

May 20th, 2026

Katherine Vierk, MPH
Office of Surveillance Strategy and Risk Prioritization,
Human Foods Program,
Food and Drug Administration,
5001 Campus Dr., College Park, MD 20740.

RE: Docket No. FDA-2025-D-2837 for “Questions and Answers About Requirements for Additional Traceability Records for Certain Foods: Guidance for Industry.”

Dear Ms. Vierk,

On behalf of the [International Fresh Produce Association](#) (IFPA), the largest and most diverse association serving the full fresh produce and floral supply chain, we appreciate the opportunity to comment on the draft guidance entitled, “Questions and Answers About Requirements for Additional Traceability Records for Certain Foods: Guidance for Industry,” that was published in the Federal Register by the U.S. Food and Drug Administration, Department of Health and Human Services on Friday, February 20, 2026.

IFPA members are responsible for implementing FSMA 204 requirements across highly perishable, high-velocity supply chains that operate with significant diversity in scale, technology access, and business models. As such, IFPA’s comments focus on how the draft guidance will be understood and applied in real-world operations, and whether it will meaningfully advance the statute’s objective of faster, more accurate traceback during food safety events.

IFPA strongly supports FSMA’s traceability goals and the public health outcomes they are intended to achieve. Our comments are offered to help ensure that the guidance promotes interoperable, feasible, and scalable traceability systems that improve outbreak response without introducing unnecessary compliance risk, supply chain disruption, or significant undue financial burdens. We have separated out comments based on overarching themes.

Areas of Uncertainty or Ambiguity in the Guidance

IFPA has identified several areas where the draft FAQs leave important operational questions unresolved or rely on assumptions that do not reflect common produce supply chain practices. Left unaddressed, these ambiguities risk inconsistent interpretation and uneven compliance expectations.

- **Relabeling and packaging changes:** Questions persist about whether minor actions (such as applying a rubber band to herbs or removing/adjusting a case sticker) constitute relabeling or

trigger new traceability events. Clearer boundaries are needed to distinguish administrative handling from substantive labeling changes.

- **Distribution center (DC) implementation:** The FAQs do not meaningfully address how distribution centers can comply with case-level receipt and ship-out requirements at scale. Scanning every case is not operationally feasible in high-velocity DC environments, and the guidance does not acknowledge or permit alternative methods (such as algorithm-based approaches) that are already used successfully for recalls.
- **Initial packer determination:** The guidance defers to supply-chain consensus without providing a default rule, model agreement, or decision framework. This leaves small and first-time shippers without a reliable way to resolve responsibility where roles are unclear.
- **Transformation and lot-level traceability in foodservice distribution:** Additional clarity is needed on how lot-level traceability expectations apply in foodservice settings characterized by high sales velocity and labor constraints, and how these expectations align with statutory direction on feasibility.
- **Exemptions:** The FAQs improve clarity around some exemptions, which is welcomed. Additional consistency and specificity would further reduce confusion for mixed-operation firms operating across covered and exempt channels.

Risks or Unintended Consequences from the Guidance

Most unintended consequences identified by industry arise from the structure of the rule itself rather than from the draft guidance for industry. That said, aspects of the guidance amplify or fail to mitigate these risks.

- **Systemic compliance risk from independent KDE responsibility:** Response 26 reinforces that each covered entity bears independent responsibility for the accuracy of its own key data elements, with no safe harbor for reliance on upstream suppliers. This creates disproportionate burden for downstream partners where verifying received KDEs represents a continuous administrative cost that larger entities are better positioned to absorb but are not immune from.
- **Partial exemptions and mixed-channel operations:** As clarified in Response 24, the traceability plan requirement for partially exempt firms presents a compliance trap for small farms selling primarily through direct channels with limited wholesale volume. These operations are treated

identically to large integrated shippers for traceability plan purposes, despite fundamentally different risk profiles and resources.

