PARTNERSHIP FOR FOOD TRACEABILITY

FSMA 204 Pilot Program Invitation

Lot Code and Lot Code Source Flexibility

Sponsored by the Partnership for Food Traceability

Purpose

The Partnership for Food Traceability (PFT) is inviting food supply chain stakeholders to participate in a collaborative pilot program focused on practical approaches to Traceability Lot Code (TLC) and Traceability Lot Code Source (TLCS) implementation under FSMA 204.

This pilot program provides a structured framework for companies to document their experiences, whether from completed pilots, ongoing implementation efforts, or planned testing, and share findings with FDA through the PFT in its capacity as a public-private partnership. The goal is to demonstrate workable compliance approaches for supply chain segments where lot code capture and transmission represent new operational requirements.

Background

FSMA 204 establishes traceability recordkeeping requirements for foods on the Food Traceability List, including the capture of Traceability Lot Codes (TLC) and Traceability Lot Code Sources (TLCS) at Critical Tracking Events. The rule provides flexibility in how traceability lot codes are assigned and documented.

However, current business practices in significant portions of the supply chain (particularly from distribution to retail and restaurants) do not include lot code information in routine transactions. Outbound shipments from distributors typically communicate product identification and quantity but not lot-level detail. Most retail receiving operations are currently not configured to capture incoming lot information.

This operational reality requires practical solutions. Companies across the supply chain are exploring approaches including:

- Calculated lot codes based on inventory rotation practices and shipment timing
- System modifications to capture and transmit TLC and TLCS information
- Electronic interoperability practices (ASN, EPCIS, etc.) that accurately reflect transmission of TLC and TLCS data
- Process changes at shipping and receiving points

This pilot program creates an opportunity to document these approaches, evaluate their effectiveness, and share learnings that benefit the broader industry and inform FDA's understanding of implementation realities.

Pilot Goals

1. **Document current-state practices** for TLC and TLCS capture and transmission across different supply chain segments
2. **Test and evaluate flexible lot code methods,** including calculated TLC and TLCS and process modifications
3. **Identify implementation requirements,** including system modifications, trading partner coordination, and process changes
4. **Capture lessons learned** regarding workflow integration, cost considerations, and operational feasibility
5. **Provide actionable recommendations** for industry stakeholders and the FDA based on real-world implementation experience

Pilot Scope and Example Methodologies

Participants will define their own pilot scope based on their operations and the real-world scenarios they encounter. Examples of relevant TLC methodologies include, but are not limited to:

- **Definitive TLCs:** The exact TLCs are captured when product is shipped and shared downstream during the shipping event. An example of this is the scanning of individual cases during shipment. It is important to note that individual case scanning is subject to an error rate.

- **Calculated/Inferred TLCs:** Often leveraging a warehouse management system (WMS), inbound TLCs are received and managed. These systems then leverage First-In-First-Out (FIFO) or First-Expired-First-Out (FEFO) processes to calculate or infer what TLC has been selected for shipment within a narrow rate of error. While the calculated/inferred TLC is shared downstream, the error/accuracy rate is not.

- **Ranges of TLCs**: Similar to the calculated/inferred method, inbound TLCs are received and managed. Based on known inventory configuration in the WMS, an organization provides a range of likely TLCs associated with an outbound shipment. For example, rather than documenting that the TLC associated with a shipping event is TLC A, an organization documents and shares that the TLC is likely from Lot A, B, or C. This method captures and provides all TLCs that could reasonably be associated with a shipping event at the time product was selected, but specific probabilities are not assigned to each TLC.

- **Probabilistic TLCs:** Similar to the TLC Range method, inbound TLCs are received and managed, and the range of likely TLCs being shipped are identified. In addition, however, specific probabilities of likelihood are assigned to each TLC in the range. For example, an organization may use probabilities to determine that the TLC is 90% likely to be from Lot A, 5% likely to be from TLC B, and 5% likely to be from TLC C.

It should be noted that the methodologies explained above require optimized processes to ensure data output is reliable; companies should consider the following:

1. Define the organization's receiving process, including the validation steps (e.g., auditing or testing) taken, to ensure a reliable level of accuracy of its inbound TLC data. This is important because that inbound data is then tied to internal systems to enable the calculation of outbound data. Inbound data should be electronically received (e.g., via ASN) to support reliability.

