May 12, 2025

By Electronic Submission

Mr. Russell T. Vought
Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Attn: Kelsi Feltz

Re: OMB Request for Information on Deregulation (Docket No. OMB-2025-0003)

Dear Director Vought:

The International Foodservice Distributors Association ("IFDA") appreciates the opportunity to submit these comments in response to the Office of Management and Budget's Request for Information on Deregulation (90 Fed. Reg. 15481, April 11, 2025) and seeks full review of the U.S. Food and Drug Administration's ("FDA") Final Rule on Requirements for Additional Traceability Records for Certain Foods ("traceability rule" or "rule").[1] As part of this review, we ask that OMB consider practical solutions for addressing certain components of the rule that are particularly burdensome and that exceed FDA's statutory authority, including, specifically, the de facto case-level tracking requirement the rule places on distributors.

IFDA is a non-profit trade association representing businesses in the foodservice distribution industry. Our $400+ billion industry delivers approximately 33 million cases of food and related products to more than one million professional kitchens across America every day. IFDA members 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, our members 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. Because foodservice distributors receive and ship thousands of foods that are subject to the traceability rule, they are uniquely attuned to the impacts of this rule.

While IFDA appreciates the core objectives of the traceability rule, and our members continue to dedicate significant time and resources to building traceability programs to meet its requirements, we seek modifications to the rule to address burdensome requirements and fundamental impediments to its implementation. We are pleased with FDA's March 20, 2025, announcement that it intends to provide the food industry with an additional 30 months to comply with the rule beyond its original January 20, 2026, compliance date.[2] This additional

[1] 21 C.F.R. Part 1, Subpart S.

[2] FDA Constituent Update, FDA Intends to Extend Compliance Date for Food Traceability Rule (March 20, 2025).

time is essential, and we encourage FDA to finalize this compliance date extension as soon as possible. However, we remain concerned that certain components of the rule continue to be overly complex and place undue compliance burdens and costs on industry, especially foodservice distributors and operators, without providing corresponding public health benefits. In particular, the rule imposes a de facto case-level tracking requirement that presents considerable challenges for distributors and that expressly exceeds FDA's statutory authority.

We believe the traceability rule should be revised to address the immense burdens and implementation challenges of certain provisions of the rule, and we support practical solutions that will facilitate our industry's ability to comply with the rule and advance the agency's goals of improving foodborne illness investigations through enhanced traceability. Detailed below are a few key concerns.

I. The traceability rule imposes burdensome and costly requirements that Congress clearly did not intend.

Section 204 of the Food Safety Modernization Act ("FSMA") required FDA to establish additional recordkeeping requirements for entities that manufacture, process, pack, or hold foods designated by FDA as "high risk" foods. Importantly, Congress placed limitations on what FDA could and could not require, including that such requirements:

- "shall **not require product tracking to the case level** by persons subject to such requirements."[3]
- "shall relate only to information that is **reasonably available and appropriate.**"[4]
- "shall to the extent practicable, **not require a facility to change business systems** to comply with such requirements."[5]
- "shall be **scale-appropriate and practicable** for facilities of varying sizes and capabilities with respect to costs and recordkeeping burden, and **not require the creation and maintenance of duplicate records** where the information is contained in other company records kept in the normal course of business."[6]
- "shall ensure that the **public health benefits** of imposing additional recordkeeping requirements **outweigh the cost of compliance** with such requirements."[7]

IFDA has consistently held that certain recordkeeping requirements of the rule exceed one or more of these limitations, as outlined below:

A. The traceability rule requires de facto case-level tracking.

Under the traceability rule, covered entities are required to maintain records containing specific key data elements ("KDEs") when engaging in critical tracking events ("CTEs"), such as receiving and shipping, for foods listed on FDA's food traceability list ("FTL") or foods

[3] FSMA § 204(d)(1)(L) (21 U.S.C. § 2223(d)(1)(L)) (emphasis added).

[4] *Id.* § 204(d)(1)(A) (emphasis added).

[5] *Id.* § 204(d)(1)(G) (emphasis added).

