February 22, 2021

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

Re: Requirements for Additional Traceability Records for Certain Foods (Sept. 23, 2020), Docket No. FDA-2014-N-0053

Dear Sir or Madam,

FMI- The Food Industry Association (FMI) appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA's) Proposed Rule, *Requirements for Additional Traceability Records for Certain Foods* (Proposed 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. www.FMI.org.

FMI supports FDA fulfilling its Congressional mandate under Section 204 of the FDA Food Safety Modernization Act (FSMA) to develop a system within the agency for product tracing and to establish recordkeeping requirements for high-risk foods. FMI's members share FDA's goal of protection public health by facilitating quick traceback activities to enable swift identification of contaminated product, help prevent future public health outbreaks, and avoid sweeping public advisories. Our members are well versed in traceback investigations and recalls. Retailers have made significant strides on their own in terms of supporting quick traceback activities, and in almost all cases they are able to use currently available information to assist FDA in its investigations.

Although we support the goals of the Proposed Rule, the novel recordkeeping regime it would create is not workable given industry realities, especially for the retail sector. FMI has a diverse membership in terms of size and structure. It includes self-distributing retailers, private brands, central kitchens, independent operators, wholesalers, and a new category of product suppliers

that includes some of the largest multinational food manufacturers. Assessing the impact of the rule has been an incredibly complex process because it varies based on the type of operation, by supply chain structure, and the foods being produced and distributed.

While the Proposed Rule affects our members differently depending on their operations, a common concern among them is that the proposed recordkeeping requirements do not take into account their commonly used practices. To name just a couple of examples of the challenges that would limit retailers' ability to comply with the rule, many retail stores currently rely on paper records and do not have existing capabilities to convert those records into an electronic format. Most retailers also have no way of knowing whether the foods they receive have undergone a kill step, rendering the partial exemption moot for our industry.

In light of the substantial revisions to the Proposed Rule we believe are necessary to ensure a workable rule, we respectfully request that FDA either rescind the current Proposed Rule and issue a new proposal or issue a Supplemental Proposed Rule. In revising its proposal, we encourage FDA to develop a framework that is as simple as possible. The simpler the rule, the better industry will be able to comply, and the more accurate information provided to FDA will be. In our comments, we hope to demonstrate to FDA the complex supply chain operations of retailers and the need for greater simplicity in order to create a recordkeeping system that is feasible for all members of the food industry.

I. Executive Summary

In our detailed comments below, we elaborate on the challenges the Proposed Rule presents, our suggestions for solutions to those challenges, and areas of the proposal we support. Common among our detailed comments are the following themes.

- Supply chains are complex and dynamic, and the entities within food supply chains vary significantly in terms of size and capabilities. Any new traceability recordkeeping system must provide enough flexibility to accommodate industry practices and be simple enough that it can be adopted uniformly across industry.

- We encourage FDA to add flexibility for intracompany shipments. Because most food companies maintain records at corporate offices, it is not necessary to retain records under the rule for intracompany shipments from a manufacturing facility to a warehouse or from a warehouse to a store. The company's corporate records already should be sufficient to provide any information needed for a traceback investigation.

- Presently, many common industry supply chain operations would not fit within the Proposed Rule's framework for CTEs. Consequently, the Proposed Rule's recordkeeping regime is not workable.

- There remains significant uncertainty concerning what foods are and are not included on the Food Traceability List (FTL) as well as how the list will be managed. (Hereinafter we refer to foods on the FTL as "listed foods.") This threshold issue is fundamental to a covered entity's analysis of its compliance duties under the Proposed Rule.

- Distribution centers and retail food establishments do not have insight into whether the foods they receive have undergone a kill step and are therefore no longer subject to record-keeping requirements.

- FDA includes numerous proposed exemptions to the Proposed Rule, which FMI supports in theory, but which would not work in practice. Consequently, the scope of the rule is greater than FDA anticipates.

- The Proposed Rule is overly complex. It requires too intensive an analysis to assess, for each food, what CTE an entity performs and the associated KDEs for each. FDA needs to simplify the CTEs and reduce the number of KDEs so that industry can implement the rule effectively.

- Implementing a new recordkeeping system requiring interconnectedness throughout the supply chain would be difficult. Our members are committed to dedicating the time and resources to realize the public health benefits of a faster traceability system, but FDA should take a phased approach to ensure the rule is implemented effectively.

- The Proposed Rule must not dictate electronic recordkeeping or any other recordkeeping technology, which would happen if covered entities were required to produce records in an electronic, sortable spreadsheet. The requirement to deliver records in an electronic format is both too great a burden for some entities, and a limitation for others that may seek to use emerging technologies.

- We appreciate and support the FDA's exemption for non-profit establishments. Food donations are significant in the food industry and retailers and wholesalers are often the top source of donated products. Recordkeeping for foods shipped to and received by non-profits would be a burden on the system and might result in a more complex and limited donation systems. We encourage the FDA to maintain this exemption in the final rule.

