

**PFT-FDA Joint Q&A Roundtable:
Food Traceability Rule Lot-Level Tracking Requirements
September 25, 2026**

SUMMARY

PFT's role in the Roundtable summarized in this report was primarily facilitation of the exchange of information amongst stakeholders and FDA. This report summarizes the comments and recommendations of participants at the Roundtable. PFT takes no position on the comments or recommendations made by those participants and summarized in this report.

Background and Scope

The [Partnership for Food Traceability \(PFT\)](#) is an independent, sector-neutral nonprofit Public-Private Partnership driving industry-led solutions for electronic interoperable traceability across the food supply chain. PFT works collaboratively to streamline compliance with [FDA's Food Traceability Rule](#) by developing flexible and efficient implementation frameworks built on mutual accountability. Through the formal Public-Private Partnership structure, PFT provides a forum in which FDA and industry can work together, with FDA's technical assistance and advisement, to coordinate food traceability approaches across diverse supply chain sectors to comply with the Food Traceability Rule, with the goal of effectively removing potentially contaminated products from the market more rapidly.

On September 25, 2026, PFT and FDA held a joint Roundtable through the Public-Private Partnership, to aid FDA in its [statutory requirement](#) to meet with stakeholders on a quarterly basis to discuss lot-level tracking. The session provided an opportunity for FDA to engage stakeholders on Food Traceability Rule implementation of lot-level tracking, challenges facing regulated entities, and potential solutions. The key objectives of the meeting were to:

- Identify and discuss specific questions and challenges around lot-level tracking as companies work toward implementation of the Food Traceability Rule.
- Provide an opportunity for bi-directional Q&A for FDA and industry on additional information that is needed on lot-level tracking, flexibilities, compliance and implementation challenges, pilot learnings, and new ideas for meeting the requirements of the Food Traceability Rule.

The Roundtable was structured with two main components. During the first half of the meeting, PFT members and certain non-members representing sectors and perspectives not covered by the PFT membership presented on operational challenges in implementing lot-level traceability, potential solutions, and examples of how industry is working toward implementation. During the second half, FDA and participants engaged in discussion and dialogue around existing challenges and presented solutions.

PFT membership includes 21 trade associations, representing thousands of individual companies—many of whom are not PFT members—as well as individual industry and technical expert members. In

addition, several organizations outside of PFT's membership participated in the discussion to ensure that perspectives across all industries impacted by the Rule were present, along with organizations of different sizes.

This Roundtable was the second in a series of joint PFT-FDA engagements in 2026, providing a forum for FDA to hear feedback from stakeholders on lot-level traceability efforts and challenges facing industry. The summary of the March 6 meeting can be found here:

- March 6, 2026: [PFT-FDA Joint Roundtable: Food Traceability Rule Lot-Level Tracking](#)

Summary

Participants discussed challenges and solutions to support compliance with FDA's Food Traceability Rule, which establishes enhanced recordkeeping requirements for those who manufacture, process, pack or hold foods on FDA's Food Traceability List (FTL). The Rule mandates lot-level tracking for foods on the FTL, requiring businesses to assign unique codes, known as Traceability Lot Codes, and record Key Data Elements (KDEs) at specific Critical Track Events (CTEs), like initial packing, transformation, and shipping. The goal of lot-level tracking is to enable rapid tracing and identification of the source of potentially contaminated foods during an outbreak. The rule is recognized as having the additional benefit of narrowing the scope of recalls and removing affected product from the supply chain quickly. The current compliance date for the Food Traceability Rule is July 20, 2028.¹

FDA emphasized that it continues to hear different implementation challenges across industry sectors and is interested in understanding both those challenges and potential solutions. FDA is reviewing the 26 comments submitted in response to its May discussion paper on potential flexibilities and encouraged industry to continue providing detailed feedback. FDA is also reviewing comments on its February draft Q&A guidance.

Several key themes emerged throughout the discussion, particularly around the operational challenges companies are encountering as they build systems and exchange traceability data with trading partners. The discussion provided FDA with specific examples of where implementation is proving difficult in practice and explored potential flexibilities that could facilitate implementation while maintaining access to useful and accurate traceability information to meet the requirements of the Rule.

Industry needs timely clarity on flexibilities to support successful implementation.