- **Lack of a core data exchange standard:** Without a common baseline (or safe harbor) for how traceability data are transmitted (e.g., EDI, ASN, barcode/QR standards), firms are forced to customize solutions for each trading partner. This fragmentation drives cost, strains IT capacity, and undermines interoperability across the supply chain.
 - **Data transmission and system incompatibility:** Significant supply chain disruption risk stems from incompatible ERP systems, the absence of standardized data transmission methods, and the proliferation of customer-specific portals. There are meaningful challenges of electronic data interchange (EDI) and barcode standards, and not all parties are equipped with GS 128 or compatible systems, which hinders seamless information transfer. Managing multiple, non-aligned platforms for submitting duplicative traceability data creates inefficiency, increases the likelihood of error, and raises barriers to participation for smaller suppliers.
- **Distribution and foodservice operational impacts:** High-velocity distribution and foodservice models face particular risk from lot-level traceability expectations that do not account for labor constraints, sales velocity, or existing recall practices. The guidance does not sufficiently address how these sectors can operationalize compliance without disrupting product flow and causing undue financial burden.
- **Direct marketing and mixed-source sales:** Scenarios such as farmers market stalls selling both self-produced and neighboring farm product create real-world compliance complexity, with different regulatory obligations applying at the same point of sale. This structural issue persists regardless of clarification language.
- **Retail handling gaps:** Retail activities that involve removing product from original packaging and consolidating or returning product may unintentionally undermine upstream traceability, yet the guidance does not address how such actions should be handled within FSMA 204's framework.

Operational Realities Not Reflected in the Guidance

Several assumptions embedded in the draft FAQs appear to presume a level of technological uniformity and centralized control that does not exist in much of the produce sector. Without acknowledging these

operational realities, the guidance risks setting expectations that are technically compliant but practically unattainable.

- **Technology access and variability:** The guidance does not meaningfully acknowledge the wide variability in technology access across firm sizes. Many small and mid-sized operations will rely on spreadsheets, basic systems, or paper records rather than enterprise-level platforms, yet the guidance implicitly assumes more advanced digital capability.
- **Lack of attention to technology implementation:** FDA does not clearly address how traceability data are expected to be generated, managed, or transmitted at scale. Key operational questions (such as how different systems interface, or how compliance is demonstrated in low-tech environments) remain unresolved.
- **Supply chain structure and control:** The guidance does not adequately reflect realities such as cross-docking (and if there is a time limit for how long an entity can hold a product before it is no longer considered cross-docking), brokered transactions, or third-party harvesting, where physical possession, product ownership, and data responsibility may reside with different parties at different points in time.
- **Responsibility for data transmission failures:** There is no clear framework for how responsibility is allocated when traceability data are lost, delayed, or corrupted during transmission between systems, leaving firms exposed to compliance risk for failures outside their control.
- **Commingling and physical constraints:** While the rule acknowledges that not all product moves in full pallets, the guidance does not address practical limitations where commingled pallets and small case sizes make universal case-level scanning physically infeasible.

Largest Compliance Burdens and Alternative Approaches

IFPA members consistently identify transformation and repacking requirements, electronic record expectations, and the absence of data transmission standards as the most significant compliance burdens under FSMA 204. These challenges are not theoretical: they reflect everyday operational constraints that, if left unaddressed, will divert resources from food safety outcomes toward administrative compliance.