Our more detailed comments follow.

II. Background on Retailer Supply Chains and Operations

To help put our comments into context, we thought it would be helpful to outline some of industry's current practices that present the greatest challenges for compliance with the Proposed Rule. As mentioned above, each entity's operations are different, and they may experience some or all of these challenges.

- Individual retailers receive thousands of products, including all the foods on the FTL, and receive multiple shipments of product each day. The volumes are staggering and will result in a tremendous amount of data being captured and shared for each shipment.

- Retailers have no way of knowing whether the listed foods they receive have undergone a kill step. For example, a retailer would not know whether foods like peanut butter crackers or salsa have undergone a kill step, as that may vary. As a result, they have no way of knowing if recordkeeping is no longer required for a listed food.

- Many retailers rely on paper records to document receipt of a product, and store-level employees typically are responsible for handling receipt of goods and associated recordkeeping. Substantial changes in recordkeeping practices and staffing, along with new technologies, would be needed to comply with the rule to manage paper records or to shift to electronic records. Companies with electronic systems currently rely on manual data entry, which takes a significant amount of time. We anticipate that new systems to expedite this process will need to be developed and will require significant time to develop and manage.

- Some retailers engage in a practice referred to as direct store deliveries (DSD). Under DSD systems, a food manufacturer will deliver food directly to a retailer. In most cases, the retailer's clerk will check the order compared to an invoice. Then, an employee of the manufacturer—not the retailer—will stock the retail shelves with the food. When the supplier and retailer are operating under a sale's guarantee, the foods supplied via DSD remain the property of the supplier until they are scanned at checkout. DSD may apply to both dry grocery and perishable food (both fresh and frozen). Typically, invoices will be transmitted on paper or electronically, and the shared information will include only an invoice number, the item's Global Trade Identification Number (GTIN), cost, and quantity. The store receiving clerk will provide a receipt to the supplier once the invoice is reconciled. Ownership might stay with the supplier or could be transferred to the retailer at the time of delivery.

- Cross docking is a practice used throughout many distribution chains. Product will be shipped and delivered to a cross docking station, where it is then picked up by another transporter and delivered to the purchaser. In some models, the product is never received by the cross-docking station but transported immediately, with minimal handling involved. Most cross-dock vendors rely on paper records, and the shipments never technically enter the vendor's inventory.

- Most retail distribution centers receive product on pallets, and an individual pallet may contain product with multiple different lot codes assigned by the supplier. The distribution center will then ship individual cases from the pallet to retail locations. Sometimes pallets that are shipped to retail may also contain cases from different lot codes. Currently, distribution centers do not record the lot code of the individual cases distributed to retail locations, as a result, requiring lot level traceability will require case-level tracking.

- The point in the supply chain where ownership of product transfers from one entity to another is highly variable. The flow of information throughout the supply chain depends on the type of financial transaction and often still involves paper-based processes.

- The following are some of the numerous different distribution pathways in the food supply chain, all of which must be accommodated in the Proposed Rule:

  Supplier → distributer → retailer
  Supplier → broker → distributor → retailer
  Supplier → broker (or not) → importer → distributor/wholesaler → retailer
  Supplier → DSD → retailer
  Supplier → broker → wholesaler → retailer
  Supplier → distributor → processing → distributor →retail
  Supplier → manufacturer →distributor → retailer
  Supplier → distributor → manufacturer → retailer
  Supplier → distributor → cross-dock → retailer
  Grower → packer → distributor → retailer
  Grower → retailer

The issues identified above are not meant to be an exhaustive list of the circumstances that can frustrate retailers' compliance with the rule. Rather, they are intended to demonstrate the complexity of entities' operations and demonstrate the need for simplicity in the recordkeeping framework.

III. Scope of the Proposed Rule

Although the Proposed Rule is intended to apply only to entities that manufacture, process, pack, or hold a listed food or a food that contains a listed food as an ingredient, with numerous additional exemptions, in practice the Proposed Rule would apply to nearly all foods and entities throughout the supply chain. The unintentionally broad scope of the rule is due, in part, to retailers' inability to take advantage of many of the exemptions and exceptions to the Proposed Rule. Each time the scope of the rule broadens, so does the resulting burden on retailers. We are concerned that the scope is so broad as to be unworkable for our industry. We also are concerned that by broadening the rule, particularly with respect to covered foods, FDA has exceeded its statutory authority under FSMA.

The Food Traceability List and Proposed Exemptions

The Proposed Rule, on paper, would apply only to entities that manufacture, process, pack, or hold a listed food or a food containing a listed ingredient, and the Proposed Rule includes numerous exemptions to further narrow the scope of the rule's reach. In practice, however, many of these efforts to narrow the scope of the rule are unworkable, and as a result the scope of the rule is much broader than the agency intended. Below we offer feedback on the challenges the rule presents, as well as our suggestions for how the scope of the FTL and the rule could be tailored to be less burdensome.

