May 21, 2026

U.S. Food and Drug Administration
Division of Dockets Management, HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

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

Dockets Management Staff,

Western Growers is pleased to submit comments to the Food and Drug Administration ("FDA" or "the agency") on the agency's draft guidance "Questions and Answers About Requirements for Additional Traceability Records for Certain Foods: Draft Guidance for Industry" (the "Draft Guidance"). Western Growers is an organization that represents producers and handlers of specialty crops - fresh fruits, nuts and vegetables grown, harvested, packaged, processed, and shipped from the states of California, Arizona, Colorado, and New Mexico. Our members provide half the nation's fresh fruits, vegetables and tree nuts, including locally grown produce and a third of America's fresh organic produce. Some members also farm throughout the U.S. and in other countries providing consumers with year-round access to nutritious food. For generations, we have provided nutritional variety and healthy choices as the first line of defense against obesity, chronic illness, and disease: we grow the best medicine in the world.

Western Growers members share FDA's goal of facilitating quick traceback activities to help prevent public health outbreaks by enabling swift and precise identification of contaminated products and to avoid sweeping public health advisories. Our members are committed to improving traceability in our industry, and for several years have extensive experience with traceback activities through traceback exercises and mock recalls. Many are compliant with GS1 standards and have participated in broader voluntary efforts to improve traceability, such as the Produce Traceability Initiative (PTI) and the Leafy Greens Traceability Pilot to better understand traceability challenges and enhance traceability practices. In short, our members have long supported and are committed to promoting an end-to-end traceability system. In our comments below, we offer feedback and suggestions to enhance the Draft Guidance; specifically, we recommend that the agency expand the scope of the guidance. Please consider the following specific suggestions and feedback for industry guidance.

Overarching Feedback

From a grower and shipper perspective, we appreciate that FDA's guidance provides additional clarity in several key areas, including exemptions, commingling, initial packing, and expectations

related to traceability lot codes, such as how lot codes should be captured, how lot code sources should be identified, and whether coordinates or other location-based information is required. This information addresses several important stakeholder questions. However, the guidance would benefit from additional clarification on practical implementation challenges, particularly the collection and transmission of key data elements across the supply chain. We provide additional comments on these issues below.

Specific Comments

1. Definition of "Lot-Level Traceability."

Successful implementation of the Traceability Rule would be supported by guidance providing additional clarity regarding what constitutes a "traceability lot." We appreciate that the Traceability Rule provided significant flexibility for entities to determine how to define a "traceability lot" within their systems. Although this flexibility provides some relief to entities assigning lot codes, it will also result in less data consistency throughout the supply chain. Without a clear and shared understanding of a traceability lot definition, there is potential for inconsistency across entities, which could lead to confusion and misalignment throughout the fresh produce supply chain. In practice, lot definitions vary significantly (e.g., by field, ranch, block, or planting) among companies within the industry.

Although we recognize the agency's intent to avoid overly prescriptive definitions, we recommend the agency revise the Draft Guidance to include a discussion of traceability lots and establish the following guidelines:

- General parameters or considerations that inform what constitutes a "lot" for different entities across the supply chain.
- Examples of how lot-level traceability could be interpreted across different operational contexts.

We believe that these guidelines strike a balance between allowing entities to organize their business in a manner that is consistent with their operational goals and procedures and driving the consistency needed for interoperable traceability. We are happy to work with you on this effort.

2. Standardization and Interoperability Across the Supply Chain

As we have discussed previously in our engagement with the agency on the Traceability Rule's implementation, data standardization and interoperability are imperative to the success of the Traceability Rule. Because FDA has not provided guidance or best practices for data standardization and information sharing, upstream suppliers, such as fresh produce growers, packers, and shippers, are being forced to adopt multiple systems and redundant practices to meet demands from different downstream buyers. This results in the proliferation of multiple, incompatible systems, increased operational burden and cost, and reduced interoperability and does not provide incremental benefits to public health. Indeed, the majority of major U.S.-based growers-shippers of fresh produce have already implemented a strong traceability system that uses standardized data to communicate traceability information throughout the

supply chain under the work completed by the Produce Traceability Initiative (PTI). However, instead of utilizing this established and tested system, downstream entities are seeking the implementation of duplicative or new systems due to the lack of data standardization in the industry. As the enforcer of the Traceability Rule, the agency is uniquely positioned to assist the fresh produce supply chain—and the food industry, as a whole—in standardizing their product tracing data and eliminating the current fragmented and siloed approaches. Currently, growers and shippers of fresh produce continue to be forced to adopt multiple incompatible systems that create burden on the fresh produce industry and augment fragmentation instead of efficiency, which is ultimately counterproductive to the goal of this regulation.

In order to support industry implementation and data standardization, the Draft Guidance should be revised to include recommendations or considerations for both technology solution providers and downstream supply chain entities requesting traceability data to promote more consistent, practical, and efficient implementation across the supply chain. Specifically, we ask that FDA promote a single standardized approach for data sharing throughout the supply chain. FDA should leverage existing industry investments and established traceability practices, including labeling practices consistent with those used currently in the produce industry to drive standardization. We believe this guidance will facilitate greater interoperability in the supply chain, which in turn will drive more efficient and effective traceback investigation and greater public health benefits.