- **Transformation and Repacking:** The guidance only briefly addresses the operational and compliance implications of repacking, such as when traceability codes may need to change, and lacks detailed examples for common industry practices.
- **Mixed lots and mixed pallets as a structural reality:** Mixed pallets containing multiple lot codes are common to meet demand and manage production variability. In recall scenarios, traceability often defaults to the largest or most visible lot contributor, even where commingling is unavoidable. The guidance does not acknowledge how this reality is currently managed or how compliance should be demonstrated without disrupting commerce.
- **Electronic record expectations without standards:** The requirement to provide sortable electronic records within 24 hours lacks defining detail regarding acceptable formats, data fields, or structure. Without a baseline standard, firms are forced to accommodate multiple, incompatible templates and customer-specific requirements, significantly increasing compliance cost.
- **Key Data Elements and Common Industry Records:** While the guidance lists KDEs by critical tracking event, it does not bridge these requirements with how information is typically captured today. In many cases, a majority of required shipping KDEs already appear on bills of lading, though formats vary widely. Visual examples or mapping illustrations showing how existing records align with FSMA 204 requirements would materially improve readiness.
- **Lack of standardization across commodities:** Fresh produce lacks uniform packaging, labeling, and lot structure across commodities. The guidance does not address how this variability affects compliance feasibility, particularly for high-mix, short-run production environments.
- **Alternative approaches not addressed:** In prior FDA-led pilot traceability courses, participants received only high-level, nonspecific information (i.e. one page in an entire coursebook) regarding warehouse and DC traceability approaches. In addition, in several rounds of exchange before and after these courses, industry had anticipated FDA openness to alternative methods (such as algorithm-based approaches within DCs already used successfully in recalls) to manage traceability where case-level scanning or segregation is not feasible. The guidance does not acknowledge or provide a pathway for these approaches and creates a large and unworkable implementation gap.

Scenarios Where Guidance May Expand Traceability Obligations

IFPA is concerned that certain responses in the draft FAQs may be interpreted to expand traceability obligations beyond those contemplated in the final rule or its preamble, particularly in logistics and consolidation scenarios that do not involve transformation.

- **Cross-docking consolidation:** Cross-docking operations typically move product without taking ownership or fully re-documenting inbound lots, relying instead on original bills of lading and a consolidated “master” bill of lading to the final destination. The guidance does not clarify whether cross-dock facilities incur additional traceability obligations or how missing or incomplete lot-level detail should be treated when consolidation is a routine, non-transformative activity.
- **Information loss during consolidation:** Master bills of lading may not capture all upstream traceability details for individual shipments combined during cross-docking. Without explicit guidance, firms may be held responsible for information gaps created by standard logistics practices rather than by failures in traceability intent or execution.

Clarity on Initial Packer Designation

Clear designation of the initial packer is essential to consistent FSMA 204 implementation. Reliance on informal supply chain consensus, without defined criteria or documentation expectations, introduces uncertainty that undermines both compliance and enforcement consistency.

- **Complex operational scenarios:** The guidance lacks clear direction for situations involving field packing, contract packing, co-packing, and operations handling product from multiple growers. Additional examples reflecting these realities would improve consistency and compliance.
- **Separation of roles:** In some supply chains, the grower, harvester, and packer are legally and operationally distinct entities. International produce supply chains (e.g. where fruit may be sold while still on the tree and harvested, packed, and handled by different companies) illustrate how difficult it can be to identify the initial packer under a simple definition.
- **Reliance on supply-chain consensus:** FDA’s statement encouraging supply-chain entities to “communicate with each other to identify the initial packer” does not provide a default rule, decision framework, or enforcement backstop. In practice, this approach risks allowing responsibility to be shifted downstream or upstream, rather than clearly assigned.
- **Risk of misattribution:** Absent clearer guidance, firms may be identified by trading partners as responsible parties for activities they do not perform, compounding compliance risk and echoing challenges previously observed in other regulatory programs.

Feasibility of Coordinating and Documenting Responsibilities

The guidance places significant reliance on supply-chain coordination to determine and document responsibility assignments but does not provide sufficient structure to make this expectation feasible or consistent in practice.

- **Tension between expectation and deference:** The guidance simultaneously expects supply-chain partners to determine responsibility while stating that FDA will generally defer to industry judgment without substituting its own. This creates ambiguity about how FDA will evaluate initial packer determinations during inspections or enforcement, particularly where documentation is incomplete or disputed.
- **Lack of defined criteria or process:** Unlike other regulatory programs where a responsible party is explicitly designated and documented, the guidance does not provide clear criteria, stepwise decision logic, or documentation expectations for determining the initial packer. This absence increases the risk of inconsistent determinations across similarly situated firms.
- **Commingled and shared-responsibility scenarios:** The guidance does not address whether more than one initial packer could exist in commingled or consolidated scenarios, leaving uncertainty as to how responsibility should be allocated when product from multiple sources is handled together.
- **Need for structured implementation tools:** Industry would benefit from defined steps, role-based responsibility mapping, and example documentation showing how responsibility flows from grower to harvester to packer. Without such tools, smaller operators in particular may struggle to understand or demonstrate compliance.