- **FDA's Risk-Ranking Model**

Our members have concerns that FDA's approach to selecting foods for the FTL resulted in the inclusion of foods that do not present a significant public health or safety risk. FMI supports

taking a science-based, risk-driven approach to selecting foods for the FTL. However, FDA's Risk-Ranking Model assessed commodity categories, rather than specific foods, to determine which foods are included on the FTL. By using broad commodity categories, FDA has underestimated the scope of foods within each category and thus the number of foods subject to traceability recordkeeping requirements. Moreover, the categories do not accurately capture the risk of individual foods and consequently oversimplify potential public health risks associated with specific foods.

We also encourage FDA to increase transparency concerning its selection of foods on the FTL by sharing the commodity-level analyses performed and the individual foods included in the analysis for commodity categories.

Finally, while we support FDA's data-driven approach to selecting foods for the FTL, this approach requires using the most up-to-date and accurate data in order to reliably and accurately predict public health risk. We are concerned that FDA's inclusion of data as old as 1999 does not reflect current industry food safety practices and does not appropriately capture public health risks. In particular, the adoption of the Preventive Controls for Human Food rule and the Produce Safety rule have significantly improved food safety practices.

- **Scope of the FTL**

FDA proposes that the rule's recordkeeping requirements would apply only to listed foods or foods that contain a listed food as an ingredient. Due to ambiguities regarding the scope of the commodities included on the FTL, however, the rule in practice would expand well beyond this proposed scope.

For instance, while FMI appreciates FDA providing examples of the types of cheese it would consider on the FTL, it remains unclear precisely which cheeses would or would not be covered by the Proposed Rule. Would FDA assess a cheese's inclusion on the list based on whether it satisfies a standard of identity? Or perhaps whether the food has a particular moisture level? In either case, retailers typically do not have this information and could not assess whether a cheese is included on the FTL or not. Other categories on the FTL continue to have unanswered questions as well, such as which fruits are "tropical tree fruits" or what constitutes a "deli salad."

Further complicating matters, it is not clear how the Proposed Rule would apply to commodities not on the FTL when they contain a listed food as an ingredient. For instance, frozen pizzas are not a listed food, but many contain cheese—a listed food—as an ingredient. Frozen mangoes likewise are not a listed food but conceivably could be considered to contain fresh mangoes as an ingredient. Because it is not clear which foods are or are not covered by the rule, the result would be an expansion of the Proposed Rule to numerous foods that do not present the same degree of public health risk as listed foods, as well as an increased burden on retailers and distributors that is not sustainable.

To address this concern, we request that FDA update the FTL to identify with greater specificity the foods that are included in each listed commodity. Specifically, we urge FDA to provide a complete list of products that are included on the FTL. It also would be helpful for FDA to clarify

the individual foods in the non-listed commodities, so that industry can better understand which foods are and are not on the FTL.

We also recommend that FDA create an additional exemption for non-listed commodities that contain a listed food as an ingredient. For example, the rule's recordkeeping requirement could end when a listed food is incorporated into a non-listed commodity (e.g., when mozzarella cheese is used to make a frozen pizza). This exemption should apply regardless of whether a kill step has been applied.

We understand that for certain commodities such as leafy greens, FDA intends to capture both the standalone food and products such as bagged salads, which contain the leafy greens as an ingredient. FDA should address those circumstances by including the multi-ingredient products such as bagged salad mixes on the FTL (e.g., as a "fresh cut vegetable"), rather than expanding the scope of the Proposed Rule to all non-listed commodities that contain a listed food as an ingredient.

- **Updates to the FTL**

The FDA has only provided limited details on how it will update the FTL. We urge FDA to supplement the Proposed Rule with the detailed procedures it will follow when it adds or removes a food from the FTL, including the criteria it will consider when it adds or removes a food, a set timeline for when it will reassess the FTL, the process it will follow to share its analysis for individual foods, and a statement that it will follow notice and comment rulemaking procedures for any change to the FTL. We consider notice and comment rulemaking procedures to be required under the Administrative Procedure Act because the FTL establishes the scope of the Proposed Rule and therefore acts as a regulation. We also encourage FDA to create a process for stakeholders to petition the agency to add or remove a food from the FTL.

- **Retail Food Establishment Exemption**

FMI supports FDA's proposal to exempt small retail food establishments from the rule. However, the proposal to define a small retail food establishment as one with 10 or fewer full-time equivalent employees would mean practically no retailers would qualify for the exemption. Even in small, independent grocery stores, there often are around 5 cashiers, an employee at the deli counter, an employee at the meat counter, a store manager, and two employees stocking shelves at any given time. Thus, we do not think there are any retail food establishments that could fall under the exemption as proposed. Instead, we suggest a small retail food establishment should be defined based on a metric other than full-time equivalent employees.