Participants consistently emphasized that companies are actively working toward implementation but need greater clarity from FDA on potential flexibilities before they can fully design and operationalize their systems. Companies are reluctant to make significant investments in systems or processes that may need to be redesigned once FDA's approach to flexibilities is finalized.

¹ The FDA [proposed](#) to extend the compliance date for the rule by 30 months to July 20, 2028. Subsequently, the [Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act of 2026](#) directed FDA not to enforce the Food Traceability Rule prior to that same date. FDA intends to comply with this Congressional directive.



The discussion underscored that **traceability requirements that are relatively straightforward conceptually can become significantly more complicated when applied across real-world supply chains**, particularly when companies use different technologies, data standards, business models, and operational processes. Participants encouraged FDA to provide timely guidance and clear guardrails that would allow companies to continue building and testing their systems while working through implementation challenges.

Participants also offered to provide FDA with additional examples and information demonstrating what potential flexibilities would look like operationally, including the data outputs FDA could expect to receive under different approaches.

Incomplete and inaccurate data from upstream trading partners is a significant barrier to implementation.

A recurring concern was that downstream companies can only transmit accurate traceability information when they receive accurate and complete information from their suppliers. Participants described substantial challenges obtaining required traceability data even after extensive supplier outreach.

One distributor reported contacting approximately 1,600 manufacturers regarding FSMA 204 requirements but receiving responses from fewer than 20 percent of manufacturers with Food Traceability List products. Participants also described ASNs arriving late, containing inaccurate information, being available from some facilities but not others, or failing to correspond with the physical product received. In one example, only approximately 23 percent of manufacturers transmitting ASNs were considered "trusted" based on audits of the data, while approximately 75 percent of the data contained some type of error. More broadly, the discussion also highlighted the importance of creating stronger feedback loops with suppliers so data quality problems can be identified, communicated, corrected, and monitored over time.

Participants suggested that **FDA communications directly reinforcing trading partners' obligation to provide required KDEs downstream could help companies secure greater engagement from suppliers.**

Allowing a "reasonable range" of potential lot codes could address important operational realities.

A significant portion of the discussion focused on circumstances in which companies cannot in operational practice determine with certainty which individual Traceability Lot Code (TLC) is associated with a specific case. This can occur, for example, when mixed lots are physically intermingled or when lot information is not available through a scannable case-level label.

Participants discussed allowing companies in defined circumstances to provide a **reasonable range of potential TLCs**, rather than requiring certainty at the individual case level. One suggested framework was to define the reasonable range as the narrowest range a company can reliably identify without requiring universal case-level tracking.



Participants emphasized that any such flexibility would need appropriate guardrails. Questions included how companies should calculate and validate ranges, how the approach should be documented in traceability plans, how frequently assumptions should be tested, and how to prevent the number of potential lot codes from expanding excessively as products move downstream.

The discussion also highlighted a distinction between information needed by **downstream trading partners** and information needed by **FDA during a traceback**. A company might, for example, provide its customer with the most likely TLC supported by its systems while maintaining the ability to provide FDA with a sortable spreadsheet identifying the relevant range of potential TLCs.

Inferred lot codes are possible, but industry needs clear guardrails and validation approaches.

Participants discussed the use of operational and commercial data to infer which lots were associated with particular shipments when scanning every case is not reasonable. Existing information such as purchase orders, pallet identifiers, inventory movement, FIFO/FEFO practices, and product velocity may allow companies to identify a lot or narrow range of potential lots with a high degree of confidence.

Participants stressed, however, that inferred or calculated TLC approaches need **clear boundaries and methods for validation**. One pilot discussed during the roundtable involved performing a three-way match using FIFO practices, commercial data, and sample direct observations through scanning to benchmark the accuracy of inferred results.

The discussion also raised an important supply-chain question: **where should inference begin and end?** If suppliers begin transmitting multiple possible lot codes and each subsequent trading partner applies additional inference, the number of potential lots could expand as a product moves through the supply chain unless other process controls reestablish the provenance of the TLC data. Participants encouraged FDA to establish guardrails that preserve the usefulness of inferred information.

Interoperability remains both a technology and data-quality challenge.

Participants stressed that interoperability challenges extend beyond whether companies can electronically transmit data. **The accuracy, consistency, and usability of the underlying data are equally important.**

Companies described mismatches between electronic records and physical labels, barcodes that cannot be scanned or are incorrectly encoded, ASNs that arrive after the physical shipment, and internal systems that cannot accept another company's lot-code format. Hardware, software, and scanning capabilities also vary considerably by supplier and facility.