[6] *Id.* § 204(d)(1)(E) (emphasis added).

[7] *Id.* § 204(d)(1)(D) (emphasis added).

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containing FTL foods as ingredients. Entities must link the KDEs of each FTL food to a traceability lot code ("TLC") and pass forward these records whenever they ship FTL foods.

In order to be in full compliance with these requirements, distributors need to engage in case-level tracking. This becomes evident 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 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 this requirement is to track to the case level, which is not only inefficient and costly but also prohibited by statute.

B. Information is often not reasonably available or appropriate.

Additionally, determining which TLC is associated with each individual case on a mixed-lot pallet or in a pick slot requires readable, scannable labels with lot codes correctly embedded on each case, which suppliers are not required to provide under the rule. In fact, a foodservice distributor's ability to comply with the rule is highly dependent on whether upstream suppliers provide the necessary records—and in a receivable format—to facilitate compliance. Because distributors' customers often choose the suppliers from whom to source products, distributors have limited leverage to require suppliers to provide certain records—and in a way that distributors are able to receive into their own recordkeeping systems, along with records from hundreds of other suppliers with differing practices.

Moreover, even if cases were to be labeled with barcodes containing the necessary lot code information, these labels may be damaged during transit and become unreadable or unscannable. As a result, it may not only be unduly burdensome to track the TLC by case; it may also be infeasible.

C. The traceability rule requires significant changes to business systems and processes.

With or without labels on cases with TLC-embedded barcodes, most warehouse management systems are not currently capable of capturing this sort of case-level data. Foodservice distributors need to fundamentally reconfigure their warehouses, processes, and/or warehouse management systems in order to allow for this capability, requiring significant increases in labor, equipment, and space—with their associated costs. Distributors must also 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 after the rule's 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.

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D. The traceability rule's recordkeeping requirements are not scale-appropriate and practicable for all sizes of distribution facilities.

The impacts of these burdensome requirements are being felt by distributors and facilities of all sizes. Small- to mid-sized distributors who have not conducted case-level tracking may not have existing capabilities to maintain the volume of data and records required under the rule. Furthermore, they are unlikely to have the resources to restructure their core operations. Larger distributors who also have not conducted case-level tracking and have thousands of suppliers, tremendous volumes and fluidity of product, and a variety of systems must now try to navigate increased complexity to comply with the rule's requirements.

E. The costs associated with the traceability rule's recordkeeping requirements are staggering.

Finally, FDA estimates the traceability rule will cost the food industry over $24.6 billion to implement, which we believe underestimates actual compliance costs. IFDA projects 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 incur annual operational compliance costs that would amount to a range of approximately 34 cents to 1 dollar for every case that is subject to the rule.

With foodservice distributors delivering 12 billion cases of product each year and up to 30 percent of that product being subject to the rule, the new requirements could add hundreds of millions of dollars to over a billion dollars in annual, ongoing costs for foodservice distributors.

II. A practical solution to address major challenges and reduce the regulatory burden.

IFDA supports practical solutions to address the regulatory complexity and costs of the traceability rule while providing for enhanced traceability. For example, IFDA believes the burden of case-level tracking would be reduced by amending the rule to give certain entities in the supply chain, including foodservice distributors, the flexibility to maintain and pass forward a reasonable range of possible TLCs associated with shipments. Under this approach, when receiving and assembling orders from pallets and pick slots that contain multiple TLCs, distributors would no longer be required to determine the precise TLCs contained in each shipment from that pallet. Instead, they would be able to identify the limited range of TLCs that could be in each shipment, based on the TLCs that were received on the pallets or in the pick slots. Such flexibility would help to reduce many of the challenges outlined above—and align with the statutory limitations—while still providing FDA with quick access to the information needed to carry out efficient traceback investigations.

This is one example of a practical solution that could significantly reduce the regulatory burdens associated with the traceability rule while still advancing the rule's core public health objectives.

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IFDA appreciates OMB's consideration of these comments, and we are available to provide any additional information that might be helpful as the agency reviews the traceability rule.

Respectfully submitted,

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