We propose that FDA create an exemption comparable to the exemption to the agency's Menu Labeling regulation, where restaurants and retail food establishments would be exempt from the regulation if they are not a part of a chain with 20 or more locations.[1] This solution would ensure that small retail food establishments are indeed exempt from the rule, and it would rely on a framework with which industry already is familiar.

[1] For clarity, we also suggest that FDA expressly identify entities such as restaurants, online food retailers, and meal kit delivery companies in the definition of a retail food establishment.

If FDA does not adopt this approach, then we urge the agency to define small retail food establishments using another metric such as the volume of food sold or the establishment's revenues that better accounts for size and ability to comply with the rule.

- **Intracompany Shipments**

As proposed, "shipping" would be defined as an event in a food's supply chain in which a food is arranged for transport from a defined location to another defined location at a different farm, a first receiver, or a subsequent receiver. "Receiving" would be defined as an event in a food's supply chain in which a food is received by a customer (other than a consumer) at a defined location after being transported from another defined location. We respectfully request FDA explicitly exempt intra-company shipments from the recordkeeping requirements of the rule. When goods move within a company system (e.g., from one distribution center to another, or from a distribution center to a retail store), there are appropriate recordkeeping practices in place to ascertain the whereabouts of the food because ownership stays within the company and transactions are internal.

It would be burdensome, however, for companies to be required to keep records documenting each movement between company owned warehouses for example; particularly if every movement must be accounted for in an electronic sortable spreadsheet and provided to FDA in 24 hours. We do not believe that this additional recordkeeping would add value. Because the company would know its suppliers and customers, it could provide relevant traceability information to FDA as needed. In contrast, including intracompany shipments within the scope of the rule would increase covered entities' recordkeeping responsibilities under the rule by many magnitudes. As such, FMI encourages FDA to include an express exemption for intracompany shipments in the final rule.

- **Modified Requirements for Foods Subject to a Kill Step**

While seemingly straightforward, FDA's proposed partial exemption for foods that undergo a kill step similarly would present logistical challenges for our members. Distribution centers and retail food establishments do not have insight into whether the foods they receive have undergone a kill step, and therefore cannot differentiate between listed foods that remain subject to the rule or a listed food that has undergone a kill step and no longer requires recordkeeping.

Requiring shippers to communicate to receivers that a food has undergone a kill step would not be a workable solution to this issue. For starters, it would eliminate much of the benefit of an exemption, because recordkeeping would continue to be required. Furthermore, the paperwork burden associated with simply passing along this information, much like the written disclosure requirement of the Produce Safety Rule, would be overwhelming.

FMI proposes that the best option would be to create a safe harbor provision, discussed in greater detail below.

- **Food Produced and Packaged on a Farm**

FDA also proposes a partial exemption for certain food produced and packaged on a farm, which similarly cannot be implemented practically. FDA proposes that this exemption would apply only when the packaging of the food remains in place until the food reaches the consumer; the packaging maintains the integrity of the product and prevents subsequent contamination or alteration of the product; and the labeling of the food that reaches the consumer includes the name, complete address, and business phone number of the farm on which the food was produced and packaged. Ascertaining questions such as whether a product is in packaging to maintain the integrity of the product and whether labeling includes the required information for the farm where the food was produced and packaged would be a significant burden for retailers and wholesalers, especially considering how easily these questions could change for a single product based on different suppliers (e.g., cherry tomatoes, cucumbers). As a result, retailers will not be able to take advantage of this exemption.

- **Small Originators**

FDA proposes a partial exemption for small originators with an average annual monetary value of food sold during the previous 3-year period of no more than $25,000. In theory, entities that receive a listed food from these would not require information from these originators and would know that they need to establish a traceability lot code for the food. In practice, however, the receivers will nevertheless require information from the small originator to satisfy their requirements to send information to subsequent receivers (e.g., location identifier and location description of the originator and of the place where the food was packed and cooled). Receivers also will have no way of knowing whether the originator is a small originator without receiving this information from the originator. These steps necessary to demonstrate the application of the exemption eliminate any benefit of the exemption.

- **Proposed Safe Harbor**

To help address situations where a receiver does not have insight into whether a food or supplier is covered by the rule, FMI recommends that FDA create a safe harbor for receivers, whereby if a shipper does not provide the required traceability information for a food, the receiver can assume such recordkeeping is not required, so long as the receiver has no affirmative knowledge that the food is covered by the rule and receives a one-time, ongoing guaranty from the supplier that it will provide traceability information when required by the rule.[2] Otherwise, receivers will have no way to know whether a given product or supplier is covered by the rule, without doing detailed investigations into their supply chains. Such investigations create burden and impose costs without commensurate public health benefit. Thus, FDA should ensure that when a shipper does not provide traceability information for a food, the receiver is not penalized either under the rule or in practice.