2. Define the organization's well-controlled inventory management practices (e.g., FIFO, FEFO) and how those practices support and enable the calculation of the TLC/TLC range/TLC probabilities for shipments.

3. Document the methodology of the Flexible Method, including the processes used for validating and verifying the methodology.

4. Ensure the Flexible Method provides a level of accuracy of TLC tracking that is comparable to a definitive method.

5. Define a process for routine sampling/auditing to ensure the level of performance defined in #4 is met.

Who Should Participate

We encourage participation from all supply chain stakeholders, with particular interest in:

- **Distributors and wholesalers** navigating TLC and TLCS and transmission requirements
- **Retailers** implementing TLC and TLCS receipt and recordkeeping processes
- **Food manufacturers and processors** working with trading partners on TLC and TLCS communication
- **Technology and solution providers** offering tools for TLC and TLCS management and data exchange

Companies that have already conducted internal pilots, proof-of-concept testing, or implementation efforts are especially encouraged to share their experiences by March 6th. See the Timeline section for more details.

Why Participate?
Across the industry, organizations have developed significant pilot learnings, but there is no centralized mechanism to collect those learnings and deliver them to FDA. By participating in this pilot program you will:

- Have the opportunity to participate in meetings or webinars to share your experience with FDA and learn from others' pilot experiences.
- Help inform industry and FDA's continued implementation of traceability. Remember, by May 9, 2026 as mandated by congress, FDA is directed to provide industry stakeholders with recommendations for additional flexibilities satisfying the Rule's lot-level tracking requirement, as appropriate.
- Identify new collaboration opportunities for additional pilots.
- Receive an early release of the PFT compiled report as well as PFT branded merchandise.

Timeline

The timeline for this project will be split into three tracks.

- Track 1: For interested companies **who have already completed** a pilot with the present scope, to share with FDA on March 6.
- Track 2: For interested companies who are **currently completing or will imminently start** a pilot with the present scope, to share with FDA ahead of their May 9th deadline.
- Track 3: For interested companies who plan to complete a pilot with the present scope in the future.

TABLE 1: Timeline and Milestones

Track	Milestone	Date
All	Pilot invitation released (all)	February 20, 2026
Track 1	Participant registration deadline	February 27, 2026
	Report submissions to PFT Due	March 3, 2026
	Sharing information with FDA	March 6, 2026
Track 2	Participant registration deadline	March 30, 2026
	Report submissions to PFT Due	April 13, 2026
	Sharing information with FDA	April 17, 2026
Track 3	Participant registration deadline	Ongoing
	Draft submissions to PFT Due	Ongoing

Report Framework

Participants will document their pilot activities and findings using the Appendix below. The template includes sections for:

- **Participant Description:** Organization overview, supply chain role, and current traceability capabilities
- **Pilot Approach:** Objectives, scope, timeline, and scenarios addressed
- **Traceability Lot Code Activities:** Current state assessment, approaches tested, system/process modifications
- **Traceability Lot Code Source Documentation:** TLCS documentation methods, data quality findings, trading partner coordination
- **Findings:** Operational feasibility, workflow integration, cost considerations, organizational factors
- **Recommendations:** For industry stakeholders, FDA consideration, and future guidance development
- **Additional Information** *(Optional)***:** Future implementation plans, testing additional scenarios, technology or process innovations, topics for further industry discussion, and workflow illustrations

Data Handling

PFT provides a template report in Appendix A that participants can use to communicate results of their pilots. There is no expectation to submit or share raw data. Participants can choose which form of final work product can be shared (either company submitted report or PFT created and de-identified general summary). Participants can also choose which audiences have access to view final reports or summaries. See Table 2 for more details.

PFT can coordinate with submitters so that public facing confidentiality can be maintained for reports submitted, however company names and information must be disclosed to PFT in order to participate in the program.

TABLE 2: Participant selection of how they would like results to be shared and can specify what audience(s) have access to the results.

