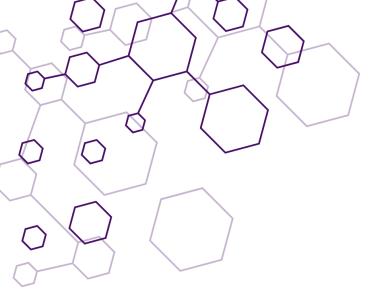# Industry Roundtable Series

Supplemental Report: FSMA Food Traceability Rule Pilots

SEPTEMBER 2025

REAGAN–UDALL
FOUNDATION
FOR THE FDA

About the Reagan-Udall Foundation for the FDA

The Reagan-Udall Foundation for the FDA (Foundation) is an independent 501(c)(3) created by Congress to advance the mission of the FDA to modernize product development, accelerate innovation, and enhance product safety. The Foundation works to advance regulatory science, support development and dissemination of reliable information, and facilitate engagement and information exchange.

Table of Contents

Overview

In 2024, at the request of the U.S. Food and Drug Administration (FDA), the Reagan-Udall Foundation for the FDA convened three invitational roundtable discussions with industry stakeholders directly involved in implementing the FDA's final rule on the Food Safety Modernization Act's Requirements for Additional Traceability Records for Certain Foods (Food Traceability Rule). This rule introduces enhanced traceability recordkeeping requirements, beyond those in existing regulations, for entities that manufacture, process, pack, or hold foods listed on the Food Traceability List (FTL).

Through facilitated cross-sector dialogue, industry representatives were able to share concerns and discuss strategies that could support successful implementation of the rule. The discussions from across the farm-to-table continuum highlighted concerns such as low awareness and readiness, complexities of traceability lot codes and labeling, and capabilities of warehouse management systems. Potential strategies for success included education and the sharing of best practices, pilot programs, a staggered implementation schedule, and a public private partnership to support collaboration. Learnings were shared in a summary report prior to a fall 2024 virtual public meeting that gathered public comments on similar themes. A common theme throughout was the need for more time to strategically test and implement the requirements of the rule. In August 2025, the FDA proposed extending the compliance deadline for the rule from January 20, 2026, to July 20, 2028.

A fourth roundtable, held in May 2025, focused on remaining key implementation challenges, insights from recent industry-led pilots, and alignment with outbreak investigation processes. A July 2025 public webinar further explored these insights. A recording and transcript of the webinar is available on the Foundation's website at www.reaganudall.org.

The following summary outlines the key learnings from the 2025 events, including a brief review of critical points related to FDA outbreak investigations and references to relevant FDA and Foundation resources to inform implementation of the Food Traceability Rule.

Systems Interoperability Across the Supply Chain

The traceability rule introduces new requirements for sharing product tracing data between industry members and with the FDA. In order to comply with the rule, some firms are establishing new communication platforms and implementing changes to processes and procedures. Implementing these changes can be complex, especially for foods that pass through multiple parties due to existing technological fragmentation – such as incompatible field lengths for GLNs and varied data formats – resulting in incompatible or incomplete systems among growers, manufacturers, distributors, and retailers. Other challenges include legacy platforms; the absence of uniform standards; diverse customer requirements for earlier implementation timelines than those mandated by the rule; and diverse supplier practices such as different barcode types and labeling methods. Additionally, smaller suppliers often struggle with technical and financial limitations and may lack sufficient training to ensure process understanding and compliance. Pilot projects highlighted the need for accurate master data, upgrades to warehouse management systems, and better data-sharing protocols.

Roundtable participants discussed the need for standardization efforts, including initiatives like the Partnership for Food Traceability, to address many of these issues. While transitioning from paper to digital remains an ongoing challenge, there was optimism among participants about future digital information sharing that could provide greater efficiency and cost-effectiveness.

Traceability Lot Code Source & Labeling

A traceability lot code (TLC) source is the physical location where a food product is assigned a traceability lot code—commonly at the point of initial packing or transformation. This data is crucial for supply chain tracking and recall management, yet it is often missing or ambiguously defined, or unsupported by current packaging and labeling practices, especially since it's not typically printed on shipping cases. Such gaps impact both upstream and downstream traceability, limit the utility of data during recalls and make outbreak investigations slower.