Participants emphasized that many supplier problems stem from uncertainty about technical requirements rather than unwillingness to comply. Supplier education, onboarding, testing, and ongoing performance monitoring were therefore identified as important components of successful implementation.



Participants also discussed the potential value of vendor-neutral, broadly accessible technology approaches that could reduce interoperability barriers and make adoption easier across companies of different sizes and levels of technological maturity.

Different supply chain models create distinct implementation challenges.

The discussion reinforced FDA's observation that implementation challenges vary considerably by sector and business model.

Third-party logistics providers (3PLs) face particular difficulties because they may physically handle products without owning them or having visibility into the underlying supplier relationships. This can limit their ability to independently obtain or verify traceability information. Requirements to maintain lot integrity may also necessitate breaking down and rebuilding pallets, increasing operational burden, cost, and opportunities for manual error.

Retailers and independent grocers raised challenges associated with intracompany and store-to-store transfers, particularly movements intended to address shortages or prevent food loss. Participants suggested that low-volume transfers between affiliated locations could potentially rely on existing business records rather than being treated like conventional commercial distribution.

Retail participants also identified challenges associated with small-scale retail transformation. Creating and managing new finished-product TLCs can be particularly burdensome for smaller operations where products and records are managed manually rather than through integrated manufacturing systems. Participants encouraged FDA to consider simplified approaches that preserve traceability back to ingredients while reducing unnecessary recordkeeping burdens.

Participants encouraged FDA to clarify how existing and centrally maintained records may be used to meet requirements. For example, for smaller retailers without integrated systems, records may be maintained by a third party or at corporate headquarters rather than at an individual store.²

Participants suggested allowing those records to be transmitted directly to FDA on a store's behalf instead of requiring store personnel to manually recreate records locally. The discussion emphasized that centralized personnel may, in some circumstances, be better positioned to assemble and provide traceability information quickly.³

Participants also requested additional clarity about activities that do or do not constitute transformation events, including activities such as markdowns, in-store labeling, and trimming produce for quality without repacking or materially changing the product.⁴

² FDA encourages stakeholders to review the following [FSMA 204 FAQs](#) related to this topic: TISCD.3, TLC.7, and TRMA.7

³ FDA encourages stakeholders to review the following [FSMA 204 FAQs](#) related to this topic: TRMA.6 and TRMA.7

⁴ FDA encourages stakeholders to review the following [FSMA 204 FAQs](#) related to this topic: TRFE.2



Implementation will require continued testing, monitoring, and supplier engagement.

A broader theme throughout the roundtable was that implementation is an **iterative process rather than a one-time technology deployment**. Participants described testing data exchanges, monitoring scan and ASN performance, reporting errors back to suppliers, helping suppliers correct barcode and data problems, and incorporating traceability performance into broader supplier business reviews.

Participants emphasized the value of developing simple, repeatable processes that can work across trading partners using different recordkeeping methods and at different stages of implementation. The discussion also highlighted the potential value of a common approach for demonstrating readiness, exchanging sample data, and testing interoperability between trading partners.

Conclusion

The roundtable demonstrated that industry participants are actively investing in implementation and testing potential solutions, but that several important policy and operational questions remain unresolved. Across the discussion, participants consistently emphasized the importance of timely FDA clarity, practical flexibilities, reliable supplier data, clear guardrails for inferred or ranged lot information, and approaches that accommodate differences in supply-chain operations and technological maturity.

FDA emphasized that the detailed operational examples shared during the roundtable are helpful as the agency evaluates potential flexibilities and reiterated the importance of continued industry feedback. FDA will be hosting a public meeting in November, which will provide another opportunity for stakeholders to build on the discussion, including by responding to questions in FDA's discussion paper and providing additional examples of how potential flexibilities could work in practice.

Overall, the discussion reinforced a shared focus on moving implementation forward while identifying practical approaches that provide FDA with useful traceability information without imposing unnecessary operational complexity. The roundtable highlighted an ongoing need for stakeholder collaboration, development of concrete implementation examples to facilitate greater consistency across trading partners, and translation of industry experience into actionable input for FDA.

