May 21, 2026

Documents Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1601
Rockville, MD 20825

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and Answers About Requirements for Additional Traceability Records for Certain Foods: Guidance for Industry – Draft Guidance"

To Whom it May Concern:

The Food Industry Association ("FMI") appreciates the opportunity to comment on the U.S. Food and Drug Administration's ("FDA" or "the agency") Draft Guidance titled "Questions and Answers About Requirements for Additional Traceability Records for Certain Foods: Guidance for Industry" ("Draft Guidance"). 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 members are committed to protecting public health by facilitating quick traceback activities to enable swift identification of contaminated products, help prevent future public health outbreaks, and avoid sweeping public advisories. We appreciate FDA's continued engagement, including the Draft Guidance and other resources, to help covered entities design and implement compliant traceability programs.

The Draft Guidance, as published, provides some helpful information for companies working to understand and comply with the Traceability Rule. Nonetheless, FMI believes that additional guidance and flexibilities are still needed for the industry to effectively implement the rule. We appreciate that the Draft Guidance explicitly addresses some of the questions posed by industry to date. FMI stands ready to work with FDA to identify solutions to prevalent implementation challenges. We appreciate FDA's participation in quarterly meetings with industry and look forward to future engagement with the Agency to address the challenges that companies throughout the supply chain have encountered while coming into compliance with the rule. We are committed to improving traceability up and down the supply chain, but it needs to be done in a cost-efficient and effective way that doesn't increase operational challenges. The food industry is working tirelessly to keep costs low for consumers, and FDA should not impose burdensome requirements that unnecessarily raise food costs without a corresponding public benefit to public health.

Additionally, we want to reiterate our concerns around supply chain readiness and education, FMI has been working diligently with our members to help educate covered entities throughout the supply chain and increase awareness of the rule's compliance requirements, however additional agency support is still needed to ensure that all covered stakeholders are aware of their responsibilities under the rule well ahead of the compliance date.

In these comments, we provide specific areas where additional guidance from the agency is needed and provide direct feedback on certain FDA responses in the Draft Guidance. Specifically, the Draft Guidance does not adequately address many key implementation challenges that have been outlined in FMI's previously submitted comment letters and other engagement with the agency, including: (1) the de facto requirement for case-level tracking; (2) the use of Traceability Lot Code Source References; and (3) flexibility for intracompany shipments.

I. AREAS WHERE MORE FLEXIBILITY IS NEEDED

While the Draft Guidance seeks to offer clarity for industry stakeholders, it does not address a critical concern—the implicit requirement in the Traceability rule for case-level tracking. Furthermore, although the Draft Guidance outlines the agency's approach to traceability lot code source references and intracompany shipment requirements, the Guidance does not address the most substantial operational challenges associated with both requirements. Accordingly, we respectfully request increased flexibility in these areas as doing so will lessen the burden on industry without undermining the public health goals of the Traceability Rule.

A. Case-Level Lot Code Tracking

We recognize that FDA is in the process of engaging with stakeholders through the Partnership for Food Traceability (PFT), of which FMI is a member, to assist the industry in complying with the lot code tracking requirement imposed by the Traceability Rule. This initiative is being completed in order to fulfill the Congressional directive put forth in the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 passed in November 2025.[1] We reiterate that the de facto case-level tracking requirement established by the Traceability Rule is the single most burdensome element of the rule at the distribution and retail level. Consistent with Congressional intent and the appropriations bill, FDA should ensure that entities are not required to engage in case-level tracking by allowing firms at the distribution level to pass forward a reasonable range of lot codes.

As we have discussed in previous comments,[2] in order to comply with the Traceability Rule as written, distribution centers would need to engage in case-level tracking, which will impose significant burdens for entities that handle thousands of products on the Food Traceability List (FTL) on a daily basis, resulting in an immense number of records under the rule. Because most distribution centers do not currently conduct case-level tracking, they will have to fundamentally overhaul their recordkeeping systems to satisfy this new requirement. Doing so is both cost-prohibitive and unnecessary to meet the intent of the rule. FMI supports allowing companies to provide a reasonable range of all possible traceability lot codes included in a shipment when the company determines that they cannot practicably provide key data elements for each specific traceability lot, a solution that both provides FDA with the necessary information and reduces the operational burden on distribution centers. This would eliminate the rule's de facto case-level tracking requirements because distributors would not need to determine the precise combination of traceability lot codes that are in each shipment. Instead,

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[1] 139 Stat. 558 (2025), available at: https://www.congress.gov/119/plaws/publ37/PLAW-119publ37.pdf.