Roundtable participants identified TLC source data sharing and role clarity as a major challenge. Pilot programs highlighted the inconsistent presence of TLC source information in pilot program files and persistent supplier misunderstandings resulting

in misaligned or undocumented information hindering commercial and tracking activities. While not a requirement of the rule, participants shared that case-level tracking is particularly difficult due to multi-lot pallets and cost barriers to item-level identification, especially in large-scale, high-speed distribution centers.

Uniform practices for collecting and sharing TLC sources remain elusive. Recent pilots aim to improve TLC source processes, focusing on cost-effectiveness, data accuracy, and confidentiality through solutions like GLNs and common URLs. Ongoing collaboration and flexible regulatory approaches are seen as critical for addressing these complexities and meeting evolving traceability requirements.

Divergent Customer Demands

Suppliers face significant challenges meeting diverse customer requirements, timelines, and third-party data platforms as they work to comply with the Food Traceability Rule. Several roundtable participants have implemented multiple traceability systems to accommodate the diversity and requirements of their supply chain partners. Some stakeholders have had to use five or more such systems, resulting in subscription costs that can reach tens of thousands of dollars for each customer. One participant stated, "Our customer base is diverse, with varying capabilities, and there are notable differences in how information is processed and shared. Although technology has advanced, internal and partner capabilities are sometimes misaligned, necessitating both physical and digital workflows for now. Additionally, addressing various customer preferences—such as 2D barcodes compared to GS128—is challenging when managing numerous unique specifications. Implementing a base-level compliance solution is important..."

Customer expectations are also increasing, as more companies request their suppliers to comply with additional measures beyond what the rule requires. Participants observed that major retailers now require comprehensive traceability information for all food products, not just those on the Food Traceability List (FTL). These enhanced retailer expectations are contributing to higher industry costs, while the potential benefits to public health remain uncertain.

The proposed 30-month compliance extension is generally seen as helpful in working with customers, offering additional time for collaboration and digital integration. However, some customers are adhering to the original deadlines, requiring continued adjustment. Participants underscored the importance of holistic strategies, ongoing improvements, open communication about systems integration, and flexibility to satisfy both FTR and individual customer needs.

Progress Made Through Pilots

While industry-led pilot projects have driven notable progress, real-world complexities remain significant. Stakeholders expressed a strong preference for the FDA to support scalable, cross-sectoral pilot programs and to embrace an approach that values "progress over perfection" during initial implementation stages. Previous Food Traceability Rule roundtable discussions featured insights from early small-scale, independent pilots conducted by industry participants to evaluate current systems and pinpoint areas needing improvement. There was widespread interest in launching additional integrated pilots on a larger scale to test food traceability requirements across the full supply chain and facilitate knowledge sharing. Consequently, the fourth roundtable focused on analyzing lessons learned from recent large-scale, integrated pilot projects aimed at evaluating food traceability procedures and identifying optimization opportunities.

Highlighted pilot initiatives included a major distributor's efforts to improve traceability for both inbound and outbound shipments within an expansive supplier network. A key point of discussion was consideration of alternatives to lot-level tracking including further discussion on the definition of "transformation."   Another project, led by a prominent retailer, assessed multiple supply chains and operational sites—including suppliers, distributors, processors, logistics hubs, distribution centers, and retail outlets—to determine readiness for the Food Traceability Rule and regulatory compliance with an emphasis on accurately capturing critical tracking events (CTEs). A leading produce company also participated, targeting growers, processors, and distributors, with particular emphasis on recording and sharing essential data during critical tracking events like harvesting, packing, shipping, and transformation. Findings underscored the value of standardizing transaction commonalities amid diverse operations and acknowledged the crucial role that technology plays in enabling efficient supply chain transactions.

Simulated supply chains were also piloted to extract valuable insights and inform efforts overseen by the Partnership for Food Traceability. Simulations, concentrating on FTL foods, sought to replicate realistic conditions for testing process effectiveness, data creation, and data transfer across the supply chain. An important metric was the duration required for investigators to trace outbreak sources once traceback commenced—a fundamental objective of the regulation.

Roundtable participants found these pilots highly instructive and there is considerable interest in further initiatives. There was recognition that successful pilot programs depend on clear education, effective team mobilization, precise item identification, and

continuous process evaluation. Establishing standardized methodologies and embracing technological advancements are critical to navigating supply chain intricacies and achieving robust traceability. Ultimately, consensus on traceability definitions and the demonstration of organizational value are vital—not only for regulatory adherence, but also to advance public health goals through rapid removal of contaminated products and improved outbreak response.

