October 25, 2024

By Electronic Submission

Reagan-Udall Foundation for the FDA
1333 New Hampshire Ave. NW, Ste. 420
Washington, DC 20036
FinalRule@reaganudall.org

Re: Reagan-Udall Foundation Roundtables and Virtual Public Meeting on FDA's Food Traceability Rule

To Whom It May Concern:

The International Foodservice Distributors Association ("IFDA") is pleased to submit these comments in response to the Reagan-Udall Foundation's ("the Foundation") roundtable series and virtual public meeting regarding FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods ("traceability rule" or "the rule"). IFDA is a non-profit trade association that represents businesses in the foodservice distribution industry. Our industry delivers approximately 33 million cases of food and related products to more than 1 million professional kitchens across America every day. As part of this work, foodservice distributors receive and ship thousands of foods on FDA's Food Traceability List ("FTL") on a daily basis and are therefore significantly affected by the traceability rule. IFDA appreciates the Foundation's efforts to examine the practical challenges posed by the traceability rule and to work with stakeholders to identify solutions to those challenges.

Foodservice distributors are deeply committed to food safety and have a proven track record of providing FDA with critical traceback information in a timely manner. Due to both the volume of foods they handle and their central role in the supply chain, foodservice distributors likely assist with more traceback investigations than any other segment of the supply chain. As a result, foodservice distributors have developed highly effective tracking and tracing systems to ensure they have robust records identifying the source, internal movement, and recipient of all products they handle.

IFDA appreciates the core objectives of the traceability rule, and our members continue to dedicate significant time and resources to building traceability programs to comply with the rule's requirements. We remain concerned, however, that certain components of the rule are overly complex and place undue burdens on industry, especially foodservice distributors and operators. Our members are particularly challenged by the de facto case-level tracking the rule imposes on distributors and the rule's current implementation schedule. While we appreciate that the Foundation's Top-Line Learnings Summary from the Industry Roundtable Series ("Top-Line Summary")[1] highlights some of these issues, our comments below provide additional

[1] Reagan-Udall Foundation, Industry Roundtable Series on the FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods, Top-Line Learnings Summary (Sept. 2024), https://reaganudall.org/sites/default/files/2024-09/Food%20Traceability%20Top-Line%20Summary%20090424_0.pdf.

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important details on the immense burdens these challenges place on industry and identify practical solutions that will allow FDA to resolve these issues while preserving the rule's main goals.

I. The traceability rule imposes a burdensome and costly de facto case-level tracking requirement.

As reflected in the Top-Line Summary, multiple stakeholders, including IFDA, have expressed concerns that "labeling and tracking *at the case-level* [will be] essential to generate" the records required by the traceability rule and that "much of the industry interprets [the rule's requirement that the TLC and TLC source be shared with recipients] to mean that *every case of food must be labeled and scanned* to produce the data FDA may request of downstream entities to trace a lot through the supply chain."[2] The Top-Line Summary further notes that most warehouse management systems are not currently capable of capturing this sort of case-level data and that reconfiguring systems to allow for this capability could "require years to implement" and "potentially require significant increases in labor, equipment, and space, with significant associated costs."[3] These findings underscore IFDA's longstanding concern that, by requiring entities to maintain and pass forward shipping key data element ("KDE") records that reflect *only* the specific traceability lot codes ("TLCs") included in each shipment, the rule imposes a de facto case-level tracking requirement on distributors.

This issue becomes readily apparent when considering the operational structure followed by nearly all foodservice distributors, which involves: (1) receiving products from suppliers in multi-case pallets, which may contain cases from multiple different traceability lots; (2) pulling individual cases from pallets directly or from pick slots; and (3) assembling customer orders using products pulled from pallets and/or pick slots. Because pallets and pick slots typically contain cases associated with different traceability lots, customer shipments may contain products from multiple traceability lots. Thus, to comply with the rule's requirement that shipping KDEs reflect *only* the specific TLCs included in each shipment, distributors will need to determine the precise TLC associated with each case on the pallet, track the particular case and its TLC through the distribution facility, and then track which cases, and thus which TLCs, are pulled from each pallet or pick slot and included in an order. In short, the only way for distributors to comply with the rule's current requirements is to engage in case-level tracking. Additionally, determining which TLC is associated with each case on a mixed-lot pallet or pick slot requires readable, scannable labels with lot codes correctly embedded on each case, which suppliers are not required to provide under the rule.