Clarity and Workability of Transformation Examples

While the guidance provides helpful clarification for certain activities, additional examples are needed to reflect how transformation, repacking, relabeling, and culling occur in real-world produce operations. Without more detailed, produce-specific scenarios, firms may struggle to distinguish routine workflow steps from activities that trigger new traceability events.

- **What is clear and should be preserved:** Several responses align well with real-world operations and reduce compliance uncertainty. The guidance confirms that breaking a pallet alone is not a transformation unless repacking or relabeling also occurs; that affixing an internal tracking sticker is not relabeling; and that culling produce as a standalone activity, without repacking, is not a transformation event. These clarifications are directly relevant to small specialty crop farms, packing sheds, and cross-dock distribution centers and should be preserved and codified to prevent future narrowing.
- **Repacking examples are insufficient:** While the preamble states that repacking whole fresh produce within a traceability lot constitutes transformation, the guidance provides few practical examples. Common activities (such as sorting product to remove defective units or condition-grading during repacking) are not illustrated, despite their prevalence in distribution and packing operations.
- **Relabeling scenarios need clearer treatment:** Practices such as removing incorrect PLU stickers and replacing them with correct ones, or applying stickers to individual produce units, are treated as transformation but are not clearly illustrated. Additional examples would help firms distinguish routine corrective actions from transformation events requiring new records.
- **Workflow realities in small operations:** In small specialty crop packing sheds, culling and repacking often occur in a single, continuous workflow at the same station. While culling alone is not a transformation, distinguishing it from repacking for documentation purposes can be difficult in practice. Packing-shed-level examples showing how these activities differ under a compliance review would improve workability.

Clarity of Exemptions for Produce Supply Chains

The draft FAQs improve understanding of several FSMA 204 exemptions, particularly for direct-to-consumer and small-scale sales. However, clearer guidance would further reduce confusion for operations that span both exempt and covered activities, especially where different regulatory obligations apply within the same facility or point of sale.

- **Direct-to-consumer and ad hoc retail purchases:** Exemptions for direct-to-consumer sales and ad hoc retail purchases are generally well understood and have not generated significant compliance questions in practice. Where purchases occur without an ongoing contract, firms largely view these transactions as fitting clearly within the exemption framework.

- **Small grower sales models:** For small growers engaged primarily in direct-to-consumer or direct-to-locally-important-entity sales, the exemptions are viewed as workable, particularly given the 180-day threshold and limited scope of covered activity. These exemptions appear to align with operational realities and have not been a recurring source of concern.
- **Commingled retail scenarios:** While some initial questions were raised regarding commingled racks or mixed-product retail displays, participants generally agreed that the guidance addresses the principal scenarios encountered in practice.
- **Limited downstream confusion:** Retailers and quick-service operators reported relatively few exemption-related questions, suggesting that the guidance provides sufficient clarity for these segments under most circumstances.

Additional Clarification Needed for Industry Readiness

Despite incremental improvements, important gaps remain that could hinder industry readiness and consistent implementation of FSMA 204. Additional clarity (particularly around crossdocking, technology expectations, interoperability, and training) would help covered entities better prepare for compliance while supporting FDA's goal of faster, more effective traceback.

- **Cross-docking clarity:** While the preamble explains the rationale for not exempting cross-docking activities, the guidance does not address cross-docking operationally. Given how common cross-docking is in produce distribution, its omission creates ambiguity regarding responsibilities, data capture, and documentation expectations. Explicit guidance on cross-docking scenarios would significantly improve clarity.
- **Produce-specific and technology-focused examples:** Industry continues to request produce-specific scenarios that illustrate how traceability information moves through real systems, including examples tied to digital traceability, minimum data expectations, and interoperability across platforms. Clear illustrations would help firms understand how requirements apply in practice.
- **Interoperability and technology standards:** Greater clarity is needed around technology expectations, particularly regarding interoperability across systems. Even high-level guidance on acceptable approaches or minimum functionality would help firms plan investments and reduce fragmentation.