I am comfortable with PFT sharing (select one):	I am comfortable with PFT sharing to the following audiences (select all that apply):
A report based on the report template	Share anonymously with FDA
A PFT de-identified summary	Share with all PFT membership
	Share on PFT website, available to the public

How to Participate

Organizations interested in participating should contact the Partnership for Food Traceability at Ben.Miller@AchesonGroup.com or Angela@AchesonGroup.com. Participation is voluntary and collaborative. This initiative represents an opportunity for industry to share practical implementation experiences that can inform FDA's understanding and potentially shape future guidance.

More About the Role of the Partnership for Food Traceability

The Partnership for Food Traceability (PFT) is coordinating this pilot program to facilitate more comprehensive and consistent collection of individual pilot learnings and to share those learnings with FDA. PFT is not coordinating the design and execution of individual pilots. Rather, PFT is providing a consistent framework for pilot and reporting of pilot learnings to enable greater visibility and improved ability to compare learnings across pilots. As a public-private partnership with FDA, PFT is well positioned to serve as a conduit to deliver the collective pilot experiences to FDA. Learn more about PFT here https://pftraceability.org/.

Appendix A: Report Template

1. Description of Participant
    a. Organization Overview [Describe your organization, supply chain role, and relationship to Food Traceability List products]
    b. Products and Trading Partners Involved [Describe the FTL products, categories, and trading partners included in pilot activities]
    c. Current Traceability Capabilities [Briefly describe your current systems and capabilities for traceability data capture and exchange]
2. Summary of Pilot Approach
    a. Pilot Objectives [What were you trying to learn or demonstrate?]
    b. Scope and Timeline [Describe the scope of pilot activities, timeframe, and any limitations]
    c. Scenarios Addressed [Describe real-world scenarios tested, such as: mixed-lot shipments, FIFO inventory rotation, cross-docking, transformation/repacking, multi-supplier consolidation, etc.]
3. Pilot Activities: [For example: Lot Code Approaches]
    a. Describe Current State: [For example, describe current practices for capturing and transmitting lot codes at shipping and receiving. What information is/isn't currently exchanged?]
    b. Approaches Tested [For example, describe lot code methodologies tested, such as: calculated lot codes based on inventory practices, system-generated lot codes, date-based approaches, shipment timing methods, etc.]
    c. System or Process Modifications Performed [Describe any system changes, process modifications, or trading partner coordination required]
    d. Lot code source documentation
        i. TLCS Documentation Approach [How did you document the source of lot codes at each point in the supply chain? How did you indicate whether a lot code was: assigned by manufacturer, calculated by distributor, determined at receipt, etc.?]
        ii. Data Quality and Completeness [What was the quality and completeness of TLCS information? Were there gaps or ambiguities?]

iii. Trading Partner Coordination [How did you coordinate TLCS documentation with trading partners? What challenges arose?]

4. Findings: Operational & Technical
    a. Operational Feasibility [What worked well? What was challenging from an operational perspective?]
    b. Workflow Integration [How did lot code capture and documentation integrate with existing workflows? Impact on receiving, shipping, inventory management?]
    c. System and Technology Considerations [System capabilities, limitations, interoperability with trading partners, data format/exchange challenges]
5. Findings: Business & Organizational
    a. Cost and Resource Considerations [What resources were required? Estimated costs for implementation at scale?]
    b. Organizational and Change Management [Training needs, process changes, organizational challenges, stakeholder buy-in]
    c. Trading Partner Collaboration [Experiences working with upstream and downstream trading partners on lot code information exchange]
6. Recommendations
    a. For Industry Stakeholders [Based on your experience, what recommendations would you offer to other supply chain participants implementing lot code capture and documentation?]
    b. For FDA Consideration [What guidance, clarification, or flexibility would be helpful from FDA to support practical implementation of lot code requirements?]
    c. For Future Guidance Development [What topics or scenarios would benefit from additional industry guidance or FDA clarification?]
7. Additional Information (Optional)
    a. Future implementation plans
    b. Additional scenarios you plan to test
    c. Technology or process innovations under development
    d. Questions or topics for further industry discussion
    e. Supporting data, diagrams, or workflow illustrations