[2] FMI, *Comments on Virtual Public Meeting on FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods*, submitted to FinalRule@ReaganUdall.org in October 2024.

they would be able to identify a limited range of traceability lot codes that could be included in each shipment.

Adding this flexibility would not materially undercut FDA's ability to conduct effective traceback investigations, as the framework would still require distributors to maintain and pass forward all key data elements tied to each of the limited set of traceability lot codes being provided to the next entity in the supply chain. Although this approach may marginally increase the initial scope of an investigation from one lot code to a few lot codes, it would allow stakeholders to more rapidly share accurate information because it would not require a case-level inquiry into the data. FMI believes that allowing companies to provide a limited range of lot codes when case-level tracking is overly burdensome would preserve the overall efficiency of investigations while alleviating the rule's excessive burdens on day-to-day operations at distribution centers.

B. Traceability Lot Code Source References

An additional challenge our members face is how to transmit information for the traceability lot code source. The Traceability Rule requires that the "location description," which includes the business name, phone number, and address, of the traceability lot code source be shared throughout the supply chain. Current recordkeeping practices and technologies are not readily able to transmit this type of information seamlessly throughout the supply chain. As a result, many of our members have been trying to understand whether a traceability lot code source reference can be effectively utilized instead. Specifically, our members need the flexibility to provide a single piece of data regarding the traceability lot code source that will direct FDA to the appropriate entity for more information to complete a traceback investigation. Although FDA has stated that a traceability lot code source reference could be a Food Facility Registration Number, a web address that provides FDA with the location description information for the source, a QR code, or GS1 Digital Link, we ask that FDA recognize that the GTIN or corporate entity name could be appropriate traceability lot code source references as well.

In response to a question (Question 29) regarding how to identify a traceability lot code source, FDA reiterates that the location description for the traceability lot code source must be maintained as a Key Data Element ("KDE") and provides flexibility noting that the listed phone number need not correspond to the specific location if a different phone number would promote more efficient and effective traceback. Specifically, the response to Question 29 states that a phone number that "connects to an individual who has familiarity with the farm's procedures for traceability or who can quickly identify such an individual" can be provided instead of the farm's phone number. This demonstrates that the key purpose in requiring the location description of the traceability lot code source is the ability to connect quickly with individuals able to provide additional information to facilitate the traceback investigation. We ask that FDA provide similar flexibility with respect to the traceability lot code source reference and allow companies to provide a Global Trade Item Number ("GTIN") or similar identifier for the person or corporate entity responsible for assigning the TLC, as doing so would serve an equivalent purpose as providing an alternate phone number in the example provided.

The GTIN is a global identifier that is unique to a specific product, meaning that it inherently identifies the corporate entity that manufactured the product. Once the relevant corporate entity of the traceability lot code source is provided, gathering traceback information is simple because internal product management systems are able to identify the location where a traceability lot code is assigned. FDA would simply need to contact the entity, and it would be quickly directed to an individual who is knowledgeable about the company's traceability programs. In this way, providing the GTIN or

corporate entity would simplify data sharing for industry without slowing down traceback investigations, allowing FDA to achieve the public health benefits the Traceability Rule was designed to provide.

C. Intracompany Shipments

Under the Traceability Rule, and as reiterated in response to Question 7 in the Draft Guidance, intracompany shipments where foods are transported from one street address to another are covered by the rule and require full shipping and receiving KDEs to be generated and maintained. As has been detailed in previous comments, internal recordkeeping and traceability practices implemented outside of efforts to comply with the Traceability Rule already facilitate efficient and effective internal traceback investigations making the application of the Traceability Rule to intracompany shipments unnecessary and overly burdensome. FMI strongly urges FDA to revise the Traceability Rule or provide enforcement discretion in these circumstances such that companies would not be required to maintain traceability records for intracompany shipments when internal records can facilitate traceback investigations effectively. Doing so would reduce the costs and complexity under the rule without undermining investigations.

Further, with respect to the response to Question 7 in the Draft Guidance specifically, FDA discusses ad hoc transactions between two retail or restaurant locations. The agency references instances where one location is "essentially acting as a distributor for the other location" [and notes that] it is common for inventory of highly perishable prepared foods to be shared between retail food establishments when one location does not have the proper facilities to prepare those foods themselves. In most of these arrangements, the receiving store/restaurant would only be sourcing the relevant product from the distributing store, and the company could easily determine from internal records which traceability lot codes would have been transferred to the receiving store during the time period of the records request. It would be highly burdensome for a distributing store or warehouse to be required to create full KDEs that would only be transmitted internally, when the company's recordkeeping systems would already have all the data necessary to, essentially immediately, trace that particular product back to the distributing store or warehouse where the transformation and shipping events occurred.

