October 25, 2024

Submitted via email to FinalRule@ReaganUdall.org

The Reagan-Udall Foundation
1333 New Hampshire Ave NW, Suite 420
Washington, DC 20036

Re: Comments on Virtual Public Meeting on FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods

To whom it may concern:

FMI, the Food Industry Association (FMI) appreciates the opportunity to provide comments on The Reagan-Udall Foundation's Virtual Public Meeting on the U.S. Food and Drug Administration's (FDA) Final Rule on Requirements for Additional Traceability Records for Certain Foods (the 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. Through collaborations such as the Food Industry FSMA 204 Collaboration and Partnership for Food Traceability, FMI and its members are committed to working across the supply chain to successfully implement the requirements of the Traceability Rule.

Central to FMI and our members is a commitment to providing consumers with a variety of safe and wholesome affordable foods that match their tastes and lifestyle. In achieving this mission, our members provide consumers with immense choice and convenience. Nearly all of FMI's members are directly impacted by the Rule and have been working diligently with their supply chain partners to educate industry about the rule's requirements, collaborate on creative solutions for complying with the rule, and develop resources to help drive implementation. To date, FMI and its members have spent countless hours working through the implementation of the Rule including but not limited to over a dozen meetings with FDA, taking FDA on two full-day distribution center tours and visiting a retail store to understand their operations, participating in discussions with suppliers to understand the upstream challenges of the Rule, and developing implementation guidance for members. Understanding the Rule and driving its implementation has required FMI and our members to deep dive into data standards, technology systems, and privacy concerns and these efforts have led to participation in a public-private partnership formed with the goal of aligning all of industry on uniform, interoperable solutions. FMI is uniquely positioned to identify the specific challenges posed by the rule's implementation and the biggest roadblocks to efficient traceback investigations under the Rule.

FMI participated in and agrees with several of the issues highlighted in the Top Line Learnings Summary from the Industry Roundtable Series on the Traceability Rule and we write to provide additional detail in key areas, including:

(1) The need for a solution to case-level tracking through flexibility in traceability lot codes, traceability lot code sources, and intracompany shipment requirements,
(2) The importance of pilot programs to identify pain points for both industry and FDA before more significant investments in compliance solutions are made; and

(3) The necessity of additional time to address each of these issues and ensure implementation of the Rule will facilitate our shared goal of protecting public health through more efficient traceback investigations.

Central to our comments and the efforts from our members to date is the goal of reducing public health risk by facilitating more efficient and effective traceback investigations. To our members, this means more than meeting FDA's compliance requirements. It means implementing a system that actually leads to quicker, more actionable traceback investigations.

Additional Flexibility is Needed for Lot Code Traceability, Traceability Lot Code Source and Intracompany Shipments

The number of products impacted and the nature of the food supply chain make the Rule a monumental challenge for retailers and retail distribution centers who handle the greatest volume and variety of products through the greatest number of consumer facing locations. These entities are struggling to find strategies for complying with the Rule that do not require the implementation of case-level tracking and that can be implemented within current operating constraints. Under current industry standard operating procedures, retailers and distribution centers are frequently shipping and receiving mixed pallets with multiple different Traceability Lot Codes and transferring these products among their own locations. Under their current practices, these companies are able to trace products back to their suppliers effectively. Thus, additional flexibility under the rule can be provided without jeopardizing the Rule's public health objective.

<u>De Facto Case-Level Tracking</u>

The Rule imposes a de facto case-level tracking requirement, which is the key driver of complexity for retailers and distribution centers, who have been diligently working to identify a solution since publication of the final rule almost two years ago. In the current U.S. food supply chain, distributors receive products from their suppliers in pallets that contain multiple cases of products, which, due to production realities, shipping constraints, and costs, often contain multiple different products with corresponding lot codes. Distribution centers then separate individual cases from the original pallet and build new pallets by pulling cases from the warehouse and constructing new pallets, which may contain products with multiple different traceability lot codes. Distributors must then pass forward all relevant shipping records to the retailer who has to navigate which records apply to which case on the pallet.