- **Awareness and readiness gap:** There remains a lack of urgency and understanding across parts of the supply chain regarding FSMA 204 readiness. FDA could play a constructive role by highlighting implementation challenges, sharing early adopter experiences, and reinforcing the importance of early preparation.
- **Training and workforce translation:** Practical, accessible training materials will be essential, especially for small businesses, new staff, and frontline supervisors. Clear explanations of key terms (e.g., transformation, repacking) and what they mean operationally would help ensure consistent implementation beyond regulatory or compliance specialists.
- **Implementation tools within FDA's scope:** Simple tools such as webinars, short training modules, basic certification courses, slide decks, or visual examples could materially improve understanding while remaining within FDA's resource constraints. Guidance that can be readily translated to assistant managers and operational staff would support consistent execution and inspection readiness.

Finally, a core implementation challenge of FSMA 204's Final Rule for the fresh produce industry lies in tracking the specific Traceability Lot Code (TLC) for shipments to retail stores and restaurants from distribution centers. Nearly all produce shipped is manually selected by workers, not automated systems, making consistent capture of the TLC operationally difficult and cost-prohibitive. The prevailing method (having selectors scan Produce Traceability Initiative (PTI) labels on each case) is labor-intensive, prone to human error, and not designed to capture traceability codes with precision. Because TLCs are not unique to each case, any lapse in scanning accuracy undermines traceability. Without full automation or universal TLC labeling, this task requires manual entry, increasing the labor burden and reducing productivity. Industry estimates place the annual cost of this requirement at over \$250 million in labor alone, and additional capital investments needed to expand warehouse capacity due to slowed throughput could exceed \$500 million.

To address this, the International Fresh Produce Association (IFPA) has repeatedly proposed a practical alternative in allowing Warehouse Management Systems (WMS) to calculate and assign TLCs for shipments to retail and foodservice customers. This approach aligns with Section 1.1340 of the Final Rule, which requires shippers to link the TLC to shipment records but does not mandate that TLCs be captured via scanning.

Conclusion

IFPA appreciates FDA's continued engagement with stakeholders as it works to implement the FSMA 204 traceability framework. The fresh produce industry shares FDA's commitment to faster, more effective traceback and recognizes the critical role traceability plays in protecting public health and maintaining consumer confidence. At the same time, successful implementation of FSMA 204 depends on traceability systems that are not only accurate, but also interoperable, feasible, and reflective of real-world supply chain operations. As outlined throughout these comments, aspects of the draft FAQs risk creating compliance expectations that do not align with the operational realities of produce harvesting, packing, distribution, and foodservice. Addressing these issues is essential to ensure that traceability requirements enhance, rather than undermine, the effectiveness and integrity of the food safety system.

IFPA and its members are willing, ready, and able to continue a constructive dialogue with FDA to support the practicable implementation of FSMA 204. The produce industry has accumulated significant experience through pilot programs, recalls, and existing traceability initiatives, and can offer real-world case studies, commodity-agnostic templates, and operational examples that demonstrate how traceability objectives can be met in a manner that is effective, cost-effective, and scalable. These materials (including examples related to DC operations, alternative data-linking approaches, and responsibility assignment across complex supply chains) could help FDA refine guidance to better reflect how traceability functions in practice.

IFPA strongly supports continued collaboration to ensure that FSMA 204 implementation advances public health outcomes while maintaining product flow, minimizing food waste, and enabling broad participation across the produce sector. We encourage FDA to leverage industry experience and practical tools as it finalizes guidance, and we stand ready to assist in developing workable, interoperable solutions that strengthen traceback capability across the fresh produce supply chain.

Sincerely,

A handwritten signature in black ink, reading "Eric Stevens".

Eric L. Stevens, PhD
Vice President – Food Safety & Regulatory Affairs
International Fresh Produce Association