As the Top-Line Summary suggests, this case-level tracking requirement will place immense—and costly—burdens on distributors, who will need to fundamentally reconfigure their warehouses, processes, and/or warehouse management systems in order to comply with the rule, particularly given that cases are not required to be labeled with the TLC. In doing so, distributors will need to identify and implement new technological solutions—solutions that are expensive to implement, are neither comprehensive nor segmented by industry, take time to assess, and may not be widely adopted or available until well after the rule's current compliance deadline. Implementing such changes is a resource-intensive, multi-year endeavor and will result in increased costs being passed on to the end consumer. It will be tremendously challenging to achieve these changes by January 20, 2026, and doing so will be cost-prohibitive for many distributors. The impacts of these burdensome requirements will be

[2] Top-Line Summary at 3-4 (emphasis added).

[3] Top-Line Summary at 4.

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disproportionately felt by small- and mid-sized distributors, many of whom do not have the resources to immediately restructure their core operations.

In fact, based on ongoing discussions with members, IFDA estimates that one-time program implementation costs—including everything from data management, software development, and hardware procurement to supplier and customer readiness activities and warehouse management system upgrades or replacements—could total up to approximately 10 million dollars for a mid- to large-sized foodservice distributor. In addition to these upfront costs, we estimate foodservice distributors would have annual costs associated with gathering, tracking, and sending KDEs, that would amount to a range of approximately 34 cents to 1 dollar for every case that is subject to the rule, potentially adding up to hundreds of millions to billions of dollars in annual, ongoing costs for foodservice distributors.

As also reflected in the Top-Line Summary, stakeholders have already identified practical solutions that would resolve this issue without requiring fundamental changes to the rule's structure. These include proposals that would give certain entities in the supply chain, including foodservice distributors, the flexibility to pass forward a reasonable range of possible TLCs associated with shipments in circumstances where passing forward shipping KDEs for each individual TLC would not be possible without engaging in case-level tracking. IFDA is confident that such flexibilities would significantly reduce the burdens outlined above while still providing FDA with quick access to the information needed to carry out efficient traceback investigations. IFDA urges FDA to consider adopting these added flexibilities well in advance of the rule's compliance date.

II. The rule's current implementation schedule fails to account for downstream entities' reliance on upstream entities.

IFDA remains concerned that the rule's current compliance timeframe will not afford industry sufficient time to develop and implement traceability programs and align with the upstream supply chain partners on whom entities will rely to ensure full compliance with the rule. IFDA's perspective is consistent with the stakeholder views reflected in the Top-Line Summary, which notes that "many [roundtable participants] suggested a staggered implementation schedule might offer greater efficiency and compliance" due, in part, to the fact that "each sector of the supply chain (the purchaser) [will rely] on information provided by the prior sector participant (the supplier)" to pass forward information required under the rule.[4] IFDA urges FDA to consider certain modifications to the rule's compliance timeframe, including the adoption of a staggered implementation schedule that extends the compliance date for each subsequent downstream sector in the supply chain.

The need for a staggered implementation schedule becomes apparent when considering the degree to which entities throughout the supply chain, including foodservice distributors, must rely on their upstream supply chain partners to pass forward the information necessary to ensure compliance with the rule. Consider, for example, a single foodservice distributor who receives thousands of products from hundreds of different suppliers on any given day. When developing a traceability program, the distributor must work with each individual supplier to determine (a) how the supplier will identify whether the foods it supplies are subject to the traceability rule, (b) how the supplier plans to provide KDE records for each covered food, and (c) how those records can be incorporated into the distributor's own recordkeeping system. For instance, when receiving salsa from a supplier, the distributor will need to work with the manufacturer first to determine whether the salsa is covered by the rule (e.g., whether it

[4] Top-Line Summary at 6.

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contains fresh tomatoes, fresh herbs, fresh-cut vegetables, and/or other FTL ingredients and, if so, whether the product has undergone processing that would exempt it from the rule). If the product is subject to the rule, the distributor will then need to work with the supplier to identify how the supplier will provide KDE records for the product. Only after receiving this information will the distributor be able to assess whether and how the supplier's records can be incorporated into the distributor's own recordkeeping systems and whether the distributor needs to modify its recordkeeping systems to accommodate the supplier.