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[2] This concept has similarities to Section 303 of the Federal Food, Drug and Cosmetic Act, which establishes that entities will not be subject to penalties for having received, or proffered delivery of, adulterated or misbranded food if they have established a good faith guarantee from the entity from whom they received the articles.

- **Exemption for Retail Food Establishments Receiving Food Directly from Farms**

FDA proposes to exempt retail food establishments when they receive a listed food directly from a farm, except that they would be required to establish a record documenting the name and address of the farm that was the source of the food and maintain those records for 180 days. The Proposed Rule does not clarify when a retailer would receive food directly from a farm and, if this concept is too narrowly construed, it would significantly limit the value of the exemption. FMI recommends that FDA clarify in the rule that a retail food establishment may take advantage of this exemption even when food is purchased through a broker, so long as the food is shipped directly from the farm to the retail food establishment. FMI also suggests that this exemption apply whenever food is shipped directly from a farm to a retail food establishment, even when the entity purchasing the food is the individual retailer's parent company. These clarifications will help ensure the retailers are able to make use of the exemption.

IV. Critical Tracking Events (CTEs) and Key Data Elements (KDEs)

Much of the Proposed Rule's complexity comes from the interplay between CTEs and KDEs. To ensure compliance with the rule, entities must identify what CTEs they are fulfilling and ensure their records at that step include each of the numerous KDEs required. This analysis must be completed repeatedly for each listed food or food containing a listed food as an ingredient, and sometimes multiple times for a single product, because supply chains may vary from day to day.

In our comments below, we discuss the ways in which common industry practices and the potential flow of goods through the supply chain cannot fit cleanly within the framework of the CTEs identified by FDA. We also raise concerns with the volume and level of detail of information included in the required KDEs for each CTE, many of which are not necessary to expedite a traceback investigation.

Our overall request is that the agency simplify the rule's requirements, both by making it easier to assess what requirements apply, as well as by limiting the information that must be kept to those items necessary to facilitate traceback activities.

Critical Tracking Events

One of the issues of greatest concern to our members is that the proposed framework of CTEs does not accommodate industry practices or the realities of the ways in which food travels through the distribution chain. The following are examples of the circumstances where the application of CTEs would be unworkable.

- **Direct Store Deliveries:** DSD relationships are an example of a situation where there is no clear shipper or receiver, as the goods delivered under DSD are not "received by a customer, other than a consumer." As discussed above, regularly in DSD relationships, the retailer does not take ownership of the food until it is scanned at checkout. This system creates complications under the Proposed Rule's framework because the supplier—not the retailer—would be the "receiver" and records of transactions would not take place until the food is sold.

- **Cross Docking:** Cross docking is another circumstance where the "shipper" and "receiver" CTEs do not appropriately fit the circumstances. Cross dock vendors never accept product into their inventories, and their records of transactions with transporters typically are paper based. As a result, cross dock vendors do not have the capabilities to serve as a shipper or receiver. Cross-docking is commonly used by all sizes of vendors and is common practice for external and internal shipments.

- **Palletized Product at Distribution Centers:** The proposed framework for receivers and shippers, when applied to the typical flow of product through distribution centers, will necessitate case-level tracking of product, which is prohibited by Section 204. Most distribution centers receive pallets of product, and often an individual pallet can contain product with multiple different lot codes. Currently, a distribution center tracks when a pallet is received, when it is put in storage, when it is relocated to a "pick" spot (i.e., the location where product may be selected for shipment to a retailer), and when product from a pallet is picked and shipped to a retailer. However, distribution centers do not track which individual case on a pallet is picked and shipped to a retailer. Given the potential for a single pallet to contain multiple different lot codes, distribution centers would be forced to trace product on a case-by-case basis if the Proposed Rule were finalized. This is prohibited by FSMA and if FDA were to finalize the rule as proposed, it would be exceeding its statutory authority.

- **First Receivers:** Many entities cannot apply the Proposed Rule's distinction between the CTEs of "receiving" and "first receiving" due to the day-to-day variations in product sourcing. When a retailer places an order for produce through a broker, for example, the produce may arrive at the retailer's location through multiple different avenues, including directly from the farm or from a warehouse. Even when a retailer orders the same product from the same broker, the supply chain may vary from day to day or week to week. As a result, retailers generally do not know whether they are the first non-farm entity to take physical ownership of the food. For this reason, it would be exceedingly complicated for a retailer to determine whether it is functioning as a first receiver.

  The Proposed Rule also would require first receivers to maintain information to which they often do not have access, and which is not necessary for performing a traceback investigation, including information related to where and when the food was packed, cooled, and harvested. Considering the impracticality of creating a separate CTE for first receiving and the absence of a public health rationale for the distinct information required of first receivers, we request that FDA eliminate this CTE and treat all receivers the same.