Further, we are concerned that the concept of a "general practice of sharing inventory," particularly as linked to the idea that one location "essentially acts as a distributor," could be construed too broadly in the context of modern retail operations. In large retail and club environments, documented standard operating procedures (SOPs) often govern a wide range of activities, including infrequent, need-based transfers that are operationally reactive (e.g., to address stockouts, localized overstock, or quality issues), rather than systematic distribution functions. If the mere existence of an SOP were treated as determinative of a "general practice," even where transfers are sporadic and not part of a structured supply chain function, this could result in substantial recordkeeping burdens without commensurate traceability benefits.

Traceability information is commonly transmitted through the invoicing process, which is not used for internal product transfers. Requiring companies to document KDEs for store-to-store or intracompany transfers would inevitably result in these transfers being invoiced consistent with transactions with vendors or customers, which would create significant burden and provide no incremental benefit to the efficiency or effectiveness of a foodborne illness outbreak investigation. As a result, we urge FDA to revise the rule or provide enforcement discretion exempting intracompany shipments from shipping

and receiving records, provided that the company can supply investigators with adequate traceability data in the required timeframe from their own internal recordkeeping systems.

II. SPECIFIC FEEDBACK ON THE DRAFT GUDIANCE

In addition to the above-described areas where the Draft Guidance should be revised to provide additional flexibility, we are providing comments below on the questions and responses in the Draft Guidance that will drive further clarity and support implementation of the Traceability Rule.

A. Response 6; Ad Hoc Purchases by Retail Food Establishments and Restaurants

In response to Question 6, FDA clarifies that transactions between different entities in the supply chain that occur through platforms and channels utilized by consumers are covered by the ad hoc exemption in 21 CFR § 1.1305(k), even if these transactions are made often. This clear, actionable guidance is undermined by the statement in the response explaining that "an entity such as a wholesale membership club, may be able to provide the required purchase information for a [retail food establishment] or restaurant upon request, even when the purchase was not made pursuant to a contractual relationship."[3] This language implies that there may be circumstances where FDA would expect an entity to request traceability records for foods purchased through consumer channels. This would be an unworkable expectation as FDA does not have the authority to require food retailers to maintain consumer data or provide data regarding a consumer to the agency. Further, the ad hoc exemption in 21 CFR § 1.1305(k) provides a partial exemption only. The retail food establishment or restaurant that sold the product is fully exempt, but the purchasing entity must still maintain records documenting the date of purchase and the name and address of the place of purchase. This information is likely already documented on the sales receipt and it would be unlikely that the selling entity would issue additional records. We recommend removing this language as it adds complexity without a clear practical application.

B. Response 19; Pallet Breakdown and Transformation

FMI acknowledges the Agency's clarification that breaking down a pallet is not inherently a transformation event. A rule that redefines transformation in a way that requires assignment of a new traceability lot code when a pallet is broken down would add additional costs and complexity in many operations and may be impractical for certain distributors where the volume and speed of product movement would make assigning new traceability lot codes at breakdown infeasible. That said, we understand FDA is considering flexibility that would allow companies to document the breaking down of a pallet as a transformation event and assign a new TLC code in order to help address the challenges related to case-level lot code tracking, discussed more fully above. This alternative may offer additional flexibility for some companies in specific scenarios, especially when products are received with incomplete KDEs. This could be a viable alternative to rejecting or holding product until the appropriate KDEs are provided by a supplier. As a result, FMI urges FDA to implement additional flexibilities to address the broader issue of lot level tracking. Specifically, as discussed in Section 1.A. above, FMI urges FDA to allow for a reasonable range of lot codes to be provided from distribution centers to retail and restaurant establishments. We believe this flexibility will reduce the burden faced by members, particularly those at the end of the supply chain, and still allow for efficient and effective traceback investigations.

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[3] *Questions and Answers About Requirements for Additional Traceability Records for Certain Foods: Guidance for Industry*, Response 6 p. 9 (Feb. 2026).

C. Response 21; Application in Continuous Processing Scenarios

FMI appreciates FDA's clarification in determining when a processing event should be considered continuous, specifically that "considering the food at the start of the processing event and the food at the end of the processing event, but not keeping records for any intermediate foods that might briefly exist during the processing event – can be applied to other examples of continuous processing operations." We urge the Agency to retain this principle in the final guidance.