Put simply, distributors will not be able to finalize their own traceability programs unless and until they have full visibility into how their suppliers will comply with the rule. Even then, distributors will need time to adapt their traceability programs to align with their suppliers' practices. This same pattern will be replicated at all stages of the supply chain (e.g., manufacturers will rely upon their ingredient suppliers to provide required records, and retailers and restaurants will rely upon the distributors from whom they source products to provide such records). While foodservice distributors continue to take significant steps to coordinate with their suppliers ahead of the rule's compliance date, the practical reality is that it will be virtually impossible to achieve full, industry-wide alignment by January 20, 2026. This is particularly true given that some upstream entities likely will not finalize their traceability programs until just before the compliance date, leaving downstream entities with virtually no time to adapt and finalize their own programs.

FDA can resolve this issue by implementing a staggered, sector-by-sector implementation schedule, starting with entities at the beginning of the supply chain. This could involve, for example, retaining the January 20, 2026, compliance date for growers and harvesters, but then providing for a series of extended compliance dates for manufacturers, then distributors, and then retail food establishments. This will give downstream entities the opportunity to align with their supply chain partners and proactively ensure they have access to the information they need to comply with the rule.

This staggered approach would not be without precedent. For example, under the Drug Supply Chain Security Act ("DSCSA"), which established new traceability requirements for prescription drugs, FDA has, over the course of the DSCSA's 10-year compliance window, implemented a staggered, sector-by-sector implementation schedule, starting with manufacturers and followed by repackagers, distributors, and then dispensers.[5] This model reflects the practical challenges associated with imposing multifaceted, interdependent requirements across an entire supply chain and could serve as a helpful precedent as FDA considers how it might restructure the food traceability rule's implementation schedule.

III. FDA should work with stakeholders to conduct pilot programs to assess potential implementation challenges.

The Top-Line Summary acknowledges that industry stakeholders have encouraged FDA to work with industry to conduct pilot programs to assess implementation of the rule across various sectors and segments of the food supply chain.[6] IFDA firmly agrees that FDA, state and local regulators, and industry would all benefit from the completion of well-designed pilot programs. These programs would help all stakeholders assess the real-world application of the rule, identify challenges, and implement solutions to facilitate compliance. The completion of pilot programs should be viewed as an essential prerequisite for effective implementation of the

[5] *See* Federal Food, Drug, and Cosmetic Act § 582 (21 U.S.C. § 360eee–1).

[6] Top-Line Summary at 5.

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rule, since the results of such programs will provide valuable learnings for all stakeholders. We thus urge FDA to partner with industry to conduct pilot programs and to delay implementation of the rule pending completion of those pilots.

IV. FDA should increase its efforts to enhance awareness of the rule among key stakeholders.

IFDA shares in the concerns reflected in the Top-Line Summary regarding low levels of awareness and understanding of the rule among key stakeholders.[7] IFDA is especially concerned about low levels of awareness among the state and local regulators who, in many cases, will be tasked with enforcing the rule. IFDA is also concerned about the lack of awareness or preparation among certain upstream and downstream partners, which will significantly affect foodservice distributors' ability to comply, and among small- and medium-sized businesses that may not have the resources to develop complex compliance programs. Stakeholders have consistently raised these concerns since issuance of the final rule, and similar concerns were noted in a January 2024 report issued by the Government Accountability Office.[8]

To address these concerns, IFDA urges FDA to take a broad-based, sustained approach to engaging with stakeholders, particularly those who may not be receiving FDA's current communications. As part of these efforts, we encourage FDA to issue its anticipated draft guidance on the rule. It is essential that these materials be published well in advance of the rule's compliance date so that stakeholders can rely on them while developing their traceability programs.

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IFDA appreciates the opportunity to provide these comments and would be pleased to provide the Foundation and FDA with any additional information that might be helpful as the agency works toward implementation of the rule.

Respectfully submitted,

Mala Parker

Mala Parker
Vice President, Policy & Government Affairs

[7] Top-Line Summary at 3.

[8] *See* GAO, Food Safety: FDA Should Finalize Plans to Implement Its Rule to Help Trace Source of Outbreaks, GAO-24-106563, at 35 (noting that "[s]takeholders representing nonfederal regulatory partners stressed that FDA needs to improve coordination with, and guidance to, nonfederal regulatory partners to ensure consistent enforcement of the food traceability rule across jurisdictions.").

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