- **Confidential Commercial Information**: Certain aspects of the Proposed Rule's requirements for shippers to share information with receivers can result in shippers sharing their confidential commercial information. For instance, the requirement for shippers to share with receivers the location identifier, location description, and point of contact for the traceability lot code generator could necessitate disclosure of confidential commercial

information such as the identity of a co-manufacturer or other supplier. We recommend that FDA eliminate the requirement that shippers share the lot code generator information with receivers. Instead, this information could be obtained through the course of a traceback investigation as necessary.

We support FDA's proposal not to require retail food establishments to maintain records for transformation or creation when they ship or sell the food directly to consumers. We appreciate FDA taking this practical approach to reduce the recordkeeping burden of the Proposed Rule.

Key Data Elements

Another preeminent concern among our members is the volume of KDEs that are required for each CTE and their variability among each CTE. We recommend that FDA simplify the rule by limiting required KDEs to information that already is readily available and communicated between supply partners (e.g., location of immediate previous source) and any additional information that is necessary to facilitate faster traceback investigations.

Currently, the Proposed Rule includes several KDEs that are not needed to perform a traceback investigation and would make recordkeeping requirements overly burdensome. The KDEs we recommend eliminating include the following:

- All KDEs unique to first receivers;
- Physical location name;
- Quantity and unit of measure;
- Points of contact (which change frequently);
- Entry numbers for imported food;
- Information regarding when and where a food was packed;
- Information regarding when and where a food was cooled; and
- Information regarding when and where a food was harvested.

We also recommend that FDA simplify the proposed elements for "product description." So long as the product is adequately described to distinguish it from different foods, information regarding category code/term, category description, trade name, brand name, and other details are not necessary.

Minimizing the variability of KDEs among CTEs and limiting the number of KDEs required at each CTE as suggested above would help reduce the complexity of the rule, leading to greater compliance and increased accuracy in records.

We also are concerned that that the proposed rule overlaps with existing traceability programs and would result in the creation and maintenance of duplicate records with information that is already contained in existing records kept. Creation of duplicative systems will be overly burdensome on the food industry and will add to confusion of data collection.

In particular, we request that FDA address duplication and inconsistency with the proposed KDEs and other requirements related to existing seafood and shellfish traceability requirements (e.g., shellfish/NSSP, SIMP, NOAA Seafood Traceability Program). The FDA Food Code, which is used

by state and local jurisdictions with authority over retail food establishments, requires that shellfish tags be maintained for 90 days from the date recorded on the tag. Furthermore, establishments must record on the tag the date when the last shellfish from the container is sold or served. We encourage FDA to consult with the Interstate Shellfish Sanitation Conference (ISSC) to obtain feedback and recognize existing standards. We are not aware of any gaps in traceability records being available for shellfish and have not heard of any problems or delays in initiating outbreak investigations.

Further, the National Oceanic and Atmospheric Administration (NOAA) administers several traceability programs, both domestic and international, and we encourage FDA to align with these programs and recognize the data required by these regulations.

FMI also urges FDA to evaluate whether there are redundancies with other requirements under the various rules promulgated under FSMA. To the extent there are redundancies, we urge FDA to simplify the recordkeeping requirements even further.

We also encourage the FDA to recognize global data standards currently used by the industry. For some KDEs proposed by FDA, there are existing standards that can be used and shared to comply with the rule such as Global Location Number (GLN) and Global Trade Item Number (GTIN). Aligning the KDEs with existing standards could significantly reduce the burden of recordkeeping while still providing the agency the information needed to perform traceback and outbreak investigations.

V. Traceability Program Records

FMI supports FDA's approach of requiring covered entities to include traceability program records to serve as a roadmap for the agency when it is performing traceback investigations, though we have two recommendations for reducing the burden of these records without limiting associated public health benefits.

First, we suggest that FDA eliminate the requirement for entities to maintain a list of foods on the FTL that they ship. This list is not necessary to facilitate a traceback investigation, because FDA already knows the food for which the traceback is being conducted. Moreover, maintaining an accurate list would require substantial time and resources for covered entities because the list would change regularly. We note that although individual retail stores may not be required to comply with this element, warehouses, distribution centers, central kitchens, and manufacturers would. Requiring these entities to maintain such a list would be a tremendous burden to the industry and could detract from the goal of maintaining accurate records, particularly given the volume of products carried that are foods on the FTL or contain ingredients that are on the FTL.

Second, FDA should clarify that the requirement that reference records be linked does not mean the records must be linked electronically. This clarification should explain that if an entity can use information in a reference record to identify other relevant reference records, these records will be sufficiently "linked" for purposes of the Proposed Rule.

FMI also supports the flexibility FDA provided in allowing covered entities to use whatever reference record suits their operations (e.g., bills of lading, advance shipping notices) rather than

requiring that information be retained in a particular record. We encourage FDA to retain this flexibility.