3. Pallet-Level vs. Lot-Level Traceability

We appreciate that the Draft Guidance provided additional information regarding when breaking down a pallet would be considered a transformation event. In addition to this guidance, FDA should explicitly address scenarios when pallet-level traceability is appropriate under the Traceability Rule. We understand that under the rule, a company could provide KDEs at the pallet, rather than case level, in scenarios where all cases on the pallet are from the same traceability lot. If a pallet contains a mix of traceability lots, shippers will need to ensure that KDEs are provided with sufficient specificity so that receivers are able to identify which cases on the pallet correspond with each traceability lot included in the pallet. We ask that FDA provide examples of these two scenarios in guidance. Doing so would help ensure all entities are passing forward traceability data sufficient to meet the rule's requirements.

4. Compliance for Foreign Entities

The Draft Guidance and other resources provided by FDA to date do not explain how compliance will be verified for both domestic and foreign entities. FDA should ensure its outreach and enforcement strategies address parity expectations and compliance for both domestic and foreign entities.

In addition, the rule applies to persons who manufacture, process, pack, or hold certain foods and because coverage under the rule relies on taking physical possession of a certain food, many importers and brokers of produce are not required to maintain traceability records. This structure creates a clear loophole for those entities**.** With the exclusion of brokers and importers from the rule, unless they take physical possession of the product, the rule creates an

inevitable information gap between foreign producers and domestic entities that receive foreign produce because these entities do not interact directly, but rather through the broker or importer. As a result of this loophole, those importers and downstream brokers are not required to collect or transfer traceability information. This places an unfair burden on domestic producers, as variability in traceability information requests across parts of the supply chain will result in uneven and disproportional traceability investments.

Specifically, FDA should address this issue in the Draft Guidance by clearly outlining expectations and ensuring that a comprehensive outreach and enforcement strategy is established for foreign entities before the compliance date. If this effort is not comprehensive, we will see imported produce outcompete domestic produce due to the added costs for domestic producers associated with compliance with the rule. This strategy should, at a minimum, include documentation of traceability KDEs required at the time of import.

5. Entities Without Physical Possession of Product

Consistent with the points made in Section 4 above, FDA should provide further clarification with respect to entities that do not take physical possession of the product, such as brokers or certain distributors or intermediaries, regardless of whether these entities are handling foreign or domestic products. Specifically, FDA should specify that entities that coordinate the movement of FTL foods without physical possession of the food are still participating in shipping and receiving critical tracking events. Based on this understanding, FDA should specify that if incomplete traceability records are provided to downstream entities using brokers or other intermediaries, FDA will take enforcement action against the intermediary if they are determined to have willfully ignored the rule's requirements. In addition, FDA should provide examples in guidance of how intermediaries can facilitate compliance with the Traceability Rule's requirements. These efforts will close the concerning gap under the current configuration of the rule and ensure a true, full-traceback investigation is possible.

6. Provide Flexibility for Ad Hoc Purchases

We recommend that the agency recognize spot purchases in the fresh produce supply chain as a necessary business practice that provides flexibility during unexpected events, such as weather disruptions and demand spikes. Because spot purchases are one-time or short-term purchases made at the current market price rather than under a prearranged contract or seasonal program, the agency should allow flexibility in how related information is collected. This is consistent with the approach FDA has taken for retail food establishments and restaurants making ad hoc purchases from other such establishments, as outlined in 21 CFR § 1.1305(k), where FDA has acknowledged that the ad hoc nature of these types of purchases makes it challenging for a receiver to ensure the proper KDEs are shared in a complete, accurate, and interoperable manner. As a solution, we propose fresh produce companies making a spot purchase should have the option to assign a Traceability Lot Code (TLC), similar to the approach used for exempt entities: when shipping KDEs would not include the TLC, the receiver can assign the TLC while maintaining the other required receiving KDEs. We also recommend clarifying that a spot purchase is not intended to be a routine transaction, but rather a limited accommodation

for unforeseen circumstances, consistent with the direction provided in Question/Response 6 of the Draft Guidance.

7. Expand on Practical Solutions and Other Flexibilities

We recommend that FDA's Draft Guidance clearly defines the flexibilities it supports without weakening accountability, including examples and parameters for implementation across different supply chain entities. For instance, we do not believe it is appropriate for downstream entities to rely on data generated by others as a substitute for meeting their own obligations. Investment in traceability must be shared across the supply chain. Growers and shippers have already made significant investments in traceability systems and continue to do so to meet varied buyer requirements. This is particularly important with respect to proposed probabilistic models to provide the agency with required information. We are concerned about the integrity and use of data generated by growers and shippers when other entities have not made comparable investments in data quality, verification, and widely accepted methodologies.

Closing

Overall, the Draft Guidance is a valuable resource, and addressing the points above would further strengthen its utility by supporting consistent, practical, and scalable implementation across diverse supply chain participants. Western Growers and our members have been actively engaged in efforts to improve traceability to protect consumers from potentially contaminated food and remove it from the marketplace. We have long supported and want to promote an end-to-end traceability system that is clear, simple, and consistent. We stand ready to work with the FDA to achieve this common goal. Thank you for the opportunity to comment on this important document. We hope our comments are helpful. Please do not hesitate to contact us if we can provide any further information.

Sincerely,

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