Additional Pilot Learnings

Exposed Hidden Supply Chain Roles and Data Gaps

Pilots uncovered unexpected third-party handlers, brokers, or foreign-sourced ingredients (e.g., cream cheese in parfaits) that hadn't been mapped to Food Traceability Rule requirements. Uncovering "hidden roles" and non-standard processes (e.g., returns, transfers, drop shipments, repacking, tailored product specifications, seasonal supply fluctuations, etc.) in the supply chain highlights the value of pilot/simulations in revealing blind spots and the need for ongoing process adjustments, especially around item creation, specifications, and recordkeeping to ensure proper flagging of FTL-related information.

Enhanced collaboration is needed to address these evolving supply chain challenges. Specifically, the industry recognizes the necessity of including brokers in discussions about timely and accurate lot-level information, especially when their level of product possession determines their recordkeeping responsibilities.

Need for Regular Lot Code Verification Audits

Key lessons from one pilot highlight that manual data entry is error-prone and limits capture to one code per pallet, sometimes missing critical identifiers like TLC source. Human error can cause mismatches between expected and actual lot codes during ordering and receiving. Even with scanning, some selection errors remain. To address these gaps, one pilot presenter is considering enhancements such as integrating automated scanning solutions at the item level and conducting more frequent audits at distribution centers to improve accuracy and reduce errors.

Education Needs Vary Widely Across Supply Chain

The pilots found that education and communication were essential for improving supplier partnerships. In-person meetings with traceability partners led to productive discussions and alignment on operational practices. Training needs varied, with some

requiring in-depth assistance on the rule and others needing broker-specific or language-adapted sessions. Data sharing remained a challenge, as not all partners could easily integrate key information into their systems. The findings show that tailored training is crucial for different roles in the supply chain.

Potential Opportunities

The roundtable discussion highlighted the importance of the Agency working collaboratively with industry to advance efforts. Participants identified several opportunities for both the FDA and industry to further progress these initiatives.

For FDA

- **Support Cross-Sector Pilots**: Support comprehensive, multi-stakeholder traceability pilots to test and refine real-world solutions at scale
- **Provide Assistance for Challenges**: Continue to provide assistance and guide industry efforts to find solutions to challenges such as Traceability Lot Code Source documentation
- **Develop Targeted Training Resources**: Create training resources, tailored to different supply chain segments (e.g., small suppliers, retailers, international partners)

For Industry Stakeholders

- **Adopt and Promote Data Standards**: Encourage suppliers and customers to align data standards/best practices and reduce proprietary fragmentation wherever possible
- **Invest in Digital Infrastructure and Scalable Tools**: Use the extended timeline to modernize internal systems, especially in warehousing and distribution centers
- **Engage in Joint Traceability Efforts**: Pool resources to pilot traceability tools, share learnings, and avoid duplicative system costs
- **Maintain Compliance Momentum**: Embed traceability tasks into regular operations (e.g., supplier onboarding, mock recalls) to avoid backsliding during the extension period

FDA Outbreak Investigations

The primary goals during a foodborne illness outbreak include identifying the contaminated food item, tracing its distribution throughout the supply chain, and determining suitable regulatory responses. Equally vital is the communication of findings to consumers, ensuring public health protection through clear guidance regarding preventive actions. Recent discussions underscore stakeholders' interest in the FDA's outbreak investigation procedures and the anticipated improvements in increased speed and accuracy of tracing potentially contaminated food products through the supply chain, from implementing the Food Traceability Rule.

FDA personnel have delineated the agency's multifaceted roles and responsibilities in managing multi-state outbreaks. State and local health authorities are tasked with collecting epidemiological data and conducting environmental assessments, often initiating preliminary traceback investigations within their jurisdictions. These efforts provide critical data that support larger-scale FDA investigations. The Centers for Disease Control and Prevention (CDC) oversees and assists with capturing epidemiologic information, thereby maintaining comprehensive records on food exposures and histories. For international incidents, the CDC collaborates with other public health agencies, while for domestic matters, it provides insight to assist FDA and USDA determine which cases may warrant further tracing, recognizing that not every incident requires in-depth tracking. As outbreaks evolve, the CDC continually updates exposure data, particularly during the traceback phase, to ensure the availability of current and complete epidemiological details. The FDA identifies the best cases to trace based on the available epidemiologic data and manages traceback investigations across multiple, geographically dispersed, if possible, distribution channels to pinpoint potential contamination origins. This involves engaging all relevant firms, obtaining traceability documentation, and performing inspections and sample collections as required. Synthesized data inform the FDA's subsequent actions, including requests for additional records or the initiation of further regulatory measures if a source of contamination is identified.