VI. Compliance and Enforcement

Even with the changes to the Proposed Rule we have recommended above, implementation of the Proposed Rule's new recordkeeping regime will be a substantial undertaking. This is true of all covered entities, but especially for retail food establishments, which generally are outside the scope of FDA's regulations and are not in a position to come into compliance quickly.

We offer the following comments and recommendations concerning the Proposed Rule's compliance and enforcement provisions, which will help to facilitate adherence to the rule and a smoother implementation process.

Phased Implementation: The Proposed Rule will require the adoption of new terminology and substantial changes to covered entities' recordkeeping systems. Yet no matter what amount of time and resources an entity may devote to making these changes, it cannot comply with the rule unless its supply chain partners, too, come into compliance and pass along the required information. To ensure covered entities are in a position to comply with proposed requirements to produce information in an electronic sortable spreadsheet within 24 hours, we strongly urge FDA to take a phased approach to the rule's implementation.

We recommend that the first phase of implementation consist of entities bringing their records into compliance with the rule. Within two years of the effective date of the final rule, all covered entities would be required to establish and maintain the records required by the rule and these records would be available to FDA upon request. However, the proposed requirement to produce information required by the rule in an electronic sortable spreadsheet would not take effect until the second phase of implementation, which would begin four years after the final rule's effective date.

This phased approach would provide covered entities sufficient time to work with their supply chain partners and develop the recordkeeping systems necessary to comply with the rule and, once it has that system in place, develop a system to deliver requested information to FDA within 24 hours of a request. It would ensure that FDA would have access to necessary information in the event of a traceback through the records that are maintained. Certainly, entities could voluntarily provide information to FDA in an electronic sortable spreadsheet during the interim two years, but an entity would not be penalized for an inability to do so. This would provide entities with the ability to refine their recordkeeping practices, ensure data is available from supply chain partners, and refine their systems for providing information to FDA.

Flexibility in Recordkeeping Systems: The proposed requirement to provide records to FDA in an electronic, sortable spreadsheet likely exceeds the agency's statutory authority. Section 204 expressly prohibits FDA from mandating the use of a particular technology for maintaining traceability records. Although the Proposed Rule does not identify a particular software, FMI is concerned that FDA's proposed requirement to

produce information to FDA in an electronic, sortable spreadsheet is a de facto requirement to adopt an electronic recordkeeping system. Unless records are kept in electronic form or the scope of FDA's records request was limited to a single lot, it would be virtually impossible for an entity to provide FDA with the required information in an electronic, sortable spreadsheet within 24 hours.

We also are concerned that the requirement to produce information in a sortable spreadsheet would be simultaneously overly burdensome for smaller entities that rely on paper recordkeeping systems and overly restrictive for entities that may seek to adopt emerging technologies for information exchange that may not be compatible with Excel.

In order to preserve the required flexibility in the type of technology (or lack thereof) used to maintain records and the flexibility to maintain required information across multiple documents, we respectfully request that FDA eliminate the requirement to provide information to the agency in an electronic, sortable spreadsheet and instead limit the production requirement to the information that must be produced to the agency.

- **Record Retention Period:** FMI recommends that FDA require traceability program records to be maintained for 2 years but minimize the record retention requirement for all other records to one year. This change would reduce the storage capacity required for traceability records and provide a consistent period of time (i.e., not linked to shelf life) to simplify policies. We believe a year is sufficient to ensure records remain available for any traceback investigation, because the vast majority of listed foods have short shelf lives. Most, if not all, traceback investigations are initiated within weeks of sale, and one year provides more than an adequate buffer to allow for slow or extended investigations.

- **Compliance Date:** FMI requests that FDA clarify that the rule will apply to foods that are originated, created, transformed, received, or shipped after the rule's compliance date. This clarification will be especially important for distribution centers and retail food establishments to ensure these entities are not penalized for not maintaining records for product that was in inventory before the compliance date. We also request that FDA provide the same initial compliance period for foods that are newly added to the FTL as it does for foods that are included on the original FTL.

- **Corporate-Level Records:** FMI supports the flexibility in the Proposed Rule for records to be kept at the corporate level. This flexibility is especially important for retail food establishments because individual stores do not have their own recordkeeping systems. In addition, stores do not have access to corporate computer systems and corporate records. We encourage FDA to allow for records to be maintained in secure systems at corporate headquarters, but be accessible when needed.

VII. FDA's Time and Cost Estimates

FDA's estimates in the Paperwork Reduction Act (PRA) for the recordkeeping burden of the rule and in the Preliminary Regulatory Impact Analysis (PRIA) for the cost of the rule both are far too conservative.

First, FDA's assessment of the entities that will be affected by the Proposed Rule is too narrow because it includes only those entities that manufacture, process, pack, or hold listed foods or foods containing a listed food as an ingredient. Though this assessment mirrors the scope of the Proposed Rule, in practice the new recordkeeping requirements will likely affect entities handling all foods. Covered entities will be required to revise their recordkeeping systems to comply with the rule, and it would be more time- and energy-intensive to maintain two sets of recordkeeping systems (one for listed foods and one for non-listed foods), than to apply the recordkeeping system necessary for compliance with the rule to all foods. This means that covered entities will expand their recordkeeping systems to all foods they handle, which in turn will require that their suppliers comply with the rule for the foods they provide to covered entities, whether they are listed foods or not. Those suppliers also are likely to adopt the rule's recordkeeping requirements for all foods, rather than only those for which their customers require. In sum, the Proposed Rule will have a ripple effect throughout all supply chains, covering essentially all foods and all entities throughout the supply chain, which will substantially increase the recordkeeping time and cost associated with the Proposed Rule.

Second, FDA's individual estimates for the discrete components of the rule are much too low. Below we provide data FDA can use to prepare more accurate assessments:

- **Time to Read and Understand the Rule:** FDA's estimate for reading and understanding the rule is 3.7 hours, costing $122, for a single person to read the rule (the PRA estimates 3.3 hours). Yet many of our members reported that 10 or more people within their organization will read the rule. Moreover, they have reported that the time to truly understand the rule is far more than 3.3 hours, and they continue to discuss and interpret the rule's implications.

- **Capital Investments:** FDA's estimate of approximately $7,500 for capital investments also is far too low. One member reported, for instance, that they will require a large-scale deployment of new technology across their company to capture and record data electronically, a new data repository, and new technology to train foreign suppliers. Others report that their costs will include having to pay engineering support for the new hardware, software, and data architecture they will require. While it is difficult to accurately predict the associated costs at this time, many members' cost estimates for their anticipated capital investments were hundreds of thousands to millions of dollars.

- **Training:** FDA estimates that 96,644 firms would require training, and that those entities will have a one-time training cost of $1,800. These estimates fail to account for the significant volume of employees who will require training and the time it will take to train them. In general, the time it will take to train employees will vary depending on their role.

Our larger retailers estimate that they will have several hundred associates to train. Moreover, tens of thousands of employees will require training when they are onboarded into the company. Our members' estimates for training varied significantly, but were uniformly higher than FDA's estimates, ranging from $15,000 to nearly $3 million.

- **Traceability Lots:** FDA estimates that entities other than distribution centers and warehouses handle only 1,000 food traceability lots per year, while distribution centers and warehouses would handle approximately 130,000 food traceability lots per year. In reality, entities other than distribution centers and warehouse will handle many thousands of food traceability lots, depending on their size. Meanwhile, distribution centers and warehouses likely will handle millions of food traceability lots on an annual basis.

Our members are committed to compliance and collaborating with FDA to create a more traceable food supply chain, but we hope the data above will help FDA to better appreciate the time and cost that will go into satisfying the Proposed Rule's requirements, and that the agency will adjust its compliance expectations accordingly.

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In summary, FMI shares FDA's goals of accelerating traceback investigations and supports the agency fulfilling its mandate under FSMA Section 204. As noted above, retailers have made significant strides on their own in terms of supporting quick traceback activities, and in almost all cases they are able to use currently available information to assist FDA in its investigations. To achieve the public health benefits of an enhanced traceability system, however, the system must be workable for the entities covered by it. Presently, the Proposed Rule would implement a system that would not be feasible for industry and would not achieve the anticipated public health benefits.

Considering the substantial changes that are necessary to simplify the Proposed Rule and align it with industry practices, we respectfully request that FDA issue a supplemental proposed rule, taking into account the information received by industry on the Proposed Rule. FMI appreciates the significant volume of information that was recently released by the agency related to the rulemaking. We look forward to reviewing those materials and urge FDA to continue further dialogue with industry given these developments. Reviewing, analyzing, and responding to the recently released materials will take time and warrants additional dialogue. While it develops the revised proposal, we encourage FDA to engage in workshops and listening sessions, much like it did for previous FSMA regulations. Through this collaboration with industry, FDA can gain a greater understanding of industry's dynamic supply chains, and industry can help to develop solutions that will achieve our shared public health goals.

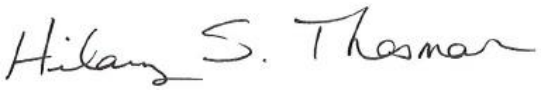
FMI members also support an extensive education program and outreach from the agency to inform the industry about the rule and to assist with compliance. Education and information about compliance should not fall on others in the supply chain.

FMI and its members would welcome the opportunity for further collaborative efforts with the agency, and we stand ready to assist in whatever way we can in the development of a revised proposal.

If you have questions about these comments or would like additional information, please feel free to contact me at sbharris@fmi.org or 202-220-0614.

Sincerely,

Stephanie K. Harris
Chief Regulatory Officer and General Counsel



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