule is to have all persons subject to the requirements come into compliance by the same date: January 20, 2026.

While participants understand this approach in theory, and participants aligned on the value of enhanced traceability, many suggested a staggered implementation schedule might offer greater efficiency and compliance. Suggestions included staggering compliance by sector or by company size to capitalize learnings that could be shared along the supply chain or between larger and smaller entities. As each sector of the supply chain (the purchaser) relies on information provided by the prior sector participant (their supplier), sector by sector implementation could start at the beginning of the supply chain and progress through to retail and create a roadmap to compliance.

Moving Forward

At the close of the third and final roundtable in the 2024 series, FDA leadership underscored that it looks forward to continued dialog about implementing the Food Traceability Rule and will solicit feedback through additional routes, including meetings, comments, and other public forums. The FDA is willing to participate as appropriate in a public-private partnership and will continue to post regular updates and resources as the compliance date approaches. The Foundation will continue its support of the effort by helping to facilitate such engagement.

Appendix A: FDA Resources

FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods Traceability List
The Food Traceability List (FTL) identifies the foods for which the additional traceability records are required.

FSMA Food Traceability Rule Frequently Asked Questions
FDA webpage with list of the most common questions about the FSMA 204 Food Traceability Rule

Electronic Sortable Spreadsheet
Electronic sortable spreadsheet template that can be used to fulfill data submission requests for FDA in accordance with the Food Traceability Rule

Overview of FDA Rule
Brief video highlighting some of the resources developed by FDA to support understanding and implementation of the Food Traceability Rule

Appendix B: Acknowledgements

The Foundation appreciates the participation and input of FDA and the following individuals who participated in the Roundtable Series.

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