D. Response 25; Requests for Records from FDA

In Response 25, FDA provides guidance as to how records can be provided to FDA when they are maintained by a third party on behalf of a facility. This discussion includes acknowledgement that FDA will likely open a dialogue with the relevant facility regarding how the records would be provided. It would be helpful for FDA to provide additional information regarding its approach to traceability information data sharing. In defining data sharing under the Traceability Rule, we recommend FDA implement the following expectations:

- FDA should ensure that any data provided under the Traceability Rule is kept confidential as commercial information;
- FDA should limit requests for an electronic, sortable spreadsheet within 24-hours to the most critical outbreak investigations;
- FDA should convene a call with the relevant facility prior to requesting data to align on what data is requested, the format it will be provided in, and the deadline for providing this information; and
- All requests for data should be made in writing.

E. Response 26; Reliance on Suppliers for Complete KDEs

FMI and our members have been working diligently to educate suppliers on expectations under the Traceability Rule to ensure implementation of the rule throughout the supply chain. However, we have serious concerns regarding enforcement of the rule's recordkeeping requirements in light of the interconnected nature of the supply chain. The burden of ensuring the supply chain is complying with the rule falls on entities at the end of the supply chain which creates substantial compliance risk for downstream entities, even where they have implemented comprehensive supplier management, contractual requirements, and auditing processes to promote data accuracy. Given the volume and speed products need to move in order to meet consumer demand, it is impractical for entities to hold or reject products when they receive incomplete KDEs from shippers. Because of this, FDA should provide enforcement discretion or establish a safe harbor that would apply to entities when they receive inaccurate, incomplete, or otherwise deficient KDEs from shippers. Providing enforcement discretion or a safe harbor in these scenarios would offer reassurance for entities that they will not be punished for supplier noncompliance when each entity is independently responsible for adhering to the rule's requirements for the CTEs they perform.

We appreciate FDA's acknowledgement that the agency will consider voluntary corrective action by a firm when determining regulatory follow-up in situations where a firm's data is inaccurate and incomplete. We encourage the agency to be transparent in sharing its plans for implementation and

enforcement of the rule ahead of the compliance date and to work closely with regulatory partners to provide clarity for regulated entities. FMI's members and the food industry work closely with FDA and state partners to facilitate efficient foodborne illness outbreak investigations on a regular basis. Collaboration, communication, and transparency between the agency, its regulatory partners, and regulated entities is essential to improving the investigative process and advancing food safety. By providing a clearer roadmap regarding how future traceback investigations will work, FDA would build goodwill with industry stakeholders and help promote collaboration going forward.

F. Response 27; Sales to Companies at the Same Physical Address

We disagree with the position taken by FDA in Question and Response 27, as the information provided is inconsistent with the text of the Traceability Rule. The question contemplates whether shipping and receiving KDEs are required when the owner of a product changes, but the location of the product (i.e., the street address) does not. The example provided considers a grocery store with a sushi bar operated by a third-party and the sushi bar obtains foods on the FTL directly from the retail location. In its response, FDA asserts that shipping and receiving records are required for this transaction. However, this interpretation is inconsistent with the definition of "shipping" under the rule, which states:

> Shipping means an event in a food's supply chain in which a food is arranged for transport (e.g., by truck or ship) from one location to another location. Shipping does not include the sale or shipment of a food directly to a consumer or the donation of surplus food. Shipping includes sending an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm.[4]

In the sushi example, the relevant food is never arranged for transport by a truck or ship and is never transported from one location to another. Therefore, the shipping and receiving critical tracking events do not occur and the associated KDEs cannot be required under the rule. In these scenarios, there will be sufficient records (i.e., a sales receipt) to facilitate a traceback investigation, especially considering that FDA has already identified the appropriate retail location for the inquiry. Requiring full shipping and receiving KDEs in these scenarios would be unnecessarily duplicative and would not provide incremental benefits to public health.

III. ADDITIONAL MINOR REVISIONS

Please note that in the listed response to Question 21 on pages 22 and 23, the scenario headers incorrectly use "FLT" to refer to the Food Traceability List.

IV. CONCLUSION

FMI appreciates FDA's continued engagement regarding implementation of the Traceability Rule and encourages FDA to implement the proposed changes to the Draft Guidance outlined in this letter to improve clarity and support the effective implementation of the Traceability Rule. In particular, FDA should:

1. Allow firms at the distribution level to pass forward a range of lot codes to their retail and restaurant partners;

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[4] 21 CFR § 1.1310.

2. Allow firms to use GTINs or corporate entity names as a traceability lot code source reference;
3. Eliminate the requirement that traceability records be maintained for intracompany transfers when companies can demonstrate effective traceability through their internal systems;
4. Provide more explicit guidance on how FDA will request data collected under the Traceability Rule; and
5. Develop and implement a safe harbor or enforcement discretion for receivers who do not receive complete or accurate KDEs from their suppliers.

Thank you for your consideration of these comments. If you have any questions, please do not hesitate to contact me.

Sincerely,

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