Currently, record requests are often broad due to limited specificity and standardization of the data being obtained. Although lot codes can help narrow record scope, such identifiers are frequently absent. The lack of availability of lot codes complicates the process of linking products along the supply chain, necessitating supplementary documentation and contributing to investigational complexity. Additionally, records often lack explanatory notes or comprehensive descriptors, resulting in protracted provider communications and investigative delays. Collecting

records at each stage of an outbreak is consequently time-intensive, especially when key information is missing, hampering swift decision-making.

The introduction of the Food Traceability Rule will facilitate access to standardized, detailed traceability data, notably the inclusion of traceability lot codes and traceability lot code source. This development is expected to increase the accuracy and focus of future record requests. With enhanced traceability, procedural redundancies may be minimized, as investigators can conduct targeted, prioritized requests and solicit information concurrently from various points in the supply chain. These changes are projected to streamline processes, expedite linkage creation, reduce administrative burdens, and accelerate investigative timelines.

When sufficient data are available to confirm or exclude specific products or sources, traceability information plays an essential role in regulatory decisions and public health actions. Regulatory responses may involve issuing import alerts, warning letters, or enforcement actions based on findings from inspections and traceability analyses.

When making these public health decisions, traceability data are essential to effective recall management, providing clear and actionable guidance to consumers and retailers regarding affected lot codes. This level of detail helps prevent the unnecessary removal of unaffected products and ensures efficient execution of recalls at retail and food service establishments. Additionally, traceability data supports the issuance of public warnings and advisories domestically and internationally, as appropriate, based on the origin of the implicated products.

Moving Forward

During the 2025 roundtable discussion, FDA indicated the Agency will use the extended implementation period to work with stakeholders, address challenges, and provide technical assistance and resources as needed. Stakeholders have also requested further clarification on the Agency's enforcement approach. The foundation will continue to facilitate engagement, as needed, as the industry addresses the requirements of the traceability rule.

Appendix A: Supplemental FDA and Foundation Resources

FDA

[FDA Proposes to Extend Compliance Date for Food Traceability Rule and Issues New FAQs and Other Resources](#)
FDA Constituent Update announcing the Agency's proposed rule to extend the compliance date for the Food Traceability Rule

Foundation Resources

2024 [Industry Roundtable Series on the FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods](#)
Foundation publication summarizing the top-line learnings from the 2024 series of roundtables held on the Food Traceability Rule

2024 [Virtual Public Meeting on FDA's Final Rule on Requirements](#)
Foundation webpage for the October 7, 2024, Virtual Public Meeting on FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods

2025 [FDA's Final Rule on Requirements for Additional Traceability](#)
Foundation webpage for the July 10, 2025, Webinar on FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods

Appendix B: Acknowledgements

The Foundation appreciates the participation and input of FDA and the following individuals who participated in the May 2025 Roundtable and/or presented in the July 2025 webinar.

Elise Binder

Haley Bittermann

Jodi Blanch

Mara M. Burr

Cameron Ciminello

Jeffrey Cree

Beth Johnson

Andrew Kennedy

Charles Leftwich

Liz Lentz

Michael Lookup

Eric Marshall

Jill McGill

Johnny McGuire

Ben Miller

Takashi Nakamura

Katia Noll

Mala Parker

Amy Parks

Kate Piche

Lory Reveil

Sonia Salas

Liz Sertl

Jeannie Shaughnessy

Hilary S. Thesmar

Ed Treacy

Arlin Valenzuela-Reyes

Daniel Vincett

Roberta Wagner

Mark Walker

Lisa Weddig

Lindy Wiedmeyer

Amy Wise

Carlos Zapata

1333 New Hampshire Ave, NW
Suite 420
Washington, DC 20036
www.reaganudall.org