This creates de facto case-level tracking that will impose significant burdens on distribution centers and retailers, many of which handle thousands of FTL products on a daily basis and will, therefore, be required to maintain an immense number of records under the rule. Because most distribution centers and retailers do not currently conduct case-level tracking, they will have to fundamentally overhaul their recordkeeping systems to satisfy this new requirement. The practical reality is that these entities cannot implement this case-level tracking, given the technology to do so is not currently available and industry reports that the vast majority of case labels don't have a scannable "data carrier" that can extract the (1) TLC and (2) TLC source from the individual case. This would be cost-prohibitive as it would result in unimaginable additional labor costs and is dependent on upstream shippers providing this information on cases in a scannable format, which is not required by the rule.

Consider, for example, the many different types of nut butters on the market today. A single nut butter manufacturer can provide numerous different varieties of peanut butter, including crunchy, creamy, no-sugar added, natural, no-stir natural, fat-free, organic, and many more. Under the Rule, this manufacturer will need to be able to provide distinct traceability records for each of these products, but even more difficult, distributors and retailers will receive each of these products from multiple different nut butter suppliers. Capturing, maintaining, and transferring all of the traceability records associated with each of these

products, particularly when multiple varieties are shipped together on a single pallet, is complicated, time-intensive, and costly. Finally, in addition to these practical challenges, this requirement also faces potential legal challenges as Congress did not intend for FDA to impose a rule that requires case-level tracking and specifically prohibited case-level tracking in the FDA Food Safety Modernization Act's (FSMA) mandate.[1]

FMI's Proposed Case-Level Tracking Solution

In order to effectively implement the Rule without the costly burden of case-level tracking, FMI urges FDA to modify the rule to allow retail stores and distribution centers to maintain a range of traceability lot codes. Specifically, we propose 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. 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, they would be able to identify a limited range of traceability lot codes that could be included in each shipment.

For example, consider a distribution center that handles fresh tomatoes. In a single shipment from its supplier, the distributor may receive a truck of fresh tomatoes containing three different traceability lots. The distributor would receive this truck and transfer the tomatoes to the appropriate pick slot without determining which cases on each pallet are associated with each of the three relevant traceability lot codes. When these tomatoes are picked to be shipped to a customer, the distributor would not need to determine which cases hold which specific traceability lot code but would instead provide the traceability lot code and related key data elements for all three possible traceability lot codes. In this way, the distributor would avoid case-level tracking while still providing accurate traceability data to its customer.

Adding this flexibility would not materially undercut FDA's ability to conduct traceability investigations. This proposed 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. This means that the next entity would still have access to all of the key data elements associated with the limited range of traceability lot codes provided and therefore FDA would have all necessary information for their traceback investigation. 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 share accurate information more quickly 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 would preserve the overall efficiency of investigations while alleviating the rule's excessive burdens on day-to-day operations at distribution centers.

We are aware of a seemingly similar proposal that would allow companies to provide multiple traceability lot codes for a single shipment based on a calculation of what the "most probable" lot codes for the shipment would be based on inventory management data. FMI appreciates that other stakeholders are considering these issues and offering solutions; however, it is our view that the "most probable lot code" calculation is too complex and confusing to be a realistic solution at this time.

Traceability Lot Code Source

The TLC source is a new KDE posing unique challenges, in addition to those presented by the TLC itself. In particular, the industry is grappling with which location identifier to use for these source locations, in the absence of a standardized location identifier required by the FDA. This approach has fostered inconsistencies, with potential location identifiers ranging from a GLN, FFRN, EIN, LEI, DUNS, customer-specific location IDs, and more, inhibiting interoperability. FDA permits a web URL as a potential option for

[1] *See* FSMA § 204(d)(1)(L) (21 U.S.C. § 2223(d)(1)(L)).

the TLC source "reference," but the introduction of unauthorized web URLs into the food system network could raise significant cybersecurity risks. Moreover, distributors and retailers face immense challenges in capturing and sharing the TLC source throughout the supply chain. Some commodities, such as produce, may be sourced from a variety of locations for a single product. As such, the TLC source can often change within a given time period. Current industry-adopted barcodes, such as the GS1-128, are unable to accommodate the TLC source in the barcode. This results in the TLC source being a human readable format on cases, which is not a reliable method for data transmission in an era of modernized, digital supply chains.

In order to effectively implement the Rule without the costly burden of case-level tracking, FMI urges FDA to modify the rule to allow retail stores and distribution centers to maintain a range of traceability lot code sources and to provide guidance on standardized location identifier requirements as it relates to the TLC source.

Intracompany Shipments

In addition to the burdens posed by case-level tracking, the volume of records required for each movement associated with each SKU is causing many entities to evaluate whether they can continue to offer certain products, limiting consumer choice and convenience. In particular, fresh cut fruits and vegetables, prepared deli salads, and sushi are products often prepared in central kitchens that are proving particularly challenging, which may cause these healthy, convenient products to be removed from store shelves. Specifically, retailers preparing covered foods in central kitchens or retail locations are struggling to implement transformation, shipping, and receiving records for products produced in one store and then shipped to another. These types of activities happen so frequently that maintaining full transformation, shipping, and receiving records will be costly and unnecessary. Internal recordkeeping systems are well equipped to trace products through intracompany shipments and requiring traceability records for these transfers adds an immense burden without driving a public health benefit. Understanding that choice and convenience are of paramount importance to consumers, we urge FDA to provide more flexibility by exempting intracompany shipments from the Rule's requirements.

Pilot Projects Must be Completed before Industry Invests Resources in Incomplete Traceability Solutions

To ensure the goals of Section 204 of FSMA are met and the Rule is implemented successfully, pilot projects must be completed to provide guidance as to how the various different entities in the supply chain will coordinate to ensure compliance. The Rule requires a higher level and different type of collaboration between members of industry and the rule's success will depend on industry working together to pass the relevant information forward from each critical tracking event. Even if industry aligns on data standardization, it will be impossible to understand whether the goals of the Rule are met and what unexpected gaps in recordkeeping may exist unless FDA and industry partner to create realistic pilot programs designed to ensure (1) industry is able to effectively transfer data throughout the supply chain with proper technology systems and (2) the records being generated during this process are in fact able to support FDA's traceback investigations.

Pilot programs are integral to ensuring that industry and FDA are working towards a system that will work for public and private purposes. The implementation efforts completed by our members to date have overwhelmingly concluded that investments in new technology systems are needed to comply with the Rule. If pilot programs are not completed, FDA and industry could uncover that, although they have managed to implement a technically compliant system, the system does not in fact make traceback investigations more efficient. Because of this, waiting to test the rule's implementation until after immense amounts of time and resources have been expended to comply with the rule would be ineffective and

wasteful. In order to ensure industry's limited resources are appropriately directed, pilot programs exploring alternative recordkeeping practices should be completed before the Rule's compliance date with accompanying reports substantiating an informed set of guidance to further help industry's compliance efforts.

Specifically, FMI supports the establishment of at least three pilot projects in coordination with food industry members operating restaurants, retail food establishments, and warehouses to explore what gaps in implementation based on current industry best practices need to be addressed. These pilot projects should also explore and evaluate the availability and effectiveness of low-cost technologies that may be available for small and medium-size companies. In order for the learnings from these pilot programs to be effectively implemented, the compliance date for the rule should be set for two years after the pilot project completion.

More Time is Needed for Effective Implementation of the Traceability Rule

Since publication of the Rule, FMI and our members have invested substantial resources in compliance efforts and have affirmed that to fully comply with the rule, industry will need to adopt new terminology, new technology, and will need to substantially overhaul recordkeeping systems. These adjustments will touch almost all aspects of technology systems from functionality to storage capacity to connectivity with internal and external systems. This process requires gathering funding, implementing technology solutions, and training employees, which will take multiple years even for the most sophisticated organizations, making the January 20, 2026 compliance date virtually impossible to meet in a way that meets FDA's public health objective.

As discussed in these comments, important industry efforts to implement the rule as efficiently as possible, such as the completion of pilot programs, the development of data standards, and the vetting of technological solutions, need to take place before the majority of these changes can be fully implemented in an effective way. Additionally, because no single company will be able to comply with the rule unless and until their supply chain partners are able to pass forward the required information, no company can be fully compliant based solely on their own individual efforts.

Industry needs additional time to work through the implementation of the novel rule, particularly to ensure that the system works seamlessly. Even if every company is technically compliant with the rule, the patchwork systems, not tested through pilot programs, could fail to improve FDA's traceback capabilities. It benefits both industry and consumers to ensure efficient and effective implementation and doing so requires more time. Therefore, FMI urges FDA to postpone the Traceability Rule's compliance date to two years after the completion of the above requested pilot projects.

We appreciate the opportunity to provide comments on FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods and The Reagan-Udall Foundation's engagement in this effort.

Sincerely,

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