By Electronic Submission **September 8, 2025**

Division of Dockets Management (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Requirements for Additional Traceability Records for Certain Foods: Compliance Date Extension; Proposed Rule, Docket No. FDA-2014-N-00

Dear Sir or Madam:

FMI, The Food Industry Association (FMI) appreciates the opportunity to provide comments on the U.S. Food and Drug Administration's (FDA's) proposed rule to extend the compliance date for FDA's final rule on *Requirements for Additional Traceability Records for Certain Foods* (Food Traceability Rule). As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain—from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services—to amplify the collective work of the industry.

FMI strongly supports FDA's proposal to extend the Food Traceability Rule's compliance date by 30 months to July 20, 2028, and we encourage the agency to finalize this proposal as soon as possible. We also appreciate FDA's recognition of the challenges that companies throughout the supply chain have encountered while coming into compliance with the rule. While FDA's proposed extension will give stakeholders much needed time to address some of these challenges, we believe that additional flexibilities are required to facilitate compliance. We therefore encourage FDA to supplement the compliance date extension with the additional targeted flexibilities outlined herein, which the agency can implement through either interpretive guidance or minor amendments to the rule. These flexibilities will remove unnecessary regulatory burdens, preserve the rule's public health benefits, and ensure that companies are best positioned to come into full compliance by July 20, 2028.

I. FMI supports FDA's proposal to extend the Food Traceability Rule's compliance date by 30 months.

As FDA notes, the Food Traceability Rule will not only mandate that covered entities maintain an incredibly large volume of records, but also will require that they obtain and pass forward many records that they do not keep or share under current business practices. To accomplish this, most (if not all) companies will need to fundamentally restructure their existing recordkeeping processes. In almost all cases, this will require companies to invest in new, interoperable technological systems that allow for seamless data exchange throughout the supply chain. Developing, piloting, implementing, and training employees on these changes is a complex and costly endeavor that will take multiple years to complete, even for the most well-resourced companies. These burdens are particularly heightened for distributors and retailers,

many of whom receive and ship thousands of foods on FDA's Food Traceability List (FTL) each day.

These challenges are exacerbated by the fact that, as FDA acknowledges, no single company will be able to comply with the rule unless and until *all* of the supply chain partners they rely upon to pass forward the information required under the rule also come into compliance. This is particularly true for downstream entities like distributors and retailers, who will be limited in their ability to fully develop compliance programs until they have full visibility into the methods by which their upstream supply chain partners will assign traceability lot codes (TLCs) and pass forward key data element (KDE) records. Thus, as FDA rightly notes, "the possibility that a significant number of supply chain entities may have great difficulty coming into compliance by the current compliance date (January 20, 2026) could substantially diminish the rule's effectiveness."[1]

These burdens have become more apparent as our members have moved towards implementation. Many of our members began developing compliance programs immediately following publication of the final rule and, by our estimate, have invested hundreds of millions of dollars and countless personnel hours on compliance efforts. FMI and its members have made significant progress in the intervening years. For example:

- FMI developed a compliance guide summarizing the rule in October 2023 and developed an implementation guide in November 2023. Both are publicly available on FMI's website as resources for all stakeholders.

- FMI, in partnership with other stakeholders, helped facilitate industry alignment around use of GS1 standards to facilitate interoperability.

- FMI, in partnership with other stakeholders, has worked to increase awareness of and education on the rule's compliance requirements for entities throughout the supply chain who handle covered products on the FTL.

- FMI has participated in the Partnership for Food Traceability, a public-private partnership with the objective of facilitating traceability compliance and interoperability.

- FMI hosts several ongoing committees and workgroups with members to regularly discuss compliance solutions and progress.

- FMI participated in numerous meetings with the agency after the rule was published, including hosting FDA officials and staff at three separate distribution centers to provide an understanding of the complexities of the rule at a critical point in the supply chain.

[1] 90 Fed. Reg. 38084, 38085 (Aug. 7, 2025).

Despite these best efforts, it will still take multiple years for most companies to fully invest in new technological solutions, ensure adequate alignment with their supply chain partners, and otherwise take the necessary steps to achieve full compliance with the rule. This is particularly true for small and mid-sized distributors and retailers, who may not have the resources to immediately implement changes at the scale required under the rule. Extending the rule's compliance date beyond January 20, 2026, will play a crucial role in relieving these pressures, while ensuring that stakeholders throughout the supply chain are best positioned to carry out the rule's public health objectives. This, in turn, is also consistent with the Trump administration's broader focus on reducing undue regulatory burdens and bringing down the cost of food.[2] FMI therefore strongly supports FDA's proposal to extend the Food Traceability Rule's compliance date by 30 months and encourages the agency to finalize this extension as soon as possible.

II. FMI encourages FDA to implement additional flexibilities to reduce regulatory burdens and facilitate compliance with the rule.

FMI appreciates FDA's commitment to continue providing "education and other forms of engagement" to facilitate implementation of the rule during the extended compliance period.[3] The resources that FDA has published to date—including FDA's Food Traceability Rule FAQs, supply chain examples, and traceability plan examples—have proven to be helpful tools as our members develop their compliance programs. We encourage the agency to continue this work and, in particular, to publish its pending Food Traceability Rule draft guidance, which we understand is currently under development, and which the agency plans to publish no later than December 2025.[4] The sooner FDA publishes these materials ahead of the rule's compliance date, the more helpful they will be for companies as they develop their compliance programs.

Even with these helpful resources, we believe it is imperative that the agency adopt additional flexibilities to address some of the core challenges stakeholders have identified during the rule's implementation period. These include challenges related to the rule's de facto case-level tracking requirement, the rule's application to intracompany shipments, and the scope of the "traceability lot code source reference" KDE requirement. Addressing these challenges now will significantly reduce the rule's regulatory burdens and advance the administration's deregulatory objectives, while still preserving—if not enhancing—the rule's

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[2] *See, e.g.*, Presidential Memoranda, *Delivering Emergency Price Relief for American Families and Defeating the Cost-of-Living Crisis* (Jan. 20, 2025); Executive Order 14192, *Unleashing Prosperity Through Deregulation* (Jan. 31, 2025); Executive Order 14219, *Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative* (Feb. 19, 2025); Presidential Memoranda, *Directing the Repeal of Unlawful Regulations* (April 9, 2025).

[3] 90 Fed. Reg. at 38085-86.

[4] *See* FDA, Foods Program Guidance Under Development, https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/foods-program-guidance-under-development (current of June 30, 2025).

public health aims. We thus urge the agency to implement these flexibilities, as outlined below, either through interpretive guidance or minor amendments to the rule.

A. FDA should implement flexibility to ensure that entities are not required to engage in case-level tracking.

The rule requires shippers and receivers to maintain and pass forward shipping records that reflect only the specific TLCs included in each shipment.[5] Absent fundamental changes in business practices of the sort that Congress did not intend for the rule to require,[6] the only way for entities in distribution channels to fulfill this requirement will be to engage in case-level tracking.

Specifically, when receiving pallets with cases from multiple traceability lots, entities will need to determine the precise TLC associated with each case on the pallet. Then, when assembling orders, they will need to track which cases (and thus which TLCs) are pulled from each pallet or pick slot and included in an order. This de facto case-level tracking requirement not only exceeds FDA's authority under FSMA—which expressly prohibits FDA from requiring "product tracking to the case level"[7]—but would place immense burdens on entities, who would have to completely restructure their recordkeeping practices and invest in new technological solutions that, for the most part, do not currently exist. These investments will be cost-prohibitive for many, particularly small- and mid-sized distributors, and could ultimately result in higher prices for consumers. At the same time, this requirement will offer few, if any, public health benefits compared to current practice, since existing recordkeeping systems for entities in distribution channels have consistently proven to be highly effective in facilitating traceback investigations. We also believe this will result in greater accuracy and fewer errors when sharing information with FDA.

FMI applauds FDA for recognizing this challenge in the preamble to the proposed compliance date extension[8] and for providing some relief by extending the compliance date. But additional time, while helpful, will not resolve the underlying cause of this issue. To do that, FDA must couple the compliance date extension with additional flexibilities. For example, FDA could issue interpretive guidance or amend the rule to provide that, when entities determine that it is not practicable in the course of their standard operations to maintain and pass forward shipping

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[5] 21 C.F.R. § 1.1340(a) (requiring that entities maintain and pass forward shipping KDE records "for each traceability lot" of each FTL food they ship and that these records be linked to each product's TLC).

[6] For example, section 204 of FSMA expressly provides that the rule shall "relate only to information that is reasonably available and appropriate" and that "to the extent practicable, [the rule shall] not require a facility to change business systems to comply with such requirements." FSMA §§ 204(d)(1)(A), 204(d)(1)(G).

[7] FSMA § 204(d)(1)(L)(iii).

[8] 90 Fed. Reg. at 38085 ("…distributors are struggling to obtain lot codes from their suppliers and experiencing challenges transmitting them to retailers in a cost effective manner.").

KDE records for each individual TLC without engaging in case-level tracking, they may instead maintain and pass forward records that reflect a reasonable range of all possible TLCs included in a shipment. This approach would still provide FDA with a detailed set of KDE records, would drastically reduce the burden on the day-to-day operations of those receiving thousands of products on the FTL like warehouses and distribution centers, and would only marginally increase the initial scope of an investigation. In fact, this streamlining of the rule could improve the overall efficiency of investigations while still meeting FDA's public health objectives. Such flexibilities would eliminate the rule's de facto case-level tracking requirement since, when receiving and assembling orders from pallets that contain multiple TLCs, warehouses and distributors would no longer be required to determine the precise combination of TLCs contained in each shipment from that pallet. Instead, they would be allowed to identify only the limited range of TLCs that could be in each shipment. At the same time, these flexibilities would not undercut the rule's public health objectives, since these entities would still need to maintain and pass forward records tied to only a limited set of TLCs and would still need to maintain and pass forward KDE records tied to each TLC. Put otherwise, warehouses and distribution centers would still maintain and pass forward, and FDA would still be able to access, a detailed set of KDE records. If anything, this approach would streamline the rule's requirements such that distributors have the capacity to develop, maintain, and quickly pass forward accurate records. This, in turn, could improve the overall efficiency of investigations while alleviating the rule's excessive burdens on the day-to-day operations of distribution centers.

B. FDA should exempt intracompany shipments from the rule's shipping and receiving KDE recordkeeping requirements.

The rule currently requires that covered entities maintain shipping and receiving KDE records for intracompany shipments. In practice, this means that companies will need to maintain and pass forward shipping and receiving records each time a covered food is moved from one location owned by a firm to any other location owned by the same firm (e.g., from one distribution center to another, or from a retail store to another retail store on a regular basis). Due to the frequency of these intracompany shipments, maintaining these records would be incredibly burdensome and, in many cases, would result in the creation of a large volume of redundant records. This requirement would be particularly burdensome for distributors, most of whom receive and ship thousands of covered foods on a daily basis. Requiring that entities maintain a high volume of largely duplicative records is very inefficient, increases the risk of recordkeeping errors, and runs directly counter to the Trump administration's deregulatory aims. Importantly, this requirement also fails to meaningfully benefit the public health compared to current practice. When ownership stays within one company system and all transactions are internal, appropriate recordkeeping practices are already in place to ascertain the whereabouts of foods. In fact, most companies maintain records at centralized corporate offices and these centralized records provide sufficient information to facilitate traceback investigations. Allowing companies to leverage these existing systems would be highly efficient and would mitigate the risk of recordkeeping errors associated with maintaining duplicative records. We therefore request that FDA issue either interpretive guidance or minor amendments to the rule to exempt intracompany shipments from the rule's recordkeeping

requirements and to instead allow companies to track these shipments using their existing internal recordkeeping systems.

C. FDA should allow the "traceability lot code source reference" KDE to identify the person responsible for assigning a food's TLC.

The final rule defines "traceability lot code source" and "traceability lot code source reference" in a manner that requires entities to identify the specific *location* where a food's TLC was assigned (i.e., "traceability lot code source" is defined as "the place where a food was assigned a traceability lot code").[9] Requiring that entities maintain records with this level of specificity will be logistically burdensome, particularly for entities, such as processors, that transform a variety of food products across many locations within one company system. Amending the rule to allow the traceability lot code source reference to identify the *person* responsible for assigning the TLC will significantly alleviate the burden imposed upon covered entities.[10] With this change, companies could list a Global Trade Item Number (GTIN) or similar identifier identifying the person responsible for assigning the TLC, provided that person is able to identify the TLC source. This amendment would allow the TLC reference to identify the corporate entity responsible for assigning the TLC, rather than providing the specific location where the TLC was assigned, which is a less onerous requirement for firms operating multiple locations.

This change would reduce the burden on industry without inhibiting FDA's ability to conduct foodborne illness outbreak investigations. The TLC source reference is intended to help FDA identify the specific food and location involved in a contamination event and determine the appropriate scope of a recall event.[11] Providing a TLC source reference that identifies the corporate entity will allow FDA to locate a point of contact within a company who can quickly identify the specific location where a TLC was assigned. In some cases, this might be even more efficient than identifying the location where the TLC was assigned, since the corporate contact might be best positioned to provide current and accurate information regarding the food in question. We therefore request that FDA either amend the definition of "traceability lot code source reference" or issue interpretive guidance to allow companies to identify the person responsible for assigning the TLC.

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[9] 21 C.F.R. § 1.1310.

[10] The rule defines "person" to include "an individual, partnership, corporation, and association." 21 C.F.R. § 1.1310.

[11] FDA, *Traceability Lot Code,* https://www.fda.gov/food/food-safety-modernization-act-fsma/traceability-lot-code (last visited Apr. 25, 2024).

III. FDA Should Participate in Pilots/Studies to Evaluate the Rule's Effectiveness in Facilitating Accurate Data Retrieval

To ensure that the rule effectively achieves its stated goal of facilitating foodborne illness investigations, we strongly encourage FDA to participate in pilot programs or other studies to evaluate how the data shared with FDA under the rule—and, in particular, data shared via electronic sortable spreadsheets—are used during investigations. The goal of these pilots/studies should be to assess whether and how the data shared under the rule facilitate FDA's ability to conduct foodborne illness investigations compared to current practices. While multiple industry pilots have been completed to evaluate traceability methods, including the FSMA-mandated pilots that were completed by FDA in 2012,[12] these pilots did not assess the Food Traceability Rule's specific recordkeeping requirements. Conducting additional pilots/studies will therefore provide a "proof of concept" that will allow FDA to assess the efficacy of certain core components of the rule, including the electronic sortable spreadsheet requirement.

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For the reasons outlined above, FMI strongly supports FDA's proposal to extend the Food Traceability Rule's compliance date until July 20, 2028, and we encourage FDA to finalize this proposal as soon as possible. In the meantime, we urge FDA to adopt the additional flexibilities discussed herein, which will further facilitate compliance with the rule while advancing the Trump administration's efforts to reduce undue regulatory burdens and bring down food prices.

Sincerely,

Stephanie Harris

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Hilary S. Thesmar

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Chief Science Officer and SVP Food and Product Safety Programs

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[12] IFT Pilot Projects for Improving Product Tracing along the Food Supply System – Final Report (August 2012) https://www.fda.gov/files/food/published/PilotProjectsforImprovingProductTracing.pdf (last visited Sept 3, 2025).