PARTNERSHIP FOR FOOD TRACEABILITY

PFT-FDA Joint Roundtable: Food Traceability Rule Lot-Level Tracking
March 6, 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)[1] 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[2] by developing flexible and efficient implementation frameworks built on mutual accountability. Through the formal Public-Private Partnership structure, PFT provides a forum in which industry can work together, with FDA's technical assistance, 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. PFT's membership spans producers (including growers and harvesters), manufacturers and processors, distributors (including packagers, wholesalers, holders, and shippers), retailers and grocers, and restaurants across diverse commodities (including produce, seafood, cheese, packaged, and prepared food). Membership includes industry members, technology experts, and numerous trade associations that, in turn, represent thousands of diverse food companies.

On March 6, 2026, PFT and FDA held a joint Roundtable through the Public-Private Partnership, to aid FDA in fulfilling Congress's directive[3] to meet with stakeholders on a quarterly basis to discuss lot-level tracking. The session provided an opportunity for FDA to engage stakeholders in cross-sector dialogue 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 the points in the supply chain where lot-level tracking has the potential to break down and the challenges this creates for establishing traceability.
- Identify and discuss specific potential solutions to those challenges, including potential regulatory flexibilities, to comply with the lot-level tracking requirements in the Food Traceability Rule.

The Roundtable was structured with two main components: during the first hour, industry associations, leveraging their breadth of visibility, presented solutions to challenges in implementing lot-level

[1] For additional information about PFT, please visit: https://pftraceability.org/.
[2] "Requirements for Additional Traceability Records for Certain Foods".
[3] Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Act, 2026.

traceability, and during the second hour FDA and participants engaged in discussion and dialogue around the presented solutions. Association presentations discussed specific flexibilities or solutions that would help overcome challenges impacting their sectors in complying with lot-level tracking, with a focus on where flexibilities are needed and how particular flexibilities or solutions would work in practice. Association presentations were given by each sector impacted by the Food Traceability Rule:

- Producers/Growers/Harvesters/Fishers;
- Manufacturers/Processors;
- Distributors/Shippers/Wholesalers;
- Retails/Grocers; and
- Restaurants.

This Roundtable included 17 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 to ensure that perspectives across all industries impacted by the Rule were present, along with organizations of different sizes.

This Roundtable was the first in a series of FDA listening sessions in 2026. PFT and FDA will host a second Roundtable in September. In addition, FDA will host public Town Halls, providing a broad forum for the public to share information on continued implementation of the Food Traceability Rule and areas of remaining concern, specifically as they relate to lot-level tracking and flexibilities for compliance. More information about the upcoming sessions can be found on our website: Upcoming FDA Meetings.

Summary

Participants discussed challenges and solutions or potential regulatory flexibilities 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 who perform specific activities to assign unique codes, known as Traceability Lot Codes (TLCs), and record Key Data Elements (KDEs) at specific Critical Tracking Events (CTEs), like initial packing, transformation, receiving, and shipping—all while keeping the assigned TLC and TLC Source information intact through the point of receiving at retail, unless the product is transformed. The goal of lot-level tracking is to enable rapid tracing of contaminated foods, narrowing the scope of recalls and removing affected products from the supply chain quickly. The original compliance date for the Food Traceability Rule was January 20, 2026, but in August 2025 FDA proposed to extend the compliance date by 30 months to July 20, 2028. Subsequently, Congress directed FDA not to enforce the rule prior to the same date of July 20, 2028. FDA has stated that they intend to comply with this Congressional directive.

Several key themes emerged as potential areas where FDA could consider additional flexibilities to enable solutions to ongoing challenges, and areas where continued collaborative discussion across FDA and industry may be helpful.

Different flexibilities will be needed for different channels.

A central theme throughout the Roundtable was that the Food Traceability Rule affects a highly diverse set of supply chain actors across diverse distribution channels and models. Participants emphasized that one-size-fits-all solutions are not likely to provide needed flexibilities across industry because operational realities differ sharply by channel. Manufacturers generally have enterprise resource planning (ERP) and warehouse management systems (WMS) that can capture and retain detailed KDEs, while others, including retailers, restaurants, distributors, and small growers, face very different constraints—mixed pallets, manual handling, limited IT budgets, and the large amount of data culminating in the last-mile (i.e., distribution to retail). Stakeholders emphasized that the challenge is not the Rule's public health objective, but rather aligning current supply chain practices with implementation of lot-level traceability under the Rule.

Participants encouraged FDA to adopt channel-specific flexibilities where needed, noting the different realities for different channels, and to avoid unintended consequences like excessive labor burden, operational cost, and increased food prices. A few of the challenges that channel-specific flexibilities could address are noted below, as well as within other key themes:

- Distributors emphasized operational practices (unpacking, mixed pallets, breaking cases) that make strict lot level or one-for-one lot tracking challenging, particularly in high-volume, low-margin environments.
- Retailers and restaurants stressed that the final mile represents the majority of locations covered by the Rule and that the amount of data they would need to capture and hold is infeasible. Many participants would prefer to rely on upstream channels to hold necessary lot code data on their behalf rather than capturing and holding lot codes themselves, an option that is permitted under the Rule *(see 21 CFR 1.1455(b))*.

Lack of data standardization is a significant risk to efficient implementation, but standardization has to be balanced with flexibility across different distribution channels.

Participants noted that the lack of data standardization creates inefficient data sharing and exchange across platforms and channels, leading to fragmented implementation across the supply chain. Stakeholders described a growing proliferation of technology platforms, data formats, labeling practices, and transmission methods, resulting in an "avalanche" of information that is difficult to ingest, validate, and use effectively, creating operational risk to efficient implementation. Retailers, grocers, and restaurants described how the burden of reconciling fragmented data will fall disproportionately at the end of the supply chain. They receive KDEs in emails, PDFs, spreadsheets, web portals, and paper documents, and without a consistent data exchange standard, managing and linking these records becomes untenable, especially for businesses with limited IT resources and narrow profit margins. Distributors echoed these concerns, pointing to challenges around the multiplicity and diversity of

barcodes, case label formats, and shipping documents used by manufacturers, that when compounded by the different scanning equipment and software used by distributors, necessitates standardization and simplification. They asserted that without a uniform standard, KDE capture and data sharing downstream could be disorganized and unsystematic, potentially causing a slowdown in a traceback investigation and a "break in the chain of traceability."

The location description KDE, which reportedly is being interpreted and applied inconsistently across industry, was highlighted as a specific example to illustrate the challenges around and need for data standardization. Some participants suggested clear, narrow guidance with a few options that FDA considers acceptable to minimize fragmented data. For example, some suggested that FDA permit an organization's corporate office to be used as the location since that office will be able to provide the required data, noting that additional solutions may be needed where co-manufacturers are involved.

Stakeholders generally agreed on the benefits of a uniform data exchange standard, which would help to reduce downstream complexity, but some expressed it should start at the beginning of the supply chain, while others expressed it can begin at the manufacturing level. At the same time, participants cautioned that rigid standardization could itself become a barrier because it is impossible to account for all of the real-world diversity in operations and technological readiness. In particular, rigid standardization would marginalize less sophisticated suppliers and could impose heavy capital costs on manufacturers and small producers. In addition, stakeholders—and manufacturers in particular—noted that implementing compliant, standardized systems takes time, investment, and production-line changes that may not be feasible for all suppliers by the rule's proposed compliance date, and that having a singular compliance date may pose challenges if upstream suppliers are not ready to pass data downstream.

While stakeholder concern was that data fragmentation, without FDA direction, may undermine the goal of rapid traceability, FDA noted that there are barriers to the agency mandating a specific data standard, and inquired whether industry is likely to coalesce around a standard. Many participants suggested that FDA endorse or recommend standards (e.g., GS1 data and labeling standards), as well as allow for flexibilities, especially within channels. Producers noted that they have been early adopters of GS1 standards, but that challenges remain with capturing and sharing TLCs between suppliers and downstream, particularly since buyers have not aligned on supplier requirements and producers must integrate with multiple systems, requiring deviation from their standards. Producers expressed that not having a clear directive results in fragmented traceability.

Flexible methods with ranges/calculations/probabilities better reflect how product moves through the supply chain and may provide more accurate data for outbreak investigations.

Range-based, probabilistic, or calculated methods were discussed extensively as flexible alternatives for capturing and sharing TLCs downstream to meet the lot-level tracking requirement in the Food Traceability Rule. In these methods, the TLC(s) included in a shipment is calculated or inferred utilizing WMS and other existing technologies and systems to provide a list of potential TLCs without

operationally scanning each case to capture the TLC (FSMA sec. 204[4] prohibits case-level tracking as a requirement). Stakeholders, particularly retailers and distributors, noted that these methods reflect real operational practices—mixed pallets, unpacking and repacking at distribution centers, and "eaches". Stakeholders suggested that these range-based, probabilistic, or calculated methods for capturing and sharing TLCs could enable FDA to narrow investigations more quickly and be more accurate than providing a single lot code. For example, distributors highlighted scenarios where no case labels exist at the point of picking, necessitating reliance on UPCs and internal handling logic rather than individual lot scans. Retailers and distributors stated that providing a reasonable range of lot codes can be both practical for industry and beneficial for public health investigations, especially when accompanied by parameters that define acceptable operational practices around utilizing these flexible methods.

Stakeholders discussed that flexible methods can improve outbreak investigations by avoiding false precision. In their estimation, when multiple lots are commingled or sequentially handled, forcing a one-to-one match may misrepresent reality and slow investigations by failing to identify TLCs that should be included. Providing a narrow range of TLCs based on date, pick slot, suppliers, and shelf life is a practice that is already being used in some parts of the supply chain. The stakeholders emphasized that flexible methods align data capture with actual handling practices.

While some concern was raised about data quality and error rates, participants agreed on the importance of pairing flexible methods with adequate validation and verification to ensure a reliable level of accuracy in both inbound and outbound data that is supported by strong internal processes, such as well-controlled inventory management practices. However, ranges may be best suited for providing to FDA in the case of a foodborne illness outbreak, since sharing multiple lot codes downstream has the potential to result in passing of inaccurate data and adds to complexity. To combat this, one stakeholder suggested that companies could utilize reference or document numbers to pass downstream. This was noted as a potential way to reduce complexity for restaurants and retailers, since as an outbreak investigation moves upstream, the supplier would be able to provide the range of TLCs.

There is dissonance between focusing on well-controlled processes that incorporate continuous improvement and stakeholders' desire for clearly defined performance levels.

Another recurring tension centered on how compliance should be evaluated: whether through adherence to well-controlled processes that continuously improve upon the current baseline or against clearly defined performance thresholds. Industry representatives framed the issue as a tension between process-oriented improvement and the need for clear, enforceable performance expectations. On one hand, many firms are investing in continuous improvement, often through technology and data quality tools, and expect traceability to improve over time. On the other hand, many stakeholders expressed interest in clear performance levels so they can design systems that meet regulatory expectations and avoid uncertainty in compliance.

[4] FDA Food Safety Modernization Act Sec. 204 - Enhancing Tracking and Tracing of Food and Recordkeeping.

Several stakeholders discussed how principle-based frameworks could allow for flexibility in process methods while setting parameters around use and best practices for implementing them, such as data quality thresholds, documentation, and auditability. As discussed above, a specific framework that was discussed was parameters for flexible methods of capturing and sharing TLCs, such as probabilistic, calculated, or range methods that calculate or infer TLCs utilizing existing data to provide a list of potential lot codes without having to scan each case. Such methods would be operationally defined in an organization's Traceability Plan, provide a level of accuracy comparable to case scanning, and ensure appropriate steps are taken for continuous validation and verification of data. Proponents suggested that such an approach would accommodate the diversity of distribution channels and models, and align to historical regulatory approaches, by focusing on organizations' adoption and implementation of well-controlled processes that could incorporate continuous improvement.

FDA participants probed whether range-based approaches are intended as stepping-stones or permanent solutions, and how such models might incentivize better data quality over time. Retailers described ongoing efforts to improve their systems as technology evolves, emphasizing that narrower ranges and more precise data become possible over time, and that companies are naturally incentivized to focus on outbreak response accuracy given the impact on public safety and reputational risk to companies. In addition, industry expressed that flexible methods support improvement across the supply chain without excluding suppliers who lack electronic data transfer or advanced labeling systems. At the same time, stakeholders indicated that a clearer articulation of how flexible methods will be assessed is important and could clarify compliance requirements without constraining companies' ability to innovate within their means.

Flexibility for intra-company models could avoid data redundancy while ensuring compliance responsibilities remain with the company.

Multiple participants, especially from the manufacturing and retail sectors, emphasized that the data and documentation requirements for intracompany transfers and transformations create additional and duplicative burden on companies with limited public health benefit. Instead, participants suggested companies should have internal visibility to intracompany transfers, and regulatory TLC tracking should not apply because ownership and custody remain within a single company's corporate system and under their operational control. Participants noted that most large companies already maintain centralized ERP or warehouse management systems that track this information, making the additional documentation requirements for recording specific KDEs redundant and inefficient, which also increases the error risk.

One retailer provided a concrete example showing how routine internal transformations can generate multiple CTEs and hundreds of KDEs, creating an unsustainable administrative burden. They used the example of preparing egg salad, which requires: receiving whole celery at their warehouse, chopping it into fresh-cut celery, shipping it to a retail store, combining it with shell eggs and other ingredients to make egg salad, and then transferring that salad to another store for sale. That simple process triggered six different CTEs, and utilizing FDA's electronic sortable spreadsheet template, required the retailer to

capture, link, and log well over 100 distinct, and 248 total, KDEs for a single batch of egg salad. The retailer noted that they make dozens of other recipes daily, across many of their stores.

Companies encouraged FDA to consider exemptions or tailored requirements that would allow firms to leverage existing internal systems and processes, reducing duplicative recordkeeping and lowering the risk of errors from maintaining parallel datasets. Participants acknowledged that compliance responsibility must remain clear and facilitate traceback, and thus flexibility for intra-company models was therefore framed not as an exemption from accountability, but as a recognition that accountability can be maintained through existing adequate and controlled internal processes rather than requiring the same data to be kept and tracked internally in a specific record format. Manufacturers noted that this would decrease the burden on companies by improving efficiency and saving money without negatively impacting the public health and traceability objectives of the rule. [Note that the Food Traceability Rule (21 CFR1.1455(f)) states that firms do not need to duplicate existing records (e.g., records kept in the normal course of business or to meet other regulatory requirements) if they contain the information required by the rule.]

Participants identified areas for continued discussion.

Based on the discussion and topics that arose during this meeting, FDA and participants identified areas where continued dialogue is needed:

Potential Solution: Should distribution centers (or others) be considered transformers?

FDA asked stakeholders whether allowing distributors to be transformers, allowing them to assign new TLCs when they aggregate or otherwise transform inbound cases into new outbound units, could be a successful solution. Proponents argued this would simplify last-mile traceability (especially for totes and mixed pallets), but noted that additional consideration is warranted. The group recommended further discussion and analysis to determine how inputs could be documented and linked to outputs, and noted that this flexibility may be better suited to certain situations rather than as a blanket designation.

Data Quality: Can downstream recipients rely on the integrity of data received?

Participants emphasized the important role of data quality in both maintaining operational efficiency and meeting the public health goals of traceability. A key aspect of maintaining operational efficiency is the extent to which the receiving entity in a shipping CTE can rely on the accuracy and integrity of the data provided to it by the shipper. Participants emphasized that if the receiving entity were to confirm the accuracy of data it receives, it would dramatically increase the operational complexity and allow the shipper to effectively transfer its data integrity responsibility to its customers.

Data Exceptions: How are known data errors handled?

While the data quality issue above raises the question of how and where data errors are identified, there is a related issue of how to operationally handle foods once a data error is identified. For example, if a receiving entity knows that it has received inaccurate TLC data, what steps must the receiving facility take to continue distribution of that food? Participants noted this as an issue that warrants further

discussion and must account for the risks and inefficiencies if distribution is disrupted, particularly for perishable foods.

Data Custodian: Can a supplier hold TLC data on behalf of their customer?

Participants highlight the significant opportunity to reduce the burden on small retailers and restaurants by positioning their suppliers to hold certain KDEs on their behalf, which, as previously noted, is already permitted under the Rule (see 21 CFR 1.1455(b)). This builds on the model widely adopted in the drug supply chain in which distributors routinely hold the regulatory traceability data on behalf of their independent pharmacy customers and allow those pharmacies to access and download that data if and when needed. While important, there was limited time for discussion of this model, and continued discussion will be valuable.

Continued dialogue between FDA and regulated stakeholders is essential to successful implementation.

The listening session was repeatedly referenced by participants as evidence that ongoing dialogue is essential to effective implementation of lot-level tracking. FDA emphasized that this engagement is the first in a broader series (as noted above) of cross-sector discussions regarding implementation of lot-level tracking and solutions for compliance. FDA invited continued feedback on potential flexibilities and resources needed. Stakeholders welcomed this approach and emphasized that continued dialogue is essential, noting that many challenges only become apparent when theory meets operational practice. Participants encouraged FDA to work with industry to develop guidance, model frameworks, and channel-specific parameters rather than imposing a rigid technical mandate that could disrupt supply chains. Several speakers encouraged FDA to use future engagements to surface channel-specific scenarios, validate proposed frameworks, and clarify how flexibility and accountability coexist.

Participants across sectors stressed that uncertainty—rather than opposition—is driving much of the concern around implementation of and compliance with the Food Traceability Rule. Questions about expectations during investigations, acceptable data models, and enforcement remain unresolved. Continued, structured dialogue, focused on meeting the goals of the Food Traceability Rule without jeopardizing efficiency, will benefit all stakeholders. Implementation will be iterative and trust between regulators and industry depends on transparent communication